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Monday,  
November 22, 1999

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**Part VIII**

**Department of  
Health and Human  
Services**

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**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 the semi-annual publication of an Agenda outlining all current, projected and recently completed rulemakings. Executive Order 12866 also requires the publication by the Department of a regulatory plan for fiscal year 2000. The Agenda thus 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 26, 1999.

**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 President's initiative to modernize the Federal regulatory system so that it helps deliver important services and benefits to the American people while creating fewer burdens.

These regulatory actions also are an indication of emerging policy mandates for HHS involving such national priorities as: strengthening and streamlining the Medicare program; assuring the safety of the American food supply; establishing improved access to health services for children; shoring up recent advances in welfare reform and health-insurance reform; and eliminating waste, fraud and abuse from the Nation's health care system. For this edition of the Department's regulatory agenda, the most significant regulatory actions are included in the Regulatory Plan, which appears in part II of this issue of the **Federal Register**. In the background of the Department's discharge of its regulatory responsibilities in all of the above-mentioned programmatic areas, there continues the focus and discipline with which the principles of Executive Order 12866 and the many subsequent regulatory reform initiatives of the Administration have vitalized the Department's regulatory functions. Public commentary is invited to assist the Department in continuing these efforts. Comments should be sent to the addresses listed below, depending on the specific agenda entry that is of interest. Comments may be sent to the Office of the Secretary, if the responsible component of the Department is not apparent or if a comment covers subjects crossing agency lines.

**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:** Rose Shannon, Executive Secretariat, 5600 Fishers Lane, Room 12-95, Rockville, Maryland, 20857; Phone 301-443-3779.

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

**LaVarne Burton,**  
*Executive Secretary to the Department.*

**Office of the Secretary—Proposed Rule Stage**

Sequence Number	Title	Regulation Identification Number
1093	Civil Money Penalties for Medicare+Choice Organizations and Medicaid Managed Care Organizations .....	0991-AB03
1094	Civil Money Penalty Safe Harbor to Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries .....	0991-AB04
1095	Safe Harbor for Ambulance Re-Stocking .....	0991-AB05
1096	Safe Harbor for Arrangements Involving Federally Qualified Health Centers .....	0991-AB06

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## Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1097	Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute .....	0991-AA66
1098	Reproduction and Sale of Official Forms and Publications .....	0991-AA83
1099	Revised OIG Civil Money Penalties Resulting From Public Law 104-191 .....	0991-AA90
1100	Shared Risk Exception to the Safe Harbor Provisions .....	0991-AA91
1101	Block Grant Programs .....	0991-AA97
1102	Health Care Fraud and Abuse Data Collection Program .....	0991-AA98
1103	Privacy Act Exempt Record System from the Healthcare Integrity and Protection Data Bank .....	0991-AA99
1104	Standards for Privacy of Individually Identifiable Health Information ( <b>Reg Plan Seq. No. 27</b> ) .....	0991-AB08

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

## Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
1105	Revised OIG Sanction Authorities Resulting From Public Law 105-33 .....	0991-AA95
1106	Revision of HHS Freedom of Information Act Regulations .....	0991-AB01
1107	Further Clarifications to the Safe Harbor Provisions Under the Anti-Kickback Statute .....	0991-AB07

## Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1108	Interstate Shipment of Biological Materials That Contain or May Contain Infectious Substances .....	0920-AA02

## Departmental Management—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1109	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
1110	Investigational Use New Animal Drug Regulations ( <b>Section 610 Review</b> ) .....	0910-AB02
1111	Natural Rubber-Containing Drugs; User Labeling .....	0910-AB56
1112	Substances Prohibited From Use in Animal Food or Feed .....	0910-AB90

## Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1113	Over-the-Counter (OTC) Drug Review .....	0910-AA01
1114	Hearing Aids; Professional and Patient Labeling; Conditions for Sale ( <b>Reg Plan Seq. No. 28</b> ) .....	0910-AA39
1115	Investigational New Drugs: Export Requirements for Unapproved New Drug Products .....	0910-AA61
1116	Adverse Drug Reaction Reporting and Recordkeeping Requirements for Marketed OTC Drugs .....	0910-AA86
1117	Direct-to-Consumer Promotion Regulations .....	0910-AA90
1118	Labeling for Human Prescription Drugs; Revised Format ( <b>Reg Plan Seq. No. 29</b> ) .....	0910-AA94

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## Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1119	Suspected Adverse Drug Reaction Reporting Requirements for Human Drug and Biological Products .....	0910-AA97
1120	Use of Ozone-Depleting Substances .....	0910-AA99
1121	Radioactive Drugs for Basic Research .....	0910-AB00
1122	Administrative Practices and Procedures; Advisory Opinions and Guidelines .....	0910-AB14
1123	Registration of Foreign Establishments and Product Listing .....	0910-AB21
1124	Blood Initiative .....	0910-AB26
1125	Suitability Determination for Donors of Human Cellular and Tissue-Based Products .....	0910-AB27
1126	Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products .....	0910-AB28
1127	Antibiotic Drug Approval and Exclusivity .....	0910-AB33
1128	Applications for FDA Approval to Market a New Drug, Complete Response Letter; Amendments to Unapproved Applications .....	0910-AB34
1129	Expanded Access to Investigational Therapies .....	0910-AB37
1130	Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs .....	0910-AB39
1131	Electronic Submission of Adverse Drug Reaction Reports .....	0910-AB42
1132	Distinguishing Marks for Drug Products Containing Insulin .....	0910-AB43
1133	Pregnancy Labeling .....	0910-AB44
1134	Supplemental Manufacturing Changes for New Animal Drugs .....	0910-AB49
1135	Pharmacy and Physician Compounding of Drug Products ( <b>Reg Plan Seq. No. 30</b> ) .....	0910-AB58
1136	Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness .....	0910-AB59
1137	Discontinuation of a Life-Saving Product .....	0910-AB60
1138	Pediatric Exclusivity .....	0910-AB62
1139	Positron Emission Tomography Drugs; Current Good Manufacturing Practices .....	0910-AB63
1140	Food Labeling: Trans Fatty Acids in Nutrition Labeling and Nutrient Content Claims .....	0910-AB66
1141	Designated Journals .....	0910-AB67
1142	Presubmission Conferences .....	0910-AB68
1143	Current Good Manufacturing Practice for Medicated Feeds .....	0910-AB70
1144	Citizen Petitions; Actions That Can Be Requested by Petition; Summary Denial; and Referral for Other Administrative Action .....	0910-AB73
1145	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ( <b>Reg Plan Seq. No. 31</b> ) .....	0910-AB76
1146	Antibiotic Resistance Labeling .....	0910-AB78
1147	Fixed-Combination Prescription and Over-the-Counter Drugs for Human Use .....	0910-AB79
1148	Repackaging Approval Requirements .....	0910-AB81
1149	Stability Testing of Drugs .....	0910-AB82
1150	Postmarketing Studies for Human Drugs and Licensed Biological Products: Status Reports .....	0910-AB83
1151	Amendment of Various Food Additive and Device Regulations to Reflect Current American Society for Testing and Materials Citations .....	0910-AB84
1152	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements ( <b>Reg Plan Seq. No. 32</b> ) .....	0910-AB88
1153	Current Good Manufacturing for Blood and Blood Components; Blood Labeling Standards; Direct Final Rule .....	0910-AB89
1154	Submission in Electronic Format of Certain Labeling Information .....	0910-AB91
1155	Fees Relating to Drugs; Waiver and Reduction of Fees .....	0910-AB92
1156	Skip Lot Testing .....	0910-AB93
1157	Food Additives: Food Contact Substances Notification System .....	0910-AB94

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	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) .....	0910-AA02
1159	Prescription Drug Marketing Act of 1987; Policy Information, Guidance, and Clarifications .....	0910-AA08
1160	Biological Product: Post-Marketing Surveillance Reports of Information Affecting Biological Product Safety and Quality .....	0910-AA12

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## Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1161	Fruit and Vegetable Juices: Development of HACCP and Label Warning Statements for Juices ( <b>Reg Plan Seq. No. 33</b> ) .....	0910-AA43
1162	Current Good Manufacturing Practice; Amendment of Certain Requirements for Finished Pharmaceuticals .....	0910-AA45
1163	Bioavailability and Bioequivalence Requirements .....	0910-AA51
1164	Drugs Used for Treatment of Narcotic Addicts .....	0910-AA52
1165	Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition .....	0910-AA74
1166	New Drug Applications; Drug Master File .....	0910-AA78
1167	Investigational New Drug Applications; Clinical Holds for Drugs for Life-Threatening Illnesses .....	0910-AA84
1168	Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation .....	0910-AA88
1169	Informed Consent for Human Drugs and Biologics; Determination That Informed Consent Is Not Feasible .....	0910-AA89
1170	Current Good Manufacturing Practice; Revision of Certain Labeling Controls .....	0910-AA98
1171	Veterinary Feed Directives .....	0910-AB09
1172	New Drugs for Human Use; Clarification of Requirements for Patent Holder Notification .....	0910-AB12
1173	Exports; Reporting and Recordkeeping Requirements .....	0910-AB16
1174	Medicated Feed Mill Licenses .....	0910-AB18
1175	Public Information; Communications With State and Foreign Government Officials .....	0910-AB22
1176	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
1177	Shell Eggs: Warning, Notice and Safe Handling Labeling Statements and Refrigeration Requirements ( <b>Reg Plan Seq. No. 34</b> ) .....	0910-AB30
1178	Progestational Drug Products for Human Use; Requirements for Labeling Directed to the Patient .....	0910-AB45
1179	Revisions to the General Safety Requirements for Biological Products; Direct Final Rule .....	0910-AB51
1180	Bulk Drug Substances for Use in Pharmacy Compounding .....	0910-AB57
1181	Manufacturing Changes for Drugs .....	0910-AB61
1182	Classification of Sheep as a Minor Species for All Data Collection Purposes .....	0910-AB69
1183	180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications .....	0910-AB80
1184	Structure/Function .....	0910-AB97

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

## Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1185	Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports .....	0910-AA04
1186	Food Labeling Review .....	0910-AA19
1187	Medical Foods .....	0910-AA20
1188	Classification of Computer Software Programs That Are Medical Devices .....	0910-AA41
1189	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution .....	0910-AA49
1190	Reinventing FDA Food Regulations .....	0910-AA58
1191	Debarment Certification Regulations for Drug Applications .....	0910-AA76
1192	Investigational New Drug Applications; Request for Information and Comments .....	0910-AA83
1193	Establishment Registration and Listing of Human Cellular and Tissue-Based Products .....	0910-AB05
1194	Requirements Pertaining to the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Use of Nontobacco Trade or Brand Names .....	0910-AB17
1195	Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments; Group 1; Group 2 .....	0910-AB19
1196	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed .....	0910-AB50
1197	Implementation of the Import Tolerance Provisions of the Animal Drug Availability Act of 1996 and the Safe Level Provisions of the Animal Medicinal Drug Use Clarification Act of 1994 .....	0910-AB71
1198	Mandatory HACCP Regulations for Manufacturers of Rendered Products .....	0910-AB72
1199	Surgeon's and Patient Examination Gloves; Reclassification .....	0910-AB74
1200	Marking Requirements for Imported Food Products That Have Been Refused Admission into the United States .....	0910-AB95
1201	Requirements for Persons Using Private Laboratories Regarding Actions Taken by the Food and Drug Administration .....	0910-AB96

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## Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1202	Dietary Supplement Regulations in Response to DSHEA .....	0910-AA59
1203	Over-the-Counter Human Drugs; Labeling Requirements .....	0910-AA79
1204	Definition of Substantial Evidence .....	0910-AB08
1205	Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License .....	0910-AB29
1206	Radiopharmaceuticals Used for In Vivo Diagnosis and Monitoring .....	0910-AB52
1207	Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents .....	0910-AB85
1208	General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors .....	0910-AB86
1209	Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma .....	0910-AB87

## 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

## Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1212	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
1213	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Corporate Shield .....	0906-AA41

## Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1214	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions .....	0906-AA51

## Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1215	Contracts Under the Indian Self-Determination Act .....	0917-AA04

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## 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

## Indian Health Service—Completed Actions

Sequence Number	Title	Regulation Identification Number
1217	Currently Effective Indian Health Service Eligibility Regulations .....	0917-AA03

## 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
1222	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program .....	0925-AA19
1223	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects .....	0925-AA20

## National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1224	Traineeships .....	0925-AA11
1225	Additional DHHS Protections for Pregnant Women and Human Fetuses Involved as Subjects in Research, and Pertaining to Human In Vitro Fertilization .....	0925-AA14
1226	National Research Service Awards .....	0925-AA16
1227	Federal Policy (Common Rule) for the Protection of Human Subjects .....	0925-AA21
1228	Service Fellowships .....	0925-AA22
1229	NIH Privacy Act System of Records, 09-25-0213, "Administration: Investigative Records" .....	0925-AA23

## National Institutes of Health—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1230	National Institutes of Health Construction Grants .....	0925-AA04

## Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1231	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers .....	0940-AA01

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Office of Public Health and Science—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1232	Standards of Compliance for Abortion-Related Services in Family Planning Service Projects .....	0940-AA00

Health Care Financing Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
1233	End Stage Renal Disease (ESRD) Conditions for Coverage (HCFA-3818-F) <b>(Section 610 Review)</b> .....	0938-AG82
1234	Criteria for Medicare Coverage of Heart, Liver, and Lung Transplants (HCFA-3835-ANPRM) .....	0938-AH17

Health Care Financing Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1235	Medicare Program; Qualifications for Establishing and Maintaining Medicare Billing Privileges (HCFA-6002-P) <b>(Reg Plan Seq. No. 35)</b> .....	0938-AH73
1236	National Standard for Identifiers of Health Plans (HCFA-4145-P) .....	0938-AH87
1237	State Child Health; Implementing Regulations for the State Children's Health Insurance Program (HCFA-2006-P) .....	0938-AI28
1238	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (HCFA-6003-P) .....	0938-AI49
1239	Prospective Fee Schedule for Ambulance Services (HCFA-1002-NR) <b>(Reg Plan Seq. No. 36)</b> .....	0938-AI72
1240	Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Intent To Form Negotiated Rulemaking Committee (HCFA-3250-P) .....	0938-AI92
1241	Decision on the Funding for the AIDS Healthcare Foundation START Program, (HCFA-2041-N) .....	0938-AJ43
1242	Protection for Women Who Elect Reconstruction After a Mastectomy (HCFA-2040-IFC) .....	0938-AJ44
1243	Accelerated Payments to Providers Furnishing Services Under Medicare Part A and Part B and Advance Payments to Suppliers Furnishing Items or Services Under Medicare Part B (HCFA-1066-FC) .....	0938-AJ45
1244	Medicare/Medicaid and CLIA Programs: Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of California (HCFA-2245-N) .....	0938-AJ47
1245	Federal Enforcement in Group and Individual Health Insurance Markets (HCFA-2019-FC) .....	0938-AJ48
1246	Medicare Program: Prospective Payment System for Inpatient Rehabilitation Hospital Services (HCFA-1069-P) <b>(Reg Plan Seq. No. 37)</b> .....	0938-AJ55
1247	DME Surety Bonds (HCFA-6006-P) <b>(Reg Plan Seq. No. 38)</b> .....	0938-AJ64
1248	Reapplication of the Joint Commission for Accreditation of Health Care Organizations JCAHO (HCFA-2058-PN) ...	0938-AJ68
1249	Reapplication of the Community Health Accreditation Program, Incorporated (CHAP for continued approval of Deeming Authority for whom Health Care Agencies HCFA-2059-PN) .....	0938-AJ69
1250	HHA Surety Bond (HCFA-6001-P) <b>(Reg Plan Seq. No. 39)</b> .....	0938-AJ81

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Health Care Financing Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1251	Additional Supplier Standards (HCFA-6004-F) .....	0938-AH19
1252	Requirements for Enrollment of Medicaid Recipients Under Cost Effective Employer-Based Group Health Plans (HCFA-2047-FC) .....	0938-AH48
1253	Terms, Definitions, and Addresses: Technical Amendments (HCFA-9877-FC) .....	0938-AH53
1254	Utilization Control and Discontinued Review Activities; Medicaid (HCFA-2101-FC) .....	0938-AH64
1255	Update of Ratesetting Methodology, Payment Rates and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective for Calendar Year 2000 (HCFA-1885-F) .....	0938-AH81
1256	National Standard Health Care Provider Identifier (HCFA-0045-F) <b>(Reg Plan Seq. No. 40)</b> .....	0938-AH99
1257	Medicare Program; Medicare+Choice Program (HCFA-1030-2-F) <b>(Reg Plan Seq. No. 41)</b> .....	0938-AI29
1258	Medicare Program; Prospective Payment System for Hospital Outpatient Services (HCFA-1005-F) <b>(Reg Plan Seq. No. 42)</b> .....	0938-AI56

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## Health Care Financing Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1259	Security and Electronic Signature Standards (HCFA-0049-F) <b>(Reg Plan Seq. No. 43)</b> .....	0938-AI57
1260	Health Insurance Reform: Standards for Electronic Transactions (HCFA-0149-F) <b>(Reg Plan Seq. No. 44)</b> .....	0938-AI58
1261	National Standard Employer Identifier (HCFA-0047-F) <b>(Reg Plan Seq. No. 45)</b> .....	0938-AI59
1262	Medicaid Program; Home and Community-Based Services (HCFA-2010-FC) .....	0938-AI67
1263	Medicaid Managed Care; Regulatory Program To Implement Certain Medicaid Provisions of the Balanced Budget Act of 1997 (HCFA-2001-P) <b>(Reg Plan Seq. No. 46)</b> .....	0938-AI70
1264	Coverage of Religious Non-Medical Health Care Institutions (HCFA-1909-IFC) .....	0938-AI93
1265	Home Health Prospective Payment System (HCFA-1059-P) <b>(Reg Plan Seq. No. 47)</b> .....	0938-AJ24
1266	Establishment of a Program To Collect Suggestions for Improving Medicare Program Efficiency and To Reward Suggestors (HCFA-4000-FC) .....	0938-AJ30
1267	The Children's Health Insurance Program: Implementing the Balanced Budget Act of 1997 (HCFA-2006-P) <b>(Reg Plan Seq. No. 48)</b> .....	0938-AJ75

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

## Health Care Financing Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
1268	Payment for Clinical Diagnostic Laboratory Tests (HCFA-1309-F) .....	0938-AB50
1269	Changes to Peer Review Organization Regulations (HCFA-3135-F) .....	0938-AD38
1270	Omnibus Nursing Home Reform Requirements (HCFA-3488-F) .....	0938-AD81
1271	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (HCFA-1719-P) .....	0938-AD95
1272	Protection of Income and Resources for Community Spouses of Institutionalized Individuals (HCFA-2023-P) .....	0938-AE12
1273	Survey Requirements and Alternative Sanctions for Home Health Agencies (HCFA-2169-F) .....	0938-AE39
1274	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (HCFA-2028-F) .....	0938-AE72
1275	Payment for Nursing and Allied Health Science Education (HCFA-1685-F) .....	0938-AE79
1276	Coverage of Screening Pap Smears (HCFA-3705-F) .....	0938-AE98
1277	Changes to the Long-Term Care Facility Survey Process (HCFA-3175-FC) .....	0938-AF02
1278	Requirements for Certain Health Insuring Organizations and OBRA '90 Technical Amendments (HCFA-1018-F) ...	0938-AF15
1279	Provider Reimbursement Determinations and Appeals (HCFA-1727-P) .....	0938-AF28
1280	Alternative Sanctions for Psychiatric Hospitals (HCFA-2191-P) .....	0938-AF32
1281	Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (HCFA-2046-FC) .....	0938-AF42
1282	Referral to Child Support Enforcement Agencies of Medicaid Families (HCFA-2051-F) .....	0938-AF68
1283	Medicaid: Outstationed Intake Locations for Certain Low-Income Pregnant Women, Infants, and Children Under Age 19 (HCFA-2052-F) .....	0938-AF69
1284	Assessing Interest Against Medicare Secondary Payer (MSP) Debts (HCFA-6108-P) .....	0938-AF87
1285	Revised Medicaid Management Information Systems (HCFA-2038-FN) .....	0938-AG10
1286	Alternative Sanctions for Renal Dialysis Facilities (HCFA-3204-P) .....	0938-AG31
1287	Description of HCFA's Evaluation Methodology for the Peer Review Organizations Fifth Scope of Work Contracts (HCFA-3207-N) .....	0938-AG32
1288	Disclosure of Confidential PRO and ESRD Network Organization Information for Research Purposes (HCFA-3208-P) .....	0938-AG33
1289	Medicare Program: Limitations on Medicare Coverage of Intermittent Positive Pressure Breathing Machine Therapy (HCFA-3781-FN) .....	0938-AG44
1290	Telephone Requests for Review of Part B Initial Claim Determinations (HCFA-4121-F) .....	0938-AG48
1291	Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, Underpayments and Overpayments (HCFA-2215-P) .....	0938-AG59
1292	Medicaid: Optional Coverage of TB-Related Services for Individuals Infected With Tuberculosis (HCFA-2082-P) ...	0938-AG72
1293	Revision of Medicare/Medicaid Hospital Conditions of Participation (HCFA-3745-F) .....	0938-AG79
1294	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Expanded to Designated Health Services (HCFA-1809-F) .....	0938-AG80
1295	Home Health Agency (HHA) Conditions of Participation (HCFA-3819-F) .....	0938-AG81
1296	Distinct Part Requirements for Nursing Homes and Prohibition of Financial Screening of Applicants for Nursing Home Admission (HCFA-3815-P) .....	0938-AG84
1297	CLIA Program: Categorization of Waived Tests (HCFA-2225-FC) .....	0938-AG99
1298	Liability for Third Parties To Pay for Services (HCFA-2080-P) .....	0938-AH01

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

Sequence Number	Title	Regulation Identification Number
1299	Definition of Skilled Nursing Facility (SNF) for Coverage of Durable Medical Equipment (DME) and Home Health (HCFA-1834-P) .....	0938-AH16
1300	State Plan Amendment (SPA) Reconsideration Process (HCFA-2096-P) .....	0938-AH24
1301	Hospice Care—Conditions of Participation (HCFA-3844-P) .....	0938-AH27
1302	CLIA Program; Cytology Proficiency Testing (HCFA-2233-N) .....	0938-AH35
1303	Medicare Coverage of Services of Speech-Language Pathologists and Audiologists (HCFA-1843-P) .....	0938-AH37
1304	Payment Amount if Customary Charges Are Less Than Reasonable Costs (HCFA-1860-FC) .....	0938-AH49
1305	Limitations on Liability (HCFA-4859-FC) .....	0938-AH51
1306	Medicare Secondary Payer Clarifications and Amendments (HCFA-1865-P) .....	0938-AH52
1307	Revision to Accrual Basis of Accounting Policy (HCFA-1876-F) .....	0938-AH61
1308	Medicaid; Estate Recoveries (HCFA-2083-P) .....	0938-AH63
1309	Medicaid Hospice Care (HCFA-2016-P) .....	0938-AH65
1310	Provider and Supplier Billing When Medicare Is Secondary Payor to Liability Insurance (HCFA-1848-P) .....	0938-AH66
1311	Medicare Technical Conforming Amendments (HCFA-1858-FC) .....	0938-AH67
1312	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
1313	Determination of Substandard Care in SNFs and NFs (HCFA-2240-P) .....	0938-AH69
1314	Waiver of Staffing Requirements for End Stage Renal Disease (ESRD) Facilities Participating in an Experiment (HCFA-2236-GNC) .....	0938-AH72
1315	Individual Market Health Ins. Reform Portability From Group to Indiv. Coverage; Federal Rules for Access in the Indiv. Market; State Alternative Mechanisms to Federal Rules (HCFA-2882-F) .....	0938-AH75
1316	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (HCFA-3887-P) .....	0938-AH83
1317	Disclosure of Peer Review Organization Information in Response to Beneficiary Complaints (HCFA-3241-P) .....	0938-AH85
1318	Medicaid Program; Amendment to the Preadmission Screening and Annual Resident Review Program (HCFA-2107-P) .....	0938-AH89
1319	Medically Needy Determinations Under Welfare Reform (HCFA-2109-IFC) .....	0938-AH92
1320	Medicaid Program; Coverage and Payment for Federally Qualified Health Center Services (HCFA-2043-P) .....	0938-AH95
1321	Revision to the Definition of an Unemployed Parent (HCFA-2106-FC) .....	0938-AH98
1322	Portability and Nondiscrimination in the Group Health Insurance Market (HCFA-2890-F) .....	0938-AI08
1323	Medicare Program; Medicare Integrity Program (HCFA-7020-F) .....	0938-AI09
1324	Medicare Program; Improvements to the Appeals Process for Medicare Beneficiaries Enrolled in HMOs, CMPs, and HCPPs (HCFA-4024-P) .....	0938-AI11
1325	Medicare Program; Physician Fee Schedule Conversion Factor for Calendar Year 1998 and Sustainable Growth Rate for Fiscal Year 1998 (HCFA-1893-FN) .....	0938-AI16
1326	Medicaid; Medical Child Support (HCFA-2081-P) .....	0938-AI21
1327	Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (HCFA-1902-F) .....	0938-AI38
1328	Medicare/Medicaid Program; User Fees for Information, Products, and Services (HCFA-6021-P) .....	0938-AI46
1329	Surety Bond Requirements for Comprehensive Outpatient Rehab. Facilities, Rehab. Agencies, Community Mental Health Centers, and Independent Diagnostic Testing Facilities (HCFA-6005-P) .....	0938-AI48
1330	State Plan Requirements for Durable Medical Equipment Providers (HCFA-2007-P) .....	0938-AI63
1331	Recognition of the Community Health Accreditation Program, Inc. (CHAP) and Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices (HCFA-2029-PN) .....	0938-AI69
1332	Elimination of Application of Federal Financial Participation Limits (HCFA-2111-IFC) .....	0938-AI73
1333	Medicaid Program; Changes to Eligibility of Non-U.S. Citizens (HCFA-2108-P) .....	0938-AI74
1334	Medicare Program; Advance Refunding of Debt and Methodology for Repayment of Loan (HCFA-1777-P) .....	0938-AI75
1335	Medicare Hospice Care (HCFA-1022-P) .....	0938-AI77
1336	Revision of Procedures for Requesting Exceptions to Cost Limits for SNFs and Elimination of Reclassifications (HCFA-1883-P) .....	0938-AI80
1337	Solvency Standards for Provider-Sponsored Organizations (HCFA-1011-F) .....	0938-AI83
1338	Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements (HCFA-3004-F) .....	0938-AI89
1339	Health Insurance Reform Universal Health Care Identifier (HCFA-0048-NOI) .....	0938-AI91
1340	Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations (HCFA-3009-N) .....	0938-AI99
1341	Replacement of Reasonable Charge Methodology by Fee Schedules (HCFA-1010-P) .....	0938-AJ00
1342	External Quality Review of Medicaid Managed Care Organizations (HCFA-2015-P) .....	0938-AJ06
1343	HHS' Recognition of NAIC Model Standards for Regulation of Medigap Policy (HCFA-2025-N) .....	0938-AJ07
1344	Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA-3006-IFC) .....	0938-AJ10

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

Sequence Number	Title	Regulation Identification Number
1345	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance: Millennium Compliance (HCFA-4002-GNC) .....	0938-AJ15
1346	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (HCFA-1910-P) .....	0938-AJ17
1347	Hospital Conditions of Participation: Laboratory Services (HCFA-3 014-P) .....	0938-AJ29
1348	Medicare Program; Procedures for Making Medical Services National Coverage Decisions (HCFA-3432-GN) .....	0938-AJ31
1349	Medicare Program; Special Payment Limits for Certain Durable Medical Equipment and Prosthetic Devices (HCFA-1050-PN) .....	0938-AJ34
1350	Medicare Hospice Care Amendments (HCFA-1022-P) .....	0938-AJ36
1351	Emergency Medical Treatment and Labor Act (EMTALA) (HCFA-1063-FC) .....	0938-AJ39
1352	Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2000 Rates (HCFA-1053-P) (Section 610 Review) .....	0938-AJ50

## Health Care Financing Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1353	Case Management (HCFA-2027-F) .....	0938-AF07
1354	Adjustment in Payment Amounts for New Technology Intraocular Lenses (HCFA-3831-F) .....	0938-AH15
1355	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Second Quarter, 1998 (HCFA-9002-N) .....	0938-AI13
1356	GME: Incentive Payments Under Plans for Voluntary Reduction in Number of Residents (HCFA-1001-F) .....	0938-AI27
1357	Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities. (HCFA-1913-IFC) .....	0938-AI47
1358	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances — First Quarter 1998 (HCFA-9879-N) .....	0938-AJ12
1359	Medicare Program State Allotments for Payments of Medicare Part B Premium for Qualifying Individuals: Federal Fiscal Year for 1999 (HCFA-2032-N) .....	0938-AJ28
1360	Medicaid Program; Civil Money Penalties for Nursing Homes (SNF/NF), Change in Notice Requirements, and Expansion of Discretionary Remedy (HCFA-2035-FC) .....	0938-AJ35
1361	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances — Third Quarter, 1998 (HCFA-9000-N) .....	0938-AJ37
1362	Recognition of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for Hospices (HCFA-2039-FN) .....	0938-AJ41
1363	Recognition of the Community Health Accreditation Program, Inc. (CHAP) for Hospices (HCFA-2029-FN) .....	0938-AJ42
1364	Prospective Payment System and Consolidated Billing for Home Health Agencies (HCFA-1059-P) .....	0938-AJ51
1365	Medicare and Medicaid Programs: Hospital Conditions of Participation; Patients' Rights (HCFA-3018-IFC) .....	0938-AJ56
1366	Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Update .....	0938-AJ58
1367	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2000 (HCFA-1065-P) .....	0938-AJ61
1368	Medicaid Managed Care; Regulatory Program to Implement Certain Medicaid Provisions of the Balanced Budget Act of 1997 .....	0938-AJ73

## Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1369	Bonus To Reward High Performance States Under the Temporary Assistance for Needy Families Block Grant .....	0970-AB66
1370	Child Support Enforcement for Indian Tribes .....	0970-AB73
1371	Family Child Care Program Option for Head Start Programs .....	0970-AB90
1372	National Medical Support Notice .....	0970-AB97
1373	Program Performance Standards for the Operation of Head Start Programs .....	0970-AB99
1374	Safeguarding Child Support and Expanded FPLS Information .....	0970-AC01

HHS

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1375	Title IV-E Foster Care Eligibility Reviews and Child and Family Services State Plan Reviews, MEPA Implementation, and ASFA Implementation .....	0970-AA97
1376	Standards for Safe Transportation .....	0970-AB24
1377	Construction of Head Start Facilities .....	0970-AB54
1378	Methodology for Determining Whether an Increase in a State's Child Poverty Rate is the Result of the TANF Program .....	0970-AB65
1379	Requirements for the Tribal Programs .....	0970-AB78
1380	Child Support Enforcement Program Omnibus Conforming Regulation .....	0970-AB81
1381	Refugee Resettlement Program: Refugee Cash and Medical Assistance Programs .....	0970-AB83
1382	Incentive Payments and Audit Penalties to States and Political Subdivisions .....	0970-AB85
1383	Head Start Appeal Timelines .....	0970-AB87
1384	Welfare-to-Work Data Collection .....	0970-AB92
1385	State Self Assessments To Determine Compliance With Federal Regulations .....	0970-AB96
1386	Priority for Previously Selected Head Start Agencies .....	0970-AB98
1387	Technical Revision of Head Start Regulations to Make Them Conform to Recent Statutory Revisions .....	0970-AC00
1388	Assets for Independence Reserve Account .....	0970-AC02

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
1389	Temporary Assistance for Needy Families (TANF) .....	0970-AB77
1390	Bonus to Reward Decrease in Illegitimacy Ratio .....	0970-AB79
1391	Implementation of AFCARS Corrective Action and Penalties and CAPTA Amendments .....	0970-AB94

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1392	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

**1093. 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 health maintenance organizations and competitive medical plans 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	04/00/00	
NPRM Comment	06/00/00	
Period End		

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Jay Schaar, 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

HHS—OS

Proposed Rule Stage

**1094. • 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:** Section 1128A(a)(5) of the Social Security Act**CFR Citation:** 42 CFR 1003**Legal Deadline:** None**Abstract:** This proposed rule would set forth in the OIG's civil money penalty provisions in 42 CFR part 1003 a new safe harbor for unlawful inducements to beneficiaries to provide protection for independent dialysis facilities that pay, in whole or in part, premiums for Supplementary Medical Insurance (Medicare Part B) or Medicare Supplemental Health Insurance policies (Medigap) for financially needy Medicare beneficiaries with end-stage renal disease (ESRD). This safe harbor would specifically establish 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	02/00/00	
NPRM Comment Period End	04/00/00	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar, 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**1095. • SAFE HARBOR FOR AMBULANCE RE-STOCKING****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 to address certain re-stocking arrangements between municipal and non-profit ambulance companies and hospitals.**Timetable:**

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

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar, 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

Phone: 202 619-0089

**RIN:** 0991-AB05**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	04/00/00	
NPRM Comment Period End	06/00/00	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar, 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-AB06Department of Health and Human Services (HHS)  
Office of the Secretary (OS)

Final Rule Stage

**1097. CLARIFICATION OF THE INITIAL OIG SAFE HARBOR PROVISIONS AND ESTABLISHMENT OF ADDITIONAL SAFE HARBOR PROVISIONS UNDER THE ANTI-KICKBACK STATUTE****Priority:** Other Significant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in

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

**Legal Authority:** PL 100-93, sec 2; PL 100-93, sec 14**CFR Citation:** 42 CFR 1001**Legal Deadline:** None**Abstract:** This final rule serves both to clarify various aspects of the original

safe harbor provisions and to add new safe harbors as authorized under section 14 of Public Law 100-93. Specifically, this rule modifies the original set of final safe harbor provisions (56 FR 35952, July 29, 1991) to give greater clarity to the rulemaking's original intent. In addition, this rule sets forth an expanded listing of safe harbor

HHS—OS

Final Rule Stage

provisions designed to protect additional payment and business practices from criminal prosecution and civil sanctions under the anti-kickback statute.

**Timetable:**

Action	Date	FR Cite
NPRM	09/21/93	58 FR 49008
NPRM Comment Period End	11/22/93	
Final Action	11/00/99	

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

**Additional Information:** This final rule incorporates the safe harbor clarification provisions previously addressed in RIN 0991-AA74 and set forth in proposed rulemaking (59 FR 37202, July 21, 1994).

**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-AA66

**1098. REPRODUCTION AND SALE OF OFFICIAL FORMS AND PUBLICATIONS****Priority:** Info./Admin./Other**Legal Authority:** PL 103-296, sec 312 (42 USC 1320b-10)**CFR Citation:** 45 CFR 101**Legal Deadline:** None

**Abstract:** This interim final rule with comment period will establish procedures for implementation of section 312 of the Social Security Independence Act. That section amends existing prohibitions against "misuse of symbols, emblems, or names in reference to Social Security or Medicare." Section 312 prohibits the "unauthorized reproduction, reprinting, or distribution for fee" of a "form, application, or other publication of the Social Security Administration or of the Department of Health and Human Services." It requires prior 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	12/00/99	

**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

**1099. REVISED OIG CIVIL MONEY PENALTIES RESULTING FROM PUBLIC LAW 104-191****Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 1003; 42 CFR 1005; 42 CFR 1006**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	03/25/98	63 FR 14393
NPRM Comment Period End	05/26/98	
Final Action	04/00/00	

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

**Agency Contact:** Joel Jay Schaer, Regulations Officer, Department of

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

RIN: 0991-AA90

**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, sec 216; 42 USC 1320a-7b; 42 USC 1395hh

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

**Abstract:** This interim final rule will establish 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 would allow remuneration between an organization and an individual or entity if a written agreement places the individual or entity at "substantial financial risk" for the cost or utilization of the items or services which the individual or entity is obligated to provide.

**Timetable:**

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

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

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

RIN: 0991-AA91

HHS—OS

Final Rule Stage

**1101. BLOCK GRANT PROGRAMS****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 300w et seq; 42 USC 300x et seq; 42 USC 300y et seq; 42 USC 701 et seq; 42 USC 1243 et seq; 42 USC 1397 et seq; 42 USC 8621 et seq; 42 USC 9901 et seq**CFR Citation:** 45 CFR 96**Legal Deadline:** None**Abstract:** The rule amends the regulations governing the administration on block grants. It updates current regulations to reflect current name and statutory petitions. It establishes submission and completion dates for funding applications from LIHEAP, CSBG and SSSBG. It clarifies that the department may specify the form of an application where this is authorized by statute. It requires to submit a obligation and expenditure for all block grants.**Timetable:**

Action	Date	FR Cite
Final Action	11/00/99	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** 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-AA97**1102. HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1320a-7e**CFR Citation:** 42 CFR 61 (New)**Legal Deadline:** Final, Statutory, January 1, 1997.**Abstract:** This final rule would implement the requirements of section 1128E of the Social Security Act, as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996. Section 1128E of the Act directs the Department to establish a national health care fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against health care providers, suppliers and practitioners. The statute also requires the Department to implement the national health care fraud and abuse data collection program in such a manner as to avoid with reporting requirements established for the National Practitioner Data Bank under the Health Care Quality Improvement Act of 1986.**Timetable:**

Action	Date	FR Cite
NPRM	10/30/98	63 FR 58341
NPRM Comment Period End	01/11/99	
Final Rule	11/26/99	64 FR 57740

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:**

Undetermined

**Additional Information:** Was previously 0906-AA46.**Agency Contact:** Joel Jay Schaar, 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-AA98**1103. PRIVACY ACT EXEMPT RECORD SYSTEM FROM THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK****Priority:** Substantive, Nonsignificant**Legal Authority:** 5 USC 552a**CFR Citation:** 45 CFR 56**Legal Deadline:** None**Abstract:** This proposed rule would exempt the new system of records for the Healthcare Integrity and Protection Data Bank (HIPDB) from certain provisions of the Privacy Act (5 U.S.C. 552a). The proposed exemption being set forth would apply to investigative materials compiled for law enforcement purposes in anticipation of civil, criminal or administrative proceedings.**Timetable:**

Action	Date	FR Cite
NPRM	10/26/99	64 FR 57619
NPRM Comment Period End	11/26/99	
Final Action	04/00/00	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar, 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-AA99**1104. • STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION****Regulatory Plan:** This entry is Seq. No. 27 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)****Completed Actions****1105. REVISED OIG SANCTION AUTHORITIES RESULTING FROM PUBLIC LAW 105-33****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 1001; 42 CFR 1002; 42 CFR 1003**Completed:**

Reason	Date	FR Cite
Final Action	07/22/99	64 FR 39420

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar

Phone: 202 619-0089

**RIN:** 0991-AA95

## HHS—OS

## Completed Actions

**1106. REVISION OF HHS FREEDOM OF INFORMATION ACT REGULATIONS****Priority:** Other Significant**CFR Citation:** 45 CFR 5**Completed:**

Reason	Date	FR Cite
NPRM Comment Period End	05/26/99	64 FR 14668
Final Rule	10/26/99	64 FR 57740

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Rosario Cirrincione  
Phone: 202 690-7453**RIN:** 0991-AB01**1107. • FURTHER CLARIFICATIONS TO THE SAFE HARBOR PROVISIONS UNDER THE ANTI-KICKBACK STATUTE****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 proposed rule would address modifications to the OIG's initial safe harbor provisions codified in 1991. The rule would specifically seek revisions to the employee safe harbor and to space rental safe harbor. The proposed changes would give

greater clarity to the rule's original intent and respond to an expressed preference for greater consistency among laws governing health care providers.

**Timetable:**

Action	Date	FR Cite
Withdrawn	11/08/99	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Joel Jay Schaar, 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-AB07**Department of Health and Human Services (HHS)  
Centers for Disease Control and Prevention (CDC)****Proposed Rule Stage****1108. INTERSTATE SHIPMENT OF BIOLOGICAL MATERIALS THAT CONTAIN OR MAY CONTAIN INFECTIOUS SUBSTANCES****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	12/00/99	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Dr. Jonathan Y. Richmond, Director, Office on Health and Safety, Department of Health and Human Services, Centers for Disease Control, MS F05, 1600 Clifton Road NE, Atlanta, GA 30333  
Phone: 404 639-2453**RIN:** 0920-AA02**Department of Health and Human Services (HHS)  
Departmental Management (HHSDM)****Proposed Rule Stage****1109. 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	01/00/00	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Timothy M. White, Associate General Counsel, Business

## HHS—HHSDM

## Proposed Rule Stage

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

**1110. 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:** 21 USC 321; 5 USC  
610; 21 USC 351; 21 USC 352; 21 USC  
353; 21 USC 360b; 21 USC 371

**CFR Citation:** 21 CFR 511; 21 CFR 512

**Legal Deadline:** None

**Abstract:** FDA is proposing to revise  
its regulations governing investigational  
use of new animal drugs by proposing  
to delete 21 CFR 511 and establish in  
21 CFR part 512 revised investigational  
use new animal drug regulations. The  
investigational use new animal drug  
regulations are expected to include  
regulations to implement provisions of  
the Animal Drug Availability Act of  
1996, specifically presubmission  
conferences, and implement parts of  
the President's National Performance  
Report, "Reinventing the Regulation of  
Animal Drugs," May 1996. In the  
reinventing regulations report, FDA  
proposed to revise its regulations to  
reflect numerous new process changes  
and programs that will enable a more  
streamlined animal drug application  
review and approval process, and  
which would result in less regulatory  
burden upon industry and FDA while  
maintaining safety and effectiveness of  
new animal drugs. In addition, FDA is  
initiating a review of this rule under  
section 610 of the Regulatory Flexibility  
Act. The purpose of the 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	01/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

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

**1111. 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  
331; 21 USC 351; 21 USC 352; 21 USC  
353; 21 USC 355; 21 USC 358; 21 USC  
360; 21 USC 371; 21 USC 374; 21 USC  
379; 42 USC 216; 42 USC 241; 42 USC  
262; 42 USC 264

**CFR Citation:** 21 CFR 201

**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	02/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

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

**1112. • SUBSTANCES PROHIBITED  
FROM USE IN ANIMAL FOOD OR  
FEED**

**Priority:** Substantive, Nonsignificant

**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:** 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  
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.

HHS—FDA

Prerule Stage

**Timetable:**

Action	Date	FR Cite
ANPRM	01/00/00	

**Regulatory Flexibility Analysis**

Required: Undetermined

Small Entities Affected: No

**Government Levels Affected:** State

**Agency Contact:** Dr. Randall A Lovell, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, 7500 Standish Place, HFV-222, Center for

Veterinary Medicine, Rockville, MD 20855

Phone: 301 827-0176

Fax: 301 594-1812

Email: rlovell@cvm.fda.gov

RIN: 0910-AB90

**Department of Health and Human Services (HHS)****Proposed Rule Stage****Food and Drug Administration (FDA)****1113. OVER-THE-COUNTER (OTC) DRUG REVIEW****Priority:** Routine and Frequent

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

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

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

**Legal Deadline:** None

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" was combined with NPRM for "Emetic Products" and repropoed as "Poison Treatment Products." NPRM for "Astringent (Wet Dressings) Products" was included in the NPRM for "Skin Protectant Products." NPRM for "Diaper Rash Products" was included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." 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 03/23/1982 (47 FR 12430)  
NPRM 01/15/1985 (50 FR 2172)  
NPRM (Amendment) 08/07/1991 (56 FR 37622)  
Final Action 08/16/1991 (56 FR 41008)

**Alcohol (Oral) in OTC Drug Products**

NPRM 10/21/1993 (58 FR 54466)  
Final Action 03/13/1995 (60 FR 13590)  
NPRM (Amendment) 05/10/1996 (61 FR 21392)  
Final Action (Amendment) 11/18/1996 (61 FR 58629)

**Anorectal Products**

ANPRM 05/27/1980 (45 FR 35576)  
NPRM 08/15/1988 (53 FR 30756)  
Final Action 08/03/1990 (55 FR 31776)  
Final Action (LYCD) 09/02/1993 (58 FR 46746)  
Final Action (Witch Hazel) 06/03/1994 (59 FR 28766)

**Antacid Drug Products**

ANPRM 04/05/1973 (38 FR 8714)  
NPRM 11/12/1973 (38 FR 31260)  
Final Action 06/04/1974 (39 FR 9862)  
NPRM (Amendment) (Overindulgence) 12/24/1991 (56 FR 66754)  
Final Action (Amendment) (Warning) 08/26/1993 (58 FR 45204)  
NPRM (Amendment) (Testing) 09/23/1993 (58 FR 49826)  
NPRM (Amendment)(Sodium Bicarb.) 02/02/1994 (59 FR 5060)  
Final Action (Technical Amendment) 11/25/1994 (59 FR 60555)  
Final Action (Amendment) (Testing) 02/08/1996 (61 FR 4822)  
Final Action (Amendment)(Sodium B.) 03/00/2000  
Final Action (Amendment) (Overindulgence) 12/00/2001

**Anthelmintic Products**

ANPRM 09/09/1980 (45 FR 59541)  
NPRM 08/24/1982 (47 FR 37062)  
Final Action 08/01/1986 (51 FR 27756)

**Antibiotic First Aid Products**

ANPRM 04/01/1977 (42 FR 17642)  
NPRM 07/09/1982 (47 FR 29986)  
Final Action 12/11/1987 (52 FR 47312)  
NPRM (Amendment) 08/18/1989 (54 FR 34188)  
Final Action 03/15/1990 (55 FR 9721)  
NPRM (Amendment) 05/11/1990 (55 FR 19868)  
NPRM (Amendment) 06/08/1990 (55 FR 23450)  
Final Action (Amendment) 10/03/1990 (55 FR 40379)  
Final Action (Amendment) 12/05/1990 (55 FR 50171)  
NPRM (Amendment) (Warning) 02/14/1996 (61 FR 5918)  
Final Action (Amendment)(Warning) 11/15/1996 (61 FR 58471)

**Anticaries Products**

ANPRM 03/28/1980 (45 FR 20666)  
NPRM 09/30/1985 (50 FR 39854)  
NPRM 06/15/1988 (53 FR 22430)  
Final Action 10/06/1995 (60 FR 52474)  
Final Action (Technical Amendment) 10/07/1996 (61 FR 52285)

**Antidiarrheal Products**

ANPRM 03/21/1975 (40 FR 12924)  
NPRM 04/30/1986 (51 FR 16138)  
NPRM (Amendment)(Trav. Diar.) 08/00/2000  
Final Action 08/00/2000

## HHS—FDA

## Proposed Rule Stage

**Antidotes, Toxic Ingestion Prdts (New Poison Treatment Prdts)**

ANPRM 01/05/1982 (47 FR 444)

**Antiemetic Products**

ANPRM 03/21/1975 (40 FR 12934)

NPRM 07/13/1979 (44 FR 41064)

Final Action 04/30/1987 (52 FR 15886)

NPRM (Amendment) 08/26/1993 (58 FR 45216)

Final Action 04/11/1994 (59 FR 16981)

NPRM (Amendment)(Warning) 08/29/1997 (62 FR 45767)

**Antiflatulent Drug Products**

NPRM 11/12/1973 (38 FR 31260)

Final Action 06/04/1974 (39 FR 19877)

NPRM (Amendment) 01/29/1988 (53 FR 2716)

Final Action (Amendment) 03/05/1996 (61 FR 8836)

**Antifungal (Topical) Products**

ANPRM 03/23/1982 (47 FR 12480)

NPRM 12/12/1989 (54 FR 51136)

NPRM (Amendment) (Diaper Rash) 06/20/1990 (55 FR 25240)

Final Action (Amdt.)(Diaper Rash) 12/18/1992 (57 FR 60430)

Final Action (Partial) 09/02/1993 (58 FR 46744)

Final Action 09/23/1993 (58 FR 49890)

NPRM (Amendment) (Indications) 07/22/1999 (64 FR 39452)

**Antimicrobial Products**

ANPRM 09/13/1974 (39 FR 33103)

NPRM 01/06/1978 (43 FR 1210)

NPRM (Amendment) (Diaper Rash) 06/20/1990 (55 FR 25246)

Final Action (Diaper Rash) 03/00/2004

**Antiperspirant Products**

ANPRM 10/10/1978 (43 FR 46694)

NPRM 08/20/1982 (47 FR 36492)

Final Action 06/00/2000

**Aphrodisiac Products**

ANPRM 10/01/1982 (47 FR 43572)

NPRM 01/15/1985 (50 FR 2168)

Final Action 07/07/1989 (54 FR 28780)

**Aspirin (Heart Labeling Warning)**

NPRM 11/16/1988 (53 FR 46204)

NPRM 10/20/1993 (58 FR 54224)

NPRM (Amendment) 06/13/1996 (61 FR 30002)

Final Action 06/00/2000

**Aspirin (Heart Labeling)**

Final Action 10/23/1998 (63 FR 56802)

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

ANPRM 09/07/1982 (47 FR 39436)

**Benign Prostatic Hypertrophy Products**

ANPRM 10/01/1982 (47 FR 43566)

NPRM 02/20/1987 (52 FR 5406)

Final Action 02/27/1990 (55 FR 6926)

**Boil Ointments**

ANPRM 06/29/1982 (47 FR 28306)

NPRM 01/26/1988 (53 FR 2198)

Final Action 11/15/1993 (58 FR 60332)

**Camphorated Oil Drug Products**

ANPRM 09/26/1980 (45 FR 63869)

Final Action 09/21/1982 (47 FR 41716)

**Cholecystokinetic Products**

ANPRM 02/12/1980 (45 FR 9286)

NPRM 08/24/1982 (47 FR 37068)

Final Action 06/10/1983 (48 FR 27004)

NPRM (Amendment) 08/15/1988 (53 FR 30786)

Final Action (Amendment) 02/28/1989 (54 FR 8320)

**Corn and Callus Remover Products**

ANPRM 01/05/1982 (47 FR 522)

NPRM 02/20/1987 (52 FR 5412)

Final Action 08/14/1990 (55 FR 33258)

**Cough/Cold (Anticholinergic) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 07/09/1982 (47 FR 30002)

Final Action 11/08/1985 (50 FR 46582)

**Cough/Cold (Antihistamine) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 01/15/1985 (50 FR 2200)

NPRM (Amendment) 08/24/1987 (52 FR 31892)

Final Action 12/09/1992 (57 FR 58356)

Final Action (Amendment)(Warning) 01/28/1994 (59 FR 4216)

NPRM (Amendment)(Diphenhydramine) 08/29/1997 (62 FR 45767)

Final Action 06/00/2000

**Cough/Cold (Antitussive) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 10/19/1983 (48 FR 48576)

Final Action 08/12/1987 (52 FR 30042)

NPRM (Amendment) (Warning) 07/06/1989 (54 FR 28442)

NPRM (Amendment) 10/02/1989 (54 FR 40412)

Final Action (Amendment) (Warning) 07/06/1990 (55 FR 27806)

Final Action (Amendment) 10/03/1990 (55 FR 40381)

NPRM (Amendment)(Warning) 06/19/1992 (57 FR 27666)

NPRM (Amendment)(Ingredients) 12/09/1992 (57 FR 58378)

Final Action (Amendment)(Warning) 10/20/1993 (58 FR 54232)

Final Action (Amdt.)(Ingredients) 06/03/1994 (59 FR 29172)

NPRM (Amendment)(Diphenhydramine) 08/29/1997 (62 FR 45767)

NPRM (Amendment)(Flammability) 07/20/1998 (63 FR 38762)

Final Action (Amendment)(Flammability) 03/00/2000

**Cough/Cold (Bronchodilator) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 10/26/1982 (47 FR 47520)

Final Action 10/02/1986 (51 FR 35326)

NPRM (Amendment)(Warning) 06/19/1992 (57 FR 27662)

Final Action (Amendment)(Warning) 10/20/1993 (58 FR 54238)

NPRM (Amendment)(MDI) 03/09/1995 (60 FR 13014)

NPRM (Amendment)(Ephedrine) 07/27/1995 (60 FR 38643)

Final Action (Amendment) (MDI) 05/20/1996 (61 FR 25142)

NPRM (Amendment)(Ephedrine) 06/00/2000

**Cough/Cold (Combination) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 08/12/1988 (53 FR 30522)

NPRM (Amendment)(DPH Combinations) 02/23/1995 (60 FR 10286)

Final Action (Theophylline) 07/27/1995 (60 FR 38636)

Final Action 03/00/2000

Final Action (Ephedrine Combo) 06/00/2000

**Cough/Cold (Diphenhydramine) Products**

Final Action/Enforcement Policy 04/09/1996 (61 FR 15700)

**Cough/Cold (Expectorant) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 07/09/1982 (47 FR 30002)

Final Action 02/28/1989 (54 FR 8494)

Final Action (Technical Changes) 06/30/1992 (57 FR 29176)

**Cough/Cold (Expectorant/Ipecac) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 07/09/1982 (47 FR 30002)

Final Action 09/14/1992 (57 FR 41857)

**Cough/Cold (Nasal Decongestant) Products**

ANPRM 09/09/1976 (41 FR 38312)

NPRM 01/15/1985 (50 FR 2220)

NPRM (Amendment) 06/19/1992 (57 FR 27658)

Final Action 08/23/1994 (59 FR 43386)

Final Action; Partial Stay 03/08/1996 (61 FR 9570)

NPRM (Phenylpropanolamine) 12/00/2000

**Dandruff, Seborrheic Dermatitis and Psoriasis Control Products**

ANPRM 12/03/1982 (47 FR 54646)

NPRM 07/30/1986 (51 FR 27346)

Final Action 12/04/1991 (56 FR 63554)

NPRM (Amendment) 04/05/1993 (58 FR 17554)

Final Action 01/28/1994 (59 FR 4000)

**Daytime Sedatives**

ANPRM 12/08/1975 (40 FR 57292)

NPRM 06/13/1978 (43 FR 25544)

Final Action 06/22/1979 (44 FR 36378)

**Diaper Rash Products (Merged w/other rulemkg)**

ANPRM 09/07/1982 (47 FR 39406)

**Digestive Aid Products**

ANPRM 01/05/1982 (47 FR 454)

NPRM 01/29/1988 (53 FR 2706)

Final Action 10/21/1993 (58 FR 54450)

**Eligibility Criteria for Additional Conditions**

ANPRM 10/03/1996 (61 FR 51625)

NPRM 12/00/1999

**Emetic Products**

ANPRM 03/21/1975 (40 FR 12939)

NPRM 09/05/1978 (43 FR 39544)

**Exocrine Pancreatic Insufficiency Products**

ANPRM 12/21/1979 (44 FR 75666)

NPRM 11/08/1985 (50 FR 46594)

NPRM (Reproposed) 07/15/1991 (56 FR 32282)

Final Action 04/24/1995 (60 FR 20162)

## HHS—FDA

## Proposed Rule Stage

**External Analgesic Products**

ANPRM 12/04/1979 (44 FR 69768)  
 NPRM 02/08/1983 (48 FR 5852)  
 NPRM (Amendment) (Dandruff)  
 07/30/1986 (51 FR 27360)  
 NPRM (Amendment) (Anorectal)  
 08/25/1988 (53 FR 32592)  
 NPRM (Amendment) (Poison Ivy)  
 10/03/1989 (54 FR 40818)  
 NPRM (Amendment) (Fvr Blister/Ext)  
 01/31/1990 (55 FR 3370)  
 NPRM (Amendment) (1%Hydrocortisone)  
 02/27/1990 (55 FR 6932)  
 NPRM (Amendment) (Diaper Rash)  
 06/20/1990 (55 FR 25234)  
 Final Action (Diaper Rash) 12/18/1992 (57  
 FR 60426)  
 NPRM (Amendment)(Warning) 08/29/1997  
 (62 FR 45767)  
 Final Action 12/00/2001

**Fever Blister Products (Internal)**

ANPRM 01/05/1982 (47 FR 502)  
 NPRM 06/17/1985 (50 FR 25156)  
 Final Action 06/30/1992 (57 FR 29166)

**First Aid Antiseptic**

ANPRM 09/13/1974 (39 FR 33103)  
 NPRM 01/06/1978 (43 FR 1210)  
 NPRM (Revised) 07/22/1991 (56 FR  
 33644)  
 Final Action 12/00/2000

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

ANPRM 09/07/1982 (47 FR 39436)

**Hair Grower and Hair Loss Prevention Products**

ANPRM 11/07/1980 (45 FR 73955)  
 NPRM 01/15/1985 (50 FR 2190)  
 Final Action 07/07/1989 (54 FR 28772)

**Healthcare Antiseptic Products**

ANPRM 09/13/1974 (39 FR 33103)  
 NPRM 01/06/1978 (43 FR 1210)  
 NPRM (Revised) 06/17/1994 (59 FR  
 31402)

**Hormone (Topical) Products**

ANPRM 01/05/1982 (47 FR 430)  
 NPRM 10/02/1989 (54 FR 40618)  
 Final Action 09/09/1993 (58 FR 57608)

**Hypo/Hyperphosphatemia Products**

ANPRM 12/09/1980 (45 FR 81154)  
 NPRM 01/15/1985 (50 FR 2160)  
 Final Action 05/11/1990 (55 FR 19852)

**Ingrown Toenail Relief Products**

ANPRM 10/17/1980 (45 FR 69128)  
 NPRM 09/03/1982 (47 FR 39120)  
 Final Action 09/09/1993 (58 FR 47602)

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

ANPRM 09/07/1982 (47 FR 39412)

**Insect Repellent Drug Products (Internal)**

ANPRM 01/05/1982 (47 FR 424)  
 NPRM 06/10/1983 (48 FR 26986)  
 Final Action 06/17/1985 (50 FR 25170)

**Internal Analgesic Products**

ANPRM 07/08/1977 (42 FR 35346)  
 NPRM 11/16/1988 (53 FR 46204)  
 NPRM (Amendment) (Overindulgence)  
 12/24/1991 (56 FR 66762)  
 NPRM (Amendment)(Sodium Bicarbonate)  
 02/02/1994 (59 FR 5068)  
 NPRM (Prof. Labeling)(Acute MI)  
 06/13/1996 (61 FR 30002)  
 NPRM (Amendment)(Alcohol Warning)  
 11/14/1997 (62 FR 61041)  
 Final Action (Alcohol Warning) 10/23/1998  
 (63 FR 56789)  
 Final Action (Aspirin Prof Label)  
 10/23/1998 (63 FR 56802)  
 Final Action (Sodium Bicarbonate)  
 03/00/2000  
 Final Action  
 (Amendment)(Overindulgence)  
 12/00/2001

**Internal Deodorant Products**

ANPRM 01/05/1982 (47 FR 512)  
 NPRM 06/17/1985 (50 FR 25162)  
 Final Action 05/11/1990 (55 FR 19862)

**Labeling of Drug Products for OTC Human Use**

NPRM (Sodium Labeling) 04/25/1991 (56  
 FR 19222)  
 NPRM 04/05/1993 (58 FR 17553)  
 Final Action 01/28/1994 (59 FR 3998)  
 NPRM (Do not mix drugs) 08/03/1994 (59  
 FR 39499)  
 NPRM (Amendment) (Do not mix drugs)  
 10/04/1995 (60 FR 52058)  
 NPRM (Unless a doctor tells you)  
 03/04/1996 (61 FR 8450)  
 Final Action (Sodium Labeling) 04/22/1996  
 (61 FR 17798)  
 NPRM (Calcium/Magnesium/Potassium)  
 04/22/1996 (61 FR 17807)  
 Withdrawal (Unless a doctor tells you)  
 02/27/1997 (62 FR 9024)  
 Final Action (Format/Examples)  
 03/17/1999 (64 FR 13254)  
 Final Action (Ca/Mg/K/Na) 01/00/2000

**Laxative Products**

ANPRM 03/21/1975 (40 FR 12902)  
 NPRM 01/15/1985 (50 FR 2124)  
 NPRM (Amendment) (Directions/Bulk)  
 10/01/1986 (51 FR 35136)  
 NPRM (Amendment) (Docusate Salts)  
 09/02/1993 (58 FR 46589)  
 NPRM (Amendment)(Sodium Phosphates)  
 03/31/1994 (59 FR 15139)  
 NPRM (Phenolphthalein) 09/02/1997 (62  
 FR 46223)  
 Final Action (Sodium Phosphates)  
 05/21/1998 (63 FR 27836)  
 NPRM (Amendment)(Phosphates Label)  
 05/21/1998 (63 FR 27886)  
 NPRM (Amendment)(Stim. Laxative)  
 06/19/1998 (63 FR 33592)  
 Final Action; stay (Na Phos. Enema)  
 12/07/1998 (63 FR 67399)  
 Part. With. (Na Phos. Prof. Lab.)  
 12/09/1998 (63 FR 67817)  
 Final Action (Phenolphthalein) 01/29/1999  
 (64 FR 4535)  
 Final Action 03/00/2000  
 Final Action (Stim. Laxative) 12/00/2003

**Leg Muscle Cramps (Nocturnal Relief) Products**

ANPRM 10/01/1982 (47 FR 43562)  
 NPRM 11/08/1985 (50 FR 46588)  
 Final Action 08/22/1994 (59 FR 43234)

**Male Genital Desensitizer Products**

ANPRM 09/07/1982 (47 FR 39412)  
 NPRM 10/02/1985 (50 FR 40260)  
 Final Action 06/19/1992 (57 FR 27654)

**Menstrual Products**

ANPRM 12/07/1982 (47 FR 55075)  
 NPRM 11/16/1988 (53 FR 46194)  
 Final Action 12/00/2001

**Mercurial (Topical) Products (To be merged w/other rulemk)**

ANPRM 01/05/1982 (47 FR 436)

**NDA Labeling Exclusivity**

NPRM 11/09/1993 (58 FR 59622)

**Nailbiting/Thumbsucking Deterrent Products**

ANPRM 10/17/1980 (45 FR 69122)  
 NPRM 09/03/1982 (47 FR 39096)  
 Final Action 09/02/1993 (58 FR 46749)

**Nighttime Sleep Aid Products**

ANPRM 12/08/1975 (40 FR 57292)  
 NPRM 06/13/1978 (43 FR 25544)  
 Final Action 02/14/1989 (54 FR 6814)  
 NPRM (Amendment) 08/26/1993 (58 FR  
 45217)  
 Final Action (Amendment) 04/11/1994 (59  
 FR 16982)  
 NPRM (Amendment) (Warning)  
 08/29/1997 (62 FR 45767)  
 Final Action 06/00/2000

**Ophthalmic Products**

ANPRM 05/06/1980 (45 FR 30002)  
 NPRM 06/28/1983 (48 FR 29788)  
 Final Action 03/04/1988 (53 FR 7076)  
 Final Action (Anti-infective) 12/18/1992 (57  
 FR 60416)  
 NPRM (Amendment) (Warning)  
 02/23/1998 (63 FR 8888)  
 Final Action 01/00/2000

**Oral Discomfort (Relief) Products**

ANPRM 05/25/1982 (47 FR 22712)  
 NPRM 09/24/1991 (56 FR 48302)  
 Final Action 06/00/2002

**Oral Health Care Products**

ANPRM 05/25/1982 (47 FR 22760)  
 NPRM 01/27/1988 (53 FR 2436)  
 NPRM (Amendment) (Antimicrobials)  
 02/09/1994 (59 FR 6084)  
 ANPRM (Plaque/Gingivitis) 01/00/2000  
 NPRM 01/00/2001

**Oral Wound Healing Products**

ANPRM 11/02/1979 (44 FR 63270)  
 NPRM 07/26/1983 (48 FR 33984)  
 Final Action 07/18/1986 (51 FR 26112)

**Otic Products (Dry Water-Clogged Ears)**

NPRM (Amendment) 08/17/1999 (64 FR  
 44671)

**Otic Products (Earwax)**

NPRM 07/09/1982 (47 FR 30012)  
 Final Action 08/08/1986 (51 FR 28656)

**Otic Products (Swimmers Ear)**

NPRM 07/30/1986 (51 FR 27366)  
 Final Action 02/15/1995 (60 FR 8916)  
 Final Action Partial Stay 08/16/1995 (60  
 FR 42435)

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**Overindulgence Remedies**

ANPRM 10/01/1982 (47 FR 43540)  
 NPRM 12/24/1991 (56 FR 66742)  
 Final Action 12/00/2001

**Overindulgence Remedies/Prevention of Inebriation**

ANPRM 10/01/1982 (47 FR 43540)  
 Final Action 07/19/1983 (48 FR 32872)

**Pediculicide Products**

ANPRM 06/29/1982 (47 FR 28312)  
 NPRM 04/03/1989 (54 FR 13480)  
 Final Action 12/14/1993 (58 FR 65452)  
 NPRM (Labeling Amendment) 12/00/1999

**Phenylpropanolamine Products (Labeling)**

NPRM 02/14/1996 (61 FR 3912)  
 Final Action 06/00/2000

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

ANPRM 09/07/1982 (47 FR 39412)

**Poison Treatment Products**

NPRM 01/15/1985 (50 FR 2244)  
 Final Action 06/00/2000  
 NPRM (Amendment) 12/00/2001

**Quinine for Malaria**

NPRM 04/19/1995 (60 FR 19650)  
 Final Action 03/20/1998 (63 FR 13526)

**Salicylate (Reye Syndrome)**

NPRM (Amendment)(Warning) 05/05/1993  
 (58 FR 26886)  
 ANPRM 10/20/1993 (58 FR 54228)  
 Final Action (Warning) 12/00/1999

**Skin Bleaching Products**

ANPRM 11/03/1978 (43 FR 51546)  
 NPRM 09/03/1982 (47 FR 39108)  
 NPRM (Reproposed) 01/00/2003

**Skin Protectant Products**

ANPRM 08/04/1978 (43 FR 34628)  
 NPRM 02/15/1983 (48 FR 6820)  
 NPRM (Amendment) (Astringent)  
 04/03/1989 (54 FR 13490)  
 NPRM (Amendment) (Poison Ivy)  
 10/03/1989 (54 FR 40808)  
 NPRM (Amendment) (Fvr Blister/Ext)  
 01/31/1990 (55 FR 3362)  
 NPRM (Amendment) (Diaper Rash)  
 06/20/1990 (55 FR 25204)  
 Final Action (Astringent) 10/21/1993 (58  
 FR 54466)  
 Final Action (Witch Hazel) 06/03/1994 (59  
 FR 28767)  
 Final Action (Poison Ivy) 12/00/1999  
 Final Action 12/00/1999

**Smoking Deterrent Products**

ANPRM 01/05/1982 (47 FR 490)  
 NPRM 07/03/1985 (50 FR 27552)  
 Final Action 06/01/1993 (58 FR 31236)

**Status of Certain Category II and III****Ingredients**

NPRM 05/16/1990 (55 FR 20434)  
 Final Action 11/07/1990 (55 FR 46914)  
 NPRM 08/25/1992 (57 FR 38568)  
 Final Action 05/10/1993 (58 FR 27636)  
 Final Action 04/22/1998 (63 FR 19799)  
 Final Action 08/24/1998 (63 FR 44996)

**Stimulant (Overindulgence) Products**

NPRM (Amendment) 12/24/1991 (56 FR  
 66758)  
 Final Action 12/00/2001

**Stimulant Products**

ANPRM 12/08/1975 (40 FR 57292)  
 NPRM 06/13/1978 (43 FR 25544)  
 Final Action 02/29/1988 (53 FR 6100)

**Stomach Acidifier Products**

ANPRM 10/19/1979 (44 FR 60316)  
 NPRM 01/15/1985 (50 FR 2184)  
 Final Action 08/17/1988 (53 FR 31270)

**Sunscreen Products**

ANPRM 08/25/1978 (43 FR 38206)  
 NPRM 05/12/1993 (58 FR 28194)  
 NPRM (Amendment) 06/08/1994 (59 FR  
 29706)  
 NPRM (Amendment)(Avobenzone)  
 09/16/1996 (61 FR 48645)  
 Final Action (Avobenzone Enf. Pol.)  
 04/30/1997 (62 FR 23350)  
 Final Action 05/21/1999 (64 FR 27666)

**Sweet Spirits of Nitre**

ANPRM 02/22/1980 (45 FR 11846)  
 Final Action 06/27/1980 (45 FR 43400)

**Topical Drug Products Containing Benzoyl Peroxide (Labeling)**

NPRM 02/17/1995 (60 FR 9554)  
 Final Action 07/00/2001

**Vaginal Contraceptive Products**

ANPRM 12/12/1980 (45 FR 82014)  
 NPRM 02/03/1995 (60 FR 6892)  
 NPRM (Amendment) 03/00/2000

**Vaginal Drug Products**

ANPRM 10/13/1983 (48 FR 46694)  
 Withdrawal 02/03/1995 (60 FR 5226)  
 NPRM (Douches) 12/00/2001

**Vitamin/Mineral Products**

ANPRM 03/16/1979 (44 FR 16126)  
 Withdrawal 11/27/1981 (46 FR 57914)

**Wart Remover Products**

ANPRM 10/03/1980 (45 FR 65609)  
 NPRM 09/03/1982 (47 FR 39102)  
 NPRM (Amendment) 03/27/1987 (52 FR  
 9992)  
 Final Action 08/14/1990 (55 FR 33246)  
 NPRM (Amendment)(Directions)  
 01/28/1994 (59 FR 4015)  
 Final Action (Amdt.)(Directions)  
 11/23/1994 (59 FR 60315)

**Water Soluble Gums**

NPRM 10/30/1990 (55 FR 45782)  
 Final Action 08/26/1993 (58 FR 45194)

**Weight Control Products**

ANPRM 02/26/1982 (47 FR 8466)  
 NPRM 10/30/1990 (55 FR 45788)  
 Final Action 08/08/1991 (56 FR 37792)  
 NPRM (Amendment) 12/00/2000

**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, Office of Drug Evaluation V, Department of Health and Human Services, Food and Drug Administration, HFD-105, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827-2222

RIN: 0910-AA01

**1114. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE**

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

RIN: 0910-AA39

**1115. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 356; 21 USC 357; 21 USC 371; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262

**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

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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	10/00/99	

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

1116. ADVERSE DRUG REACTION REPORTING AND RECORDKEEPING REQUIREMENTS FOR MARKETED OTC DRUGS

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

Abstract: The proposed rule would require manufacturers 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	04/00/00	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: 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

1117. DIRECT-TO-CONSUMER PROMOTION REGULATIONS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 334; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360e to 360i; 21 USC 360k; 21 USC 361; 21 USC 362; 21 USC 371

CFR Citation: 21 CFR 200; 21 CFR 800

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/00	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0910-AA90

1118. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

RIN: 0910-AA94

1119. SUSPECTED ADVERSE DRUG REACTION REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

Unfunded Mandates: Undetermined

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

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	03/00/00	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: 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-AA97

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**1120. USE OF OZONE-DEPLETING SUBSTANCES**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 2

**Legal Deadline:** None

**Abstract:** FDA is proposing to amend 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 proposing to amend the regulations to better conform to other statutes and regulations relating to ozone-depleting substances to eliminate potential confusion and conflicts. FDA is proposing to eliminate out-of-date transitional provisions and make other nonsubstantive housekeeping changes to its regulations on ozone-depleting substances. The intended effect of the proposed 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	12/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Agency Contact:** Leanne Cusumano, 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-AA99

**1121. RADIOACTIVE DRUGS FOR BASIC RESEARCH**

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

**Unfunded Mandates:** Undetermined

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

**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371; 42 USC 262

**CFR Citation:** 21 CFR 361

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/00	
NPRM Comment Period End	08/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

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-AB00

**1122. ADMINISTRATIVE PRACTICES AND PROCEDURES; ADVISORY OPINIONS AND GUIDELINES**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 15 USC 1451 to 1461; 21 USC 41 to 50; 21 USC 141 to 149; 21 USC 321 to 394; 21 USC 467f; 21

USC 679; 21 USC 821; 21 USC 1034; 42 USC 201; 42 USC 262; 42 USC 263b; 42 USC 264

**CFR Citation:** 21 CFR 10; 21 CFR 808

**Legal Deadline:** NPRM, Statutory, July 1, 2000.

**Abstract:** This proposed rule would amend FDA regulations in 21 CFR part 10 concerning advisory opinions and guidelines.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

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  
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**RIN:** 0910-AB14

**1123. REGISTRATION OF FOREIGN ESTABLISHMENTS AND PRODUCT LISTING**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 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; 21 USC 374; 42 USC 216; 42 USC 262

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

**Legal Deadline:** None

**Abstract:** The proposal would amend the establishment registration and product listing regulations for human drugs, biologics, 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

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

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

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-74 (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**1124. BLOOD INITIATIVE****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.

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

**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 proposing to amend 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 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 05/14/1999 (64 FR 26282)

NPRM 05/14/1999 (64 FR 26344)

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

NPRM 08/19/1999 (64 FR 45355)

Final Action 10/00/2000

**Infectious Agent Clearance**

NPRM 04/00/2000

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

ANPRM 08/19/1999 (64 FR 45383)

NPRM 10/00/2000

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

NPRM 08/19/1999 (64 FR 45340)

Final Action 10/00/2000

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

Direct Final Rule 08/19/1999 (64 FR 45366)

NPRM 08/19/1999 (64 FR 45375)

Final Action 10/00/2000

**Suitability Reqs. for Whole Blood and Source Plasma Donors**

NPRM 04/00/2000

**Regulatory Flexibility Analysis**

**Required:** No

**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  
Email: falter@a1.cber.fda.gov

**RIN:** 0910-AB26**1125. 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 proposing to require 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 proposing to amend 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 End	12/29/99	
Final Action	10/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448  
Phone: 301 827-6210

Phone: 301 827-6210

**RIN:** 0910-AB27**1126. CURRENT GOOD TISSUE PRACTICE FOR MANUFACTURERS OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS****Priority:** Other Significant

**Reinventing Government:** This rulemaking is part of the Reinventing

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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 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 (FDA) is proposing to require manufacturers of human cellular and tissue-based products to follow current good tissue practice (GTP), which includes proper handling, processing, and storage of human cellular and tissue-based products, recordkeeping, and the maintenance of a quality program. FDA is also proposing to amend 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 GTP requirements into existing good manufacturing practice regulations.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

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

Phone: 301 827-6210

**RIN:** 0910-AB28

**1127. ANTIBIOTIC DRUG APPROVAL AND EXCLUSIVITY**

**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:** PL 105-115, sec 125

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

**Abstract:** The proposed 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	01/00/00	

**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 3057 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Fax: 301 827-5562

**RIN:** 0910-AB33

**1128. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG, COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS**

**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 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	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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

**1129. 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	06/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Joseph Griffin, Regulatory Counsel, Department of

## HHS—FDA

## Proposed Rule Stage

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

### 1130. AMENDMENT OF REGULATIONS REGARDING CERTAIN LABEL STATEMENTS ON PRESCRIPTION DRUGS

**Priority:** Other Significant

**Legal Authority:** PL 105-115, sec 126

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

**Legal Deadline:** None

**Abstract:** This proposed rule would revise 21 CFR parts 201, 250, 310, and 361 by removing the requirement that prescription drugs be labeled "Caution: Federal law prohibits the dispensing without prescription" and substituting a requirement that prescription drugs be labeled "Rx only". The rule would also revise 21 CFR parts 201, 329, and 369 by removing the requirement that certain habit-forming narcotics or hypnotics bear the statement "Warning—May be habit forming." The rule would also revise 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	02/00/00	

**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 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-AB39

### 1131. ELECTRONIC SUBMISSION OF ADVERSE DRUG REACTION REPORTS

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

**Abstract:** The proposed rule would 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	02/03/99	
Period End		
NPRM	04/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Lee D. Korb, 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

### 1132. DISTINGUISHING MARKS FOR DRUG PRODUCTS CONTAINING INSULIN

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

**Unfunded Mandates:** Undetermined

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

**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	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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

### 1133. PREGNANCY LABELING

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

**Unfunded Mandates:** Undetermined

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

**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	02/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**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

RIN: 0910-AB44

HHS—FDA

Proposed Rule Stage

**1134. SUPPLEMENTAL MANUFACTURING CHANGES FOR NEW ANIMAL DRUGS****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. 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 propose 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 proposing to amend the regulations regarding supplementary new animal drug regulations to incorporate the requirements of section 116.

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/99	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** William Marnane, 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**1135. PHARMACY AND PHYSICIAN COMPOUNDING OF DRUG PRODUCTS**

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

**RIN:** 0910-AB58**1136. 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 USC 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	02/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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-AB59**1137. DISCONTINUATION OF A LIFE-SAVING PRODUCT****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** PL 105-115, sec 131**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 USC 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.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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**1138. PEDIATRIC EXCLUSIVITY****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** PL 105-115, sec 111**CFR Citation:** 21 CFR 314**Legal Deadline:** None

**Abstract:** Section 111 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 505A to the Food, Drug, and Cosmetic Act (21 USC 355A). Section 505A permits certain applications to obtain an additional six months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits information relating to the use of the drug in the pediatric population. The proposed regulations would implement the pediatric exclusivity provisions of section 111. FDA is proposing to amend 21 CFR part 314 to add pediatric exclusivity to FDA's new drug product exclusivity regulations. FDA is also proposing to add new regulations describing the requirements an applicant must fulfill

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## Proposed Rule Stage

in order to qualify for pediatric exclusivity.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Leanne Cusumano, 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-AB62

#### 1139. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 105-115, sec 121

**CFR Citation:** 21 CFR 220

**Legal Deadline:** Final, Statutory, November 21, 1999.

**Abstract:** Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The proposed rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

**Timetable:**

Action	Date	FR Cite
NPRM	02/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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-AB63

#### 1140. 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. In response to this section, FDA published a proposal on November 27, 1991 (56 FR 60366). Among other things, FDA discussed including trans fatty acids among the nutrients that could voluntarily be listed on the nutrition label but concluded that there was no basis for doing so. On January 6, 1993, FDA issued a final rule entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" (58 FR 2079) prescribing how nutrition labeling is to be provided on the food. Based on its review of the comments to the proposal, the agency stated that it was premature to consider the listing of trans fatty acids on the nutrition label because of a lack of consensus on the dietary implications of trans fatty acids intake. However, the agency acknowledged that it might be necessary to readdress the labeling of trans fatty acids in the future. FDA subsequently received a citizen petition requesting that FDA amend the definition of saturated fatty acid in section 101.9(c)(2)(i) to include trans fatty acid. In response to this petition and based on new evidence, FDA is proposing to amend its regulations to provide for the declaration of trans fatty acids in nutrition labeling, to add a requirement that permits foods to bear nutrient content claims for saturated fat

(i.e., saturated fatty acids) and cholesterol only if they contain trans fatty acids below a specified level, and to define a "trans fatty acids free" nutrient content claim.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Agency Contact:** Susan Thompson, Chemist, Department of Health and Human Services, Food and Drug Administration, HFS-165, Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-5587

Email: [snt@cfsan.fda.gov](mailto:snt@cfsan.fda.gov)

**RIN:** 0910-AB66

#### 1141. DESIGNATED JOURNALS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 360b

**CFR Citation:** 21 CFR 510.95

**Legal Deadline:** None

**Abstract:** FDA intends to remove 21 CFR 510.95. The current rule lists the veterinary and scientific journals available in FDA's library and allows sponsors to reference an article from a listed journal in applications rather than submitting a copy of the article. FDA is taking this action because the list of journals is outdated and is no longer being used by sponsors except on an extremely limited basis. Also, the application of this rule is not an efficient use of agency resources.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**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-AB67

## HHS—FDA

## Proposed Rule Stage

**1142. 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	06/00/00	

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

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

**RIN:** 0910-AB68**1143. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS****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 351; 21 USC 352; 21 USC 360b; 21 USC 371; 21 USC 374**CFR Citation:** 21 CFR 225**Legal Deadline:** None**Abstract:** 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	07/00/00	

**Regulatory Flexibility Analysis****Required:** Undetermined**Government Levels Affected:** 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:** 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**1144. CITIZEN PETITIONS; ACTIONS THAT CAN BE REQUESTED BY PETITION; SUMMARY DENIAL; AND REFERRAL FOR OTHER ADMINISTRATIVE ACTION****Priority:** Info./Admin./Other

**Legal Authority:** 5 USC 551 to 558; 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; 21 USC 1034; 28 USC 2112; 42 USC 201; 42 USC 262; 42 USC 263b to 263n; 42 USC 264

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

**Abstract:** The proposed 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 proposal would also revise the

content requirements for citizen petitions and would establish a mechanism for receiving and filing 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	12/00/99	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** Federal

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-74 (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**1145. CGMPs FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION**

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

**RIN:** 0910-AB76**1146. ANTIBIOTIC RESISTANCE LABELING****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 201.57**Legal Deadline:** None

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

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## Proposed Rule Stage

**Timetable:**

Action	Date	FR Cite
NPRM	02/00/00	

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

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

**RIN:** 0910-AB78

**1147. FIXED-COMBINATION PRESCRIPTION AND OVER-THE-COUNTER DRUGS FOR HUMAN USE**

**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 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	01/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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

**1148. REPACKAGING APPROVAL REQUIREMENTS**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 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 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	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

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

**RIN:** 0910-AB81

**1149. STABILITY TESTING OF DRUGS**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 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	06/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

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

**RIN:** 0910-AB82

**1150. POSTMARKETING STUDIES FOR HUMAN DRUGS AND LICENSED BIOLOGICAL PRODUCTS: STATUS REPORTS**

**Priority:** Other Significant

**Legal Authority:** PL 105-115

**CFR Citation:** 21 CFR 314.81; 21 CFR 601.70

**Legal Deadline:** Other, Statutory, October 1, 2001, Section 130(b) requires the FDA to report by 10/01/01 to the House and Senate committees summarizing submitted postmarketing study reports evaluating sponsor performance and the timeliness of FDA review.

**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 agreed to conduct.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

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Proposed Rule Stage

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

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

Phone: 301 827-6210

RIN: 0910-AB83

**1151. AMENDMENT OF VARIOUS FOOD ADDITIVE AND DEVICE REGULATIONS TO REFLECT CURRENT AMERICAN SOCIETY FOR TESTING AND MATERIALS CITATIONS**

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 346; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 373; 21 USC 374; 21 USC 379e

**CFR Citation:** 21 CFR 172.210; 21 CFR 172.250; 21 CFR 172.615; 21 CFR 172.862; 21 CFR 172.864; 21 CFR 172.882; 21 CFR 173.25; 21 CFR 175.250; 21 CFR 175.270; 21 CFR 175.300; 21 CFR 176.170; 21 CFR 176.180; 21 CFR 177.1040; 21 CFR 177.1200; 21 CFR 177.1210; ...

**Legal Deadline:** None

**Abstract:** The proposed rule would amend various food additive and medical device regulations. The amendments would update the references in those regulations to various standards of the American Society for Testing and Materials (ASTM) to reflect the current standards designations.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

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

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-74 (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-AB84

**1152. • CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS**

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

RIN: 0910-AB88

**1153. • CURRENT GOOD MANUFACTURING FOR BLOOD AND BLOOD COMPONENTS; BLOOD LABELING STANDARDS; DIRECT FINAL RULE**

**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 355; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264

**CFR Citation:** 21 CFR 606.121; 21 CFR 606.122

**Legal Deadline:** None

**Abstract:** The direct final rule and companion 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 alternative exception under 21 CFR 640.120.

**Timetable:**

Action	Date	FR Cite
NPRM	04/00/00	
Direct Final Rule	04/00/00	

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

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

Phone: 301 594-3074

RIN: 0910-AB89

**1154. • 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 required labeling information in new drug applications, abbreviated new drug applications, supplements, and annual reports is required to be submitted. The proposal would require that the labeling information described under 201.56 and 201.57 be submitted to FDA in electronic format as a portable document format file.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/00	

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

**Agency Contact:** Lee D. Korb, 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

HHS—FDA

Proposed Rule Stage

**1155. • FEES RELATING TO DRUGS; WAIVER AND REDUCTION OF FEES**

**Priority:** Other Significant. 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	04/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** 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  
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**RIN:** 0910-AB92

**1156. • SKIP LOT TESTING**

**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

**Legal Deadline:** None

**Abstract:** The proposed rule requests comments on when certain tests used to determine satisfactory conformance to final specifications of a batch of drug product may be performed on a periodic basis.

**Timetable:**

Action	Date	FR Cite
NPRM	04/00/00	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** 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  
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**RIN:** 0910-AB93

**1157. • FOOD ADDITIVES: FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 5 USC 550 and 552; 21 USC 321-393, 1401-1403; 18 USC 1905; 17 USC 2531-2582; 5 USC 552; 40 CFR 1500-1508; 42 USC 241,242,242a, 242i, 242n, 243, 262, 263, 263b-264a, 265, 4321, 4332, 216; EO 11524, 3 CFR 1971 Comp. 0531-533 as amended by EO 11991; 42 FR 26967; 42 USC 300a-300e, 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 the U.S. Congress amended the Federal Food, Drug, and Cosmetic Act (FFD&C) to establish a notification process whereby manufactures 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 in lieu of a premarket notification is required. 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 once the process is in place. 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 also expects to publish a proposed rule on the notification process for food contact substances by early FY 2000. FDA will provide a period for comments on the proposed rule and will need to address any comments in a final rule.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/00	

**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, S.W., Washington, DC 20204  
Phone: 202 418-3083  
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Email: mcheesem@Bangate.FDA.GOV

**RIN:** 0910-AB94

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

Final Rule Stage

**1158. NEW ANIMAL DRUG APPROVAL PROCESS; IMPLEMENTATION OF TITLE I OF THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT (GADPTRA)**

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

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

**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 360b; 21 USC 371; 21 USC 379e; 21 USC 381

**CFR Citation:** 21 CFR 514

**Legal Deadline:** Final, Statutory, November 16, 1989, The deadline applies to the GADPTRA sections. There is no deadline relating to the other sections.

**Abstract:** On December 17, 1991, the Agency published a proposed revision of the existing regulations that is consistent with the current procedural regulations for human drugs, where appropriate. The New Animal Drug Application (NADA) revisions articulate general requirements in regulations containing performance standards and would complement these regulations through detailed guidances 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 safety and effectiveness of new animal drugs and enable a more streamlined animal drug application review and approval

process which will result in less regulatory burden upon industry and FDA. The Agency also proposes to amend its regulations to implement title I of the Generic Animal Drug and Patent Term Restoration Act, which established new standards for marketing approval of generic copies of animal drugs approved after 1962.

**Timetable:**

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

**New Animal Drug Approval Process**

NPRM 12/17/1991 (56 FR 65544)  
NPRM 00/00/0000

**Reporting Requirements for Marketed Animal Drugs**

NPRM 12/17/1991 (56 FR 65581)  
Final Action 12/00/1999

**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 Epidemiology and 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.

**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

**1159. PRESCRIPTION DRUG MARKETING ACT OF 1987; POLICY INFORMATION, GUIDANCE, AND CLARIFICATIONS**

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 203

**Legal Deadline:** None

**Abstract:** The Prescription Drug Marketing Act of 1987 (PDMA) amended the Federal Food, Drug, and Cosmetic Act to: (1) require State licensing of wholesale distributors of prescription human drugs under Federal guidelines including minimum standards for storage, handling, and recordkeeping; (2) ban the reimportation of prescription human drugs produced in the United States, except when reimported by the manufacturer or for emergency use; (3) ban the sale, trade, or purchase of drug samples; (4) ban trafficking in or counterfeiting of drug coupons; (5) mandate storage, handling, and recordkeeping requirements for drug samples; (6) require licensed practitioners to request drug samples in writing; (7) prohibit, with certain exceptions, the resale of prescription human drugs purchased by hospitals or health care facilities; and (8) set forth criminal and civil penalties for violations of these provisions. In the Federal Register of September 14, 1990 (55 FR 38012), FDA issued a final rule setting forth Federal guidelines for State licensing of wholesale drug distributors. This final rule would provide information, guidance, and clarification of those sections of PDMA that are not related to State licensing of wholesale distributors.

**Timetable:**

Action	Date	FR Cite
NPRM	03/14/94	59 FR 11842
NPRM Comment	08/01/94	
Period End		
Final Action	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** Federal, State

**Additional Information:** Previously reported under RIN 0905-AD44.

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

HHS—FDA

Final Rule Stage

Fax: 301 827-5562

RIN: 0910-AA08

**1160. BIOLOGICAL PRODUCT: POST-MARKETING SURVEILLANCE REPORTS OF INFORMATION AFFECTING BIOLOGICAL PRODUCT SAFETY AND QUALITY**

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 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; 42 USC 216; 42 USC 262 to 264; 42 USC 300aa-25

**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 errors and accidents 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 error and accident reporting by unlicensed registered blood establishments and transfusion services currently reporting on a voluntary basis. The reporting requirements will expedite reporting of errors and accidents in manufacturing of biological products; provide FDA with a more accurate surveillance of the Nation's blood supply enabling FDA to monitor actions taken in response to the errors and accidents detected for all establishments involved in the manufacture of blood and blood components; and facilitate a rapid response where public health may be at risk. The cost to licensed establishments would be minimal, since they already are required to report. Unlicensed establishments would only have to make some changes in standard operating procedures. Unlicensed establishments are already required to keep records and conduct investigations. Under the 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

Action	Date	FR Cite
NPRM Comment	12/22/97	
Period End		
Final Action	06/00/00	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** Previously reported under RIN 0905-AD67.

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

Phone: 301 827-6210

RIN: 0910-AA12

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

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

RIN: 0910-AA43

**1162. CURRENT GOOD MANUFACTURING PRACTICE; AMENDMENT OF CERTAIN REQUIREMENTS FOR FINISHED PHARMACEUTICALS**

**Priority:** Other Significant

**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 211.22; 21 CFR 211.68; 21 CFR 211.82; 21 CFR 211.84; 21 CFR 211.101; 21 CFR 211.103; 21 CFR 211.110; 21 CFR 211.111; 21 CFR 211.113; 21 CFR 211.115; 21 CFR 211.160; 21 CFR 211.166; 21 CFR 211.192; 21 CFR 211.220; ...

**Legal Deadline:** None

**Abstract:** FDA is finalizing revisions to the current good manufacturing practice (CGMP) regulations at 21 CFR parts 210 and 211 regarding finished pharmaceuticals. The new regulations codify current agency policies or current industry practices. Among other things, the rule will create or clarify requirements for process and methods validation, appropriate laboratory testing procedures, and protection

against contamination. The rule is designed to update the CGMP regulations in response to technological changes and the agency's experience with the regulations.

**Timetable:**

Action	Date	FR Cite
NPRM	05/03/96	61 FR 20104
NPRM Comment	09/30/96	
Period End		
Final Action	06/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Federal

**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

**1163. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS**

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

**Unfunded Mandates:** Undetermined

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

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

**CFR Citation:** 21 CFR 320

**Legal Deadline:** None

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

**Timetable:**

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

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

HHS—FDA

Final Rule Stage

**Agency Contact:** Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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RIN: 0910-AA51

**1164. DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS**

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

**Unfunded Mandates:** Undetermined

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

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

**CFR Citation:** 21 CFR 291

**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 non-profit accrediting bodies. This new system will replace the current system which relies solely on direct FDA approval and inspection for determining whether narcotic treatment programs comply with Federal treatment standards. The 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	01/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Ellsworth Dory, Associate Director for International and Domestic Drug Control, Department of Health and Human Services, Food and

Drug Administration, HFY-342, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-7264

RIN: 0910-AA52

**1165. ALUMINUM IN LARGE AND SMALL VOLUME PARENTERALS USED IN TOTAL PARENTERAL NUTRITION**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 201.323

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	01/05/98	63 FR 176
NPRM Comment Period End	04/06/98	
Final Action	02/00/00	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Leanne Cusumano, 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-AA74

**1166. NEW DRUG APPLICATIONS; DRUG MASTER FILE**

**Priority:** Substantive, Nonsignificant

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

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

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

**Abstract:** The final rule eliminates Type I Drug Master Files, which contain information about manufacturing sites, facilities, operating procedures, and personnel, because these files contain outdated information, duplicate information contained in marketing applications, and are not used by application review divisions or field inspectors.

**Timetable:**

Action	Date	FR Cite
NPRM	07/03/95	60 FR 34486
NPRM Comment Period End	10/02/95	
Final Action	01/00/00	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Lee D. Korb, 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-AA78

**1167. INVESTIGATIONAL NEW DRUG APPLICATIONS; CLINICAL HOLDS FOR DRUGS FOR LIFE-THREATENING ILLNESSES**

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

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

HHS—FDA

Final Rule Stage

**CFR Citation:** 21 CFR 312**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	09/24/97	62 FR 49946
NPRM Comment Period End	12/23/97	
Final Action	02/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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  
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**RIN:** 0910-AA84

#### 1168. STERILITY REQUIREMENTS FOR AQUEOUS-BASED DRUG PRODUCTS FOR ORAL INHALATION

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 200**Legal Deadline:** None

**Abstract:** The final rule requires that all aqueous-based drug products for oral inhalation be manufactured to be sterile. Based on reports of adverse drug experiences from contaminated nonsterile inhalation solution products and recalls of these products, FDA is taking this action to prevent future

additional adverse health consequences.

**Timetable:**

Action	Date	FR Cite
NPRM	09/23/97	62 FR 49638
NPRM Comment Period End	12/22/97	
Final Action	12/00/99	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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  
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Fax: 301 827-5562

**RIN:** 0910-AA88

#### 1169. INFORMED CONSENT FOR HUMAN DRUGS AND BIOLOGICS; DETERMINATION THAT INFORMED CONSENT IS NOT FEASIBLE

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 50; 21 CFR 314; 21 CFR 601

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration is proposing to revoke the interim final rule, published December 21, 1990, 55 FR 52814, which permitted the Commissioner to determine, based on a request by the Department of Defense, that obtaining informed consent from military personnel for the use of investigational products is not feasible in certain military combat situations. The rule was used to permit a waiver from the informed consent requirements for pyridostigmine bromide and the botulinum toxoid vaccine during the Gulf War. The agency is proposing this 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. At the same time, it will propose to amend its new drug and biological

product regulations to identify the kind of evidence needed to demonstrate the efficacy of drug and biological products used to treat or prevent the toxicity of potentially devastating chemical or biological substances when efficacy studies in humans ethically cannot be conducted because they would involve administering a lethal or permanently disabling toxic substance to healthy human volunteers without a proven treatment.

**Timetable:**

Action	Date	FR Cite
NPRM	10/05/99	64 FR 53960
Interim Final Rule	10/05/99	64 FR 54180
Final Action	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Bonnie M. Lee, Senior Policy Analyst, Office of the Executive Secretariat, Department of Health and Human Services, Food and Drug Administration, (HF-40), Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-4450

**RIN:** 0910-AA89

#### 1170. CURRENT GOOD MANUFACTURING PRACTICE; REVISION OF CERTAIN LABELING CONTROLS

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 210; 21 CFR 211**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	07/29/97	62 FR 40489
NPRM Comment Period End	10/27/97	
Final Action	03/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

## HHS—FDA

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**Government Levels Affected:**

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-AA98

**1171. 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	07/00/00	

**Regulatory Flexibility Analysis****Required:** Undetermined**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

**1172. NEW DRUGS FOR HUMAN USE; CLARIFICATION OF REQUIREMENTS FOR PATENT HOLDER NOTIFICATION**

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

**Unfunded Mandates:** Undetermined

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

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

**Abstract:** This final rule will clarify the methods by which application holders may provide notice to patent holders.

**Timetable:**

Action	Date	FR Cite
NPRM	03/06/98	63 FR 11174
NPRM Comment Period End	06/04/98	
Final Action	04/00/00	

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

**Agency Contact:** Leanne Cusumano, 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-AB12

**1173. EXPORTS; REPORTING AND RECORDKEEPING REQUIREMENTS****Priority:** Routine and Frequent

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

**CFR Citation:** 21 CFR 1**Legal Deadline:** None

**Abstract:** The final rule would establish the recordkeeping and

notification requirements for persons exporting human drugs, animal drugs, biologics, and devices under the FDA Export Reform and Enhancement Act.

**Timetable:**

Action	Date	FR Cite
NPRM	04/02/99	64 FR 15944
Extension	06/17/99	64 FR 32442
NPRM Comment Period End	07/16/99	
Final Action	03/00/00	

**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

**1174. MEDICATED FEED MILL LICENSES****Priority:** Other Significant**Legal Authority:** PL 104-250

**CFR Citation:** 21 CFR 5; 21 CFR 207; 21 CFR 225; 21 CFR 510; 21 CFR 514; 21 CFR 515; 21 CFR 558

**Legal Deadline:** None

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

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feed from the requirement of a medicated feed mill license. The Food and Drug Administration published on July 30, 1997, a proposed rule to amend the animal drug regulations and add a new part (21 CFR 515) to provide for feed mill licensing in accordance with the ADAA. The regulation implements the requirements for feed mill licensing set forth in the ADAA. Under this regulation, those medicated feeds exempted from the MFA requirement under 21 CFR 558.4 will also be exempt from the requirement of a medicated feed mill license.

**Timetable:**

Action	Date	FR Cite
NPRM	07/30/97	62 FR 40765
NPRM Comment Period End	10/28/97	
Final Action	12/00/99	

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

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

**RIN:** 0910-AB18**1175. PUBLIC INFORMATION; COMMUNICATIONS WITH STATE AND FOREIGN GOVERNMENT OFFICIALS****Priority:** Info./Admin./Other

**Legal Authority:** 5 USC 552; 18 USC 1905; 19 USC 2531 to 2582; 21 USC 321 to 393; 21 USC 1401 to 1403; 42 USC 241; 42 USC 242; 42 USC 242a; 42 USC 242e; 42 USC 242i; 42 USC 242n; 42 USC 243; 42 USC 262; 42 USC 263; 42 USC 263b to 263n

**CFR Citation:** 21 CFR 20.88; 21 CFR 20.89

**Legal Deadline:** None

**Abstract:** The final rule would amend the regulations governing communications with State and foreign government officials. The rule would permit the Food and Drug Administration (FDA) to disclose confidential commercial information to international organizations having responsibility to facilitate global or regional harmonization of standards and requirements. These disclosures

would, in almost all instances, occur only with the consent of the person providing the confidential commercial information to FDA. The rule would also eliminate the need for a written statement by a State or foreign government official establishing that government's ability to protect from public disclosure nonpublic, predecisional documents (such as draft rules and guidance documents) provided by FDA that do not include confidential commercial information. These changes are intended to facilitate information exchanges with State and foreign governments.

**Timetable:**

Action	Date	FR Cite
NPRM	07/27/98	63 FR 40069
NPRM Comment Period End	10/13/98	
Final Action	11/00/99	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Additional Information:** 5 USC 552

**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-AB22**1176. 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 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 216

**CFR Citation:** 21 CFR 1.84**Legal Deadline:** None

**Abstract:** The 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	03/00/00	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** State

**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**1177. SHELL EGGS: WARNING, NOTICE AND SAFE HANDLING LABELING STATEMENTS AND REFRIGERATION REQUIREMENTS**

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

**RIN:** 0910-AB30

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**1178. PROGESTATIONAL DRUG PRODUCTS FOR HUMAN USE; REQUIREMENTS FOR LABELING DIRECTED TO THE PATIENT****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360b to 360f; 21 USC 360j; 21 USC 361(a); 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e**CFR Citation:** 21 CFR 310**Legal Deadline:** None**Abstract:** The final rule revokes 21 CFR 310.516, which requires that progestational drug products be dispensed with a patient package insert containing a discussion of the risks of birth defects resulting from the use of these drugs during the first four months of pregnancy. The Food and Drug Administration is revoking this labeling requirement because of changes in the currently available scientific information.**Timetable:**

Action	Date	FR Cite
NPRM	04/13/99	64 FR 17985
NPRM Comment Period End	07/12/99	
Final Action	11/00/99	

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

Undetermined

**Agency Contact:** Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Fax: 301 827-5562**RIN:** 0910-AB45**1179. 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 Withdrawal in Part	08/05/98	
Final Action	04/00/00	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Additional Information:** RFA: N**Agency Contact:** Stephen M. Ripley, 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-AB51**1180. BULK DRUG SUBSTANCES FOR USE IN PHARMACY COMPOUNDING****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 USC 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 Pharmacopoeia (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	01/00/00	

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

Undetermined

**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3057 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Fax: 301 827-5562**RIN:** 0910-AB57**1181. MANUFACTURING CHANGES FOR DRUGS****Priority:** Other Significant**Legal Authority:** 21 USC 356a**CFR Citation:** 21 CFR 314**Legal Deadline:** None

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**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 USC 356a). Pursuant to section 116, the rulemaking will revise current procedures for approving manufacturing changes and generally classify such changes into three categories. Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of a drug, require prior approval of a supplemental application. Other changes may be made pending review of a supplemental application if FDA has not notified the company within 30 days after the submission of a supplement that prior approval is required. 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	04/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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-AB61

### 1182. CLASSIFICATION OF SHEEP AS A MINOR SPECIES FOR ALL DATA COLLECTION PURPOSES

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 360b

**CFR Citation:** 21 CFR 514.1

**Legal Deadline:** None

**Abstract:** This rule would amend 21 CFR 514.1(d) to state that sheep are minor species for all data collection purposes, thereby allowing extrapolation from major species data and limited studies to fulfill the human

food safety data requirements for new animal drug applications.

**Timetable:**

Action	Date	FR Cite
NPRM	07/26/99	64 FR 40321
Final Action	08/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Margaret Oeller, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, HFV-130, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855  
Phone: 301 827-7581

**RIN:** 0910-AB69

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 314.107

**Legal Deadline:** None

**Abstract:** The proposed rule would 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	09/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**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

**RIN:** 0910-AB80

### 1184. • STRUCTURE/FUNCTION

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

**Legal Authority:** 21 USC 343(r)(6); 21 USC 321(g); 21 USC 371(a)

**CFR Citation:** 21 CFR 101.93(g)

**Legal Deadline:** Final, Statutory.

**Abstract:** The Food and Drug Administration (FDA) is issuing final regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The regulations also establish criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. This action is intended to clarify what types of claims may be made for dietary supplements without prior review by FDA and what types of claims require prior authorization as health claims or prior approval as drug claims. Final rule establishing criteria for the types of statements that may be made for dietary supplements under 21 USC 343(r)(6) without prior FDA review.

**Timetable:**

Action	Date	FR Cite
NPRM	04/29/98	63 FR 23624
Notice of Public Meeting; Reopen. of comment period	07/08/99	64 FR 36824
Final Action	01/00/00	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Ann Marlin Witt, Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, HF-11, 5600 Fishers Lane, Parklawn Bldg. rm. 14-101, Rockville, MD  
Phone: 301 827-3360  
Email: awitt@oc.fda.gov

**RIN:** 0910-AB97

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

## Long-Term Actions

**1185. 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 343; 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 07/09/1996 (61 FR 36154)  
NPRM Comment Period End 12/06/1996  
Final Action 00/00/0000

**Infant Form Cons Comp, Micro Test & Recd Retention Req**

NPRM 01/26/1989 (54 FR 3783)  
NPRM Comment Period End 03/27/1989  
Final Rule 12/24/1991 (56 FR 66566)

**Infant Formula Quality Factors**

NPRM 07/09/1996 (61 FR 36154)  
NPRM Comment Period End 12/06/1996  
Final Action 00/00/0000

**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-456, Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204  
Phone: 202 205-5365

**RIN:** 0910-AA04

**1186. 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 10/14/1993 (58 FR 53305)  
Final Action 03/05/1996 (61 FR 8781)

**Health Claims and Label Statements**

NPRM Folic Acid and Neural Tube Def 10/14/1993 (58 FR 53254)

Final Action 03/05/1996 (61 FR 8752)

**Misleading Containers; Nonfunctional Slack Fill**

NPRM 01/06/1993 (58 FR 2957)  
Final Action 12/06/1993 (58 FR 64123)

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

NPRM 06/15/1993 (58 FR 33055)  
Final Action 08/02/1996 (61 FR 40320)

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

NPRM 01/06/1993 (58 FR 2944)  
Final Action 05/10/1994 (59 FR 24232)

**Placement of Nutrition Facts Panel**

NPRM 08/18/1993 (58 FR 44091)  
Final Action 04/05/1995 (60 FR 17202)  
Final Action Effective 05/05/1995  
Final Action Correction 06/12/1995 (60 FR 30788)

**Protein Hydrolysates; Broth in Tuna; and/or Labeling**

NPRM (Declaration of Ingredients) 01/06/1993 (58 FR 2950)  
Final Action (Dec. of Ingredients) 00/00/0000

**Reference Daily Intakes**

NPRM 01/04/1994 (59 FR 427)  
Final Action 12/28/1995 (60 FR 67164)

**Small Business Exemption, Nutrition Labeling**

NPRM 03/14/1994 (59 FR 11872)  
Final Action 08/07/1996 (61 FR 40963)

**Voluntary Guidelines for Nutrition Labeling Produce**

NPRM 07/18/1994 (59 FR 36379)  
Final Action 08/16/1996 (61 FR 42742)

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Federal

**Additional Information:** Previously reported under RIN 0905-AD89.

**Agency Contact:** Gerard L. McCowin, Acting Deputy Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, HFS-150, Center for Food Safety and Applied Nutrition,

HHS—FDA

Long-Term Actions

200 C Street SW, Washington, DC 20204  
Phone: 202 205-4561  
RIN: 0910-AA19

1187. MEDICAL FOODS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 350; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360ee; 21 USC 371

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The Food and Drug Administration is considering development of regulations for medical foods, as defined by the Orphan Drug Act Amendments of 1988 (21 USC 360ee(b)(3)) to assure, among other things, the safety and effectiveness of these products, proper labeling of the nutrient content and purported uses, including adequate and appropriate directions for use, and quality control and good manufacturing practices.

Timetable:

Action	Date	FR Cite
ANPRM	11/29/96	61 FR 60661
ANPRM Comment Period End	04/28/97	
NPRM	To Be Determined	

Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD91.

Agency Contact: Robert Moore, Senior Regulatory Scientist, Department of Health and Human Services, Food and Drug Administration, HFS-456, Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204  
Phone: 202 205-4605

RIN: 0910-AA20

1188. 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

1189. REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

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

Unfunded Mandates: Undetermined

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

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 burden on manufacturers, packers, and distributors and to consolidate, reorganize, and streamline the requirements.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis

Required: Undetermined

Government Levels Affected: 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

1190. REINVENTING FDA FOOD REGULATIONS

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 101; 21 CFR 102; 21 CFR 103; 21 CFR 131; 21 CFR 133; 21 CFR 135; 21 CFR 136; 21 CFR 137; 21 CFR 139; 21 CFR 145; 21 CFR 146; 21 CFR 150; 21 CFR 152; 21 CFR 155; 21 CFR 156; ...

Legal Deadline: None

Abstract: In response to President Clinton's memorandum to heads of departments and agencies entitled "Regulatory Reinvention Initiative,"

## HHS—FDA

## Long-Term Actions

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, 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 (CED) on those regulations, promulgated under the

formal rulemaking procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 USC 371(e)), pertaining to diabetic labeling (21 CFR 105.67) and sodium intake 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 06/12/1996 (61 FR 29701)  
Comment Period Ended 10/10/1996  
NPRM 00/00/0000

**Food Standards of Identity, Quality, and Fill of Container**

ANPRM 12/29/1995 (60 FR 67492)  
Comment Period Ended 06/28/1996  
NPRM 00/00/0000

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

NPRM 12/29/1995 (60 FR 67490)  
Comment Period Ended 03/14/1996  
Extension of Comment Period 06/03/1996  
Final Action 00/00/0000

**Notification Procedures for Independent GRAS Determinations**

NPRM 04/17/1997 (62 FR 18938)  
NPRM Comment Period Ended  
07/16/1997  
Final Action 00/00/0000

**Revocation of Certain Food Labeling and Cosmetic Regulations**

NPRM 06/12/1996 (61 FR 29708)  
Comment Period Ended 08/26/1996  
Final Rule 08/12/1997 (62 FR 43071)

**Revocation of Lower Fat Milk Standards**

NPRM 11/09/1995 (60 FR 56541)  
Comment Period Ended 01/23/1996  
Partial Final 11/20/1996 (61 FR 58991)  
Confirmation of Effective Date 02/24/1997  
(62 FR 8163)

**Revocation of Lower Fat Yogurt Standards**

NPRM 11/09/1995 (60 FR 56541)  
Confirmation of Effective Date 00/00/0000  
Final Action (Yogurt) 00/00/0000

**Revocation of Obsolete Regulations**

NPRM 10/13/1995 (60 FR 53480)  
Comment Period Ended 01/11/1996  
Final Rule 06/03/1996 (61 FR 27771)  
Confirmation of Eff. Date 08/27/1996 (61  
FR 43963)

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

Phone: 202 205-4561

**RIN:** 0910-AA58

**1191. DEBARMENT CERTIFICATION REGULATIONS FOR DRUG APPLICATIONS**

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

**Abstract:** The proposed rule would amend the regulations to require applicants to submit a debarment certification statement in accordance with 21 U.S.C. 335a(k).

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Leanne Cusumano, 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-AA76

## HHS—FDA

## Long-Term Actions

**1192. INVESTIGATIONAL NEW DRUG APPLICATIONS; REQUEST FOR INFORMATION AND COMMENTS**

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

**Unfunded Mandates:** Undetermined

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

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

**CFR Citation:** 21 CFR 56; 21 CFR 312

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
ANPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

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-AA83

**1193. ESTABLISHMENT REGISTRATION AND LISTING 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 264

**CFR Citation:** 21 CFR 207; 21 CFR 807; 21 CFR 1271

**Legal Deadline:** None

**Abstract:** This action is a continuation of FDA's approach for the regulation of human tissues and is part of FDA's reinventing government initiative. The final rule requires manufacturers of human cellular and tissue-based products to register with the agency and submit a list of all such products produced. Future regulations would include the promulgation of good tissue practices (GTP) that will provide good manufacturing standards and regulations for donor screening and testing, and compliance and procedural issues. The proposed approach would provide a rational, comprehensive, and clear framework under which tissue processors can develop and market their products without being subjected to unnecessary regulation and without sacrificing the protection of the public health.

**Timetable:**

Action	Date	FR Cite
NPRM	05/14/98	63 FR 26744
NPRM Comment Period End	08/12/98	
Final Action	10/00/00	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Phone: 301 827-6210

**RIN:** 0910-AB05

**1194. REQUIREMENTS PERTAINING TO THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS; USE OF NONTOBACCO TRADE OR BRAND NAMES**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 897

**Legal Deadline:** None

**Abstract:** The proposed rule would clarify the restrictions on the use of non-tobacco product names and other

identification on tobacco products and would modify the list of established names for smokeless tobacco products.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Anne M. Kirchner, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Room 12A-55 (HF-13), Office of Tobacco Programs, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827-5321

**RIN:** 0910-AB17

**1195. EXEMPTION FROM PREEMPTION OF STATE AND LOCAL CIGARETTE AND SMOKELESS TOBACCO REQUIREMENTS; APPLICATIONS FOR EXEMPTION SUBMITTED BY VARIOUS STATE GOVERNMENTS; GROUP 1; GROUP 2**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 360k; 21 USC 371

**CFR Citation:** 21 CFR 808

**Legal Deadline:** None

**Abstract:** FDA published a notice of proposed rulemaking on November 7, 1996, announcing that the agency would be accepting applications for exemption from Federal preemption for State and local cigarette and smokeless tobacco requirements. The notice explained that FDA would consider the applications in two groups and set deadlines for submitting applications. Group 1 applications, due December 9, 1996, pertain to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco that are different from, or in addition to, FDA requirements under section 897.14(a) and section 897.14(b) of the final tobacco rule (the age and identification requirements). Group 2 applications, due May 6, 1997, pertain to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco that are different from, or in addition to, all other requirements under the final tobacco rule.

## HHS—FDA

## Long-Term Actions

**Timetable:****Group 1**

NPRM 02/19/1997 (62 FR 7390)  
NPRM Comment Period End 06/23/1997  
Final Rule 11/28/1997 (62 FR 63271)

**Group 2**

NPRM 00/00/0000

**Groups 1 and 2**

Notice 11/07/1996 (61 FR 57685)

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State,  
Local

**Additional Information:** Formerly listed  
under RIN 0910-AB03.

**Agency Contact:** Anne M. Kirchner,  
Regulatory Counsel, Department of  
Health and Human Services, Food and  
Drug Administration, Room 12A-55  
(HF-13), Office of Tobacco Programs,  
5600 Fishers Lane, Rockville, MD  
20857

Phone: 301 827-5321

**RIN:** 0910-AB19

**1196. 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	12/00/00	

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Government Levels Affected:**  
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

**1197. IMPLEMENTATION OF THE  
IMPORT TOLERANCE PROVISIONS  
OF THE ANIMAL DRUG AVAILABILITY  
ACT OF 1996 AND THE SAFE LEVEL  
PROVISIONS OF THE ANIMAL  
MEDICINAL DRUG USE  
CLARIFICATION ACT OF 1994**

**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 (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. The  
Animal Medicinal Drug Use  
Clarification Act of 1994 (Pub. L. 103-  
396) allows the Secretary to establish  
a safe level for a residue of an animal  
drug when the drug is used in an  
extralabel manner, if the Secretary finds  
that there is a reasonable probability  
that an extralabel use may present a  
risk to the public health.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/01	

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Government Levels Affected:**  
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

**1198. 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	12/00/00	

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Government Levels Affected:**  
Undetermined

**Agency Contact:** Daniel G. McChesney,  
Team Leader, Feed Safety Team,

HHS—FDA

Long-Term Actions

Department of Health and Human Services, Food and Drug Administration, HFV-222, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855  
Phone: 301 827-6653  
RIN: 0910-AB72

**1199. 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 331; 21 USC 351 to 352; 21 USC 357; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360i; 21 USC 360j; 21 USC 360l; 21 USC 371; 21 USC 374

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

**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	To Be	Determined

**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

**1200. • MARKING REQUIREMENTS FOR 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 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	To Be	Determined

**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

**1201. • REQUIREMENTS FOR PERSONS USING PRIVATE LABORATORIES REGARDING ACTIONS TAKEN BY THE FOOD AND DRUG ADMINISTRATION**

**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 private laboratories with regard to a FDA regulatory action. 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 a FDA regulatory action. 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	To Be	Determined

**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

**Department of Health and Human Services (HHS)**  
**Food and Drug Administration (FDA)**
**Completed Actions**
**1202. DIETARY SUPPLEMENT REGULATIONS IN RESPONSE TO DSHEA**
**Priority:** Other Significant

**CFR Citation:** 21 CFR 101

**Completed:**

Reason	Date	FR Cite
Final Rule-Nutrient Labeling and Ingredient Labeling; Dietary Supplements	06/05/98	63 FR 30615

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** Federal, State

**Agency Contact:** Elizabeth A. Yetley  
 Phone: 202 205-4168

**RIN:** 0910-AA59

**1203. OVER-THE-COUNTER HUMAN DRUGS; LABELING REQUIREMENTS**
**Priority:** Other Significant

**CFR Citation:** 21 CFR 201; 21 CFR 330

**Completed:**

Reason	Date	FR Cite
Final Rule	03/17/99	64 FR 13254

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Debra Bowen  
 Phone: 301 827-2222

**RIN:** 0910-AA79

**1204. DEFINITION OF SUBSTANTIAL EVIDENCE**
**Priority:** Other Significant

**CFR Citation:** 21 CFR 514.4

**Completed:**

Reason	Date	FR Cite
Final Rule	07/28/99	64 FR 40746

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Gail Schmerfeld  
 Phone: 301 827-0205

**RIN:** 0910-AB08

**1205. BIOLOGICAL PRODUCTS REGULATED UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT; IMPLEMENTATION OF BIOLOGICS LICENSE; ELIMINATION OF ESTABLISHMENT LICENSE AND PRODUCT LICENSE**
**Priority:** Other Significant

**CFR Citation:** 21 CFR 3; 21 CFR 5; 21 CFR 10; 21 CFR 20; 21 CFR 207; 21 CFR 310; 21 CFR 312; 21 CFR 316; 21 CFR 600; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 640; 21 CFR 660

**Completed:**

Reason	Date	FR Cite
Final Rule	10/20/99	64 FR 56441

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Robert A. Yetter  
 Phone: 301 827-0373

**RIN:** 0910-AB29

**1206. RADIOPHARMACEUTICALS USED FOR IN VIVO DIAGNOSIS AND MONITORING**
**Priority:** Other Significant

**CFR Citation:** 21 CFR 315; 21 CFR 601

**Completed:**

Reason	Date	FR Cite
Final Rule	05/17/99	64 FR 26657

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Steven F. Falter  
 Phone: 301 827-6210  
 Email: falter@a1.cber.fda.gov  
 Brian L. Pendleton  
 Phone: 301 594-2041

**RIN:** 0910-AB52

**1207. • REQUIREMENTS FOR TESTING HUMAN BLOOD DONORS FOR EVIDENCE OF INFECTION DUE TO COMMUNICABLE DISEASE AGENTS**
**Timetable:**

Action	Date	FR Cite
Merged With 0910-AB26	09/20/99	

**RIN:** 0910-AB85

**1208. • GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES; NOTIFICATION OF DEFERRED DONORS**
**Timetable:**

Action	Date	FR Cite
Merged With 0910-AB26	09/20/99	

**RIN:** 0910-AB86

**1209. • REVISIONS TO THE REQUIREMENTS APPLICABLE TO BLOOD, BLOOD COMPONENTS, AND SOURCE PLASMA**
**Timetable:**

Action	Date	FR Cite
Merged With 0910-AB26	09/20/99	

**RIN:** 0910-AB87

Department of Health and Human Services (HHS)

Proposed Rule Stage

Health Resources and Services Administration (HRSA)

**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 NPRM dated 9/1/98.

**Timetable:**

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
NPRM Comment Period End	01/04/99	
Second NPRM	02/00/00	
NPRM Comment Period End	05/00/00	

**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 part 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 propose rules would also provide a compliance alternative for facilities 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	04/00/00	
NPRM Comment Period End	06/00/00	
Final Action	12/00/00	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Mr. Eulas Dortch, Deputy Director, Division of Facilities Compliance and Recovery, OSP, Department of Health and Human Services, Health Resources and Services Administration, Room 10-C16, 5600 Fishers Lane, Rockville, MD 20857  
 Phone: 301 443-5656  
 Fax: 301 443-0619  
 Email: edortch@hrsa.gov

**RIN:** 0906-AA52

Department of Health and Human Services (HHS)

Final Rule Stage

Health Resources and Services Administration (HRSA)

**1212. • 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 which 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	03/00/00	

## HHS—HRSA

## Final Rule Stage

**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/HRSA/DHHS, 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  
Email: stise@hrsa.gov

**RIN:** 0906-AA53

## Department of Health and Human Services (HHS)

## Long-Term Actions

## Health Resources and Services Administration (HRSA)

**1213. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: CORPORATE SHIELD**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 11131

**CFR Citation:** 45 CFR 60.7

**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, the name of the hospital or health care organization for whose benefit the payment was made.

**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

## Department of Health and Human Services (HHS)

## Completed Actions

## Health Resources and Services Administration (HRSA)

**1214. • NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: REPORTING ADVERSE AND NEGATIVE ACTIONS**

**Timetable:**

Action	Date	FR Cite
Duplicate of 0906-AA43	09/09/99	

**RIN:** 0906-AA51

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

Proposed Rule Stage

1215. ● 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	12/00/99	

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)  
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	01/00/00	

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, 5300 Homestead Road NE, Albuquerque, NM 87110

Phone: 505 837-4245

RIN: 0917-AA02

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

Completed Actions

1217. CURRENTLY EFFECTIVE INDIAN HEALTH SERVICE ELIGIBILITY REGULATIONS

Priority: Info./Admin./Other

CFR Citation: 42 CFR 36

Completed:

Reason	Date	FR Cite
Final Rule	10/28/99	64 FR 58318

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Tribal

Agency Contact: Betty J. Penn  
Phone: 301 443-1116  
Email: bpenn@hqe.ihs.gov

RIN: 0917-AA03

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	03/00/00	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD18.

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

HHS—NIH

Proposed Rule Stage

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

**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 ten consecutive weeks of service (employment) at the NIH during which the individual is attending the institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/00	

**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 MSC 7669, 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	11/00/99	

**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 for research authorized under section 487C of the Public Health Service Act, as added by provisions of the National Institutes of Health Revitalization Act of 1993.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/00	

**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-AA18**1222. 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	11/00/99	

**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**1223. 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

HHS—NIH

Proposed Rule Stage

to reflect current policies and procedures.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/00	

**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-AA20

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

Final Rule Stage

**1224. TRAINEESHIPS****Priority:** Info./Admin./Other**Legal Authority:** 42 USC 216; 42 USC 282(b)(B); 42 USC 284(b)(1)(C); 42 USC 285a-2(b)(3); 42 USC 286b-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 Action	03/00/00	

**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

### 1225. ADDITIONAL DHHS PROTECTIONS FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED AS SUBJECTS IN RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION

**Priority:** Other Significant**Legal Authority:** 5 USC 301; 42 USC 289**CFR Citation:** 45 CFR 46, subpart B**Legal Deadline:** None**Abstract:** Current regulations which have been in effect for two decades will be revised to reflect provisions of Public Law 103-43 and recent changes in NIH and FDA policies on the involvement of women and human fetuses in research.**Timetable:**

Action	Date	FR Cite
NPRM	05/20/98	63 FR 27794
Final Action	02/00/00	

**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

### 1226. 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 set forth, specifically, that a service payback obligation is incurred only during the first twelve months of postdoctoral support and individuals may pay back this service obligation by engaging in an equal period of health-related teaching or, if the individual finished

the first twelve months of support, by engaging in a second year of NRSA supported research training.

**Timetable:**

Action	Date	FR Cite
NPRM	06/30/99	64 FR 35119
Final Action	03/00/00	

**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

### 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:** The President's Memorandum prohibits agencies from conducting or supporting classified human subject research without having proposed and promulgated the common rule and the changes.**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

## HHS—NIH

## Final Rule Stage

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.

**Timetable:**

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

**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

**1228. SERVICE FELLOWSHIPS**

**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 209; 42 USC 210; 42 USC 216

**CFR Citation:** 42 CFR 61, subpart B

**Legal Deadline:** None

**Abstract:** This final rule would amend the regulations governing service fellowships by revising the current authority citation, extending the time limitation on initial appointments from 2 to 5 years, permitting extensions of appointments for up to 5 years rather than year-to-year, and removing obsolete references to the Surgeon General and obsolete requirements regarding the qualifications of applicants. These changes are being made to provide HHS health agencies with greater flexibility to recruit and retain their talented scientists and to update obsolete references.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	02/27/98	63 FR 9949
Final Action	11/00/99	

**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-AA22

**1229. • NIH PRIVACY ACT SYSTEM OF RECORDS, 09-25-0213, "ADMINISTRATION: INVESTIGATIVE RECORDS"**

**Priority:** Info./Admin./Other

**Legal Authority:** 5 USC 301; 5 USC 552a

**CFR Citation:** 45 CFR 5b

**Legal Deadline:** None

**Abstract:** The Department of Health and Human Services is exempting a new system of records, 09-25-0213, "Administration: Investigative Records, HHS/NIH/OM/OA/OMA," from certain requirements of the Privacy Act to protect records compiled in the course of an inquiry and/or investigation and to protect the identity of confidential sources who furnish information to the Government under an express promise that the identity of such source would be held in confidence.

**Timetable:**

Action	Date	FR Cite
NPRM	07/09/99	64 FR 37081
NPRM Comment Period End	08/09/99	
Final Action	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Timothy Wheelles, NIH Privacy Act Officer, Department of Health and Human Services, National Institutes of Health, 6011 Executive Boulevard, Room 601, Rockville, MD 20852

Phone: 301 402-5347

Fax: 301 402-0169

**RIN:** 0925-AA23

## Department of Health and Human Services (HHS)

## Long-Term Actions

## National Institutes of Health (NIH)

**1230. NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS**

**Priority:** Other Significant

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

**Legal Authority:** 42 USC 216; 42 USC 285a-3; 42 USC 285d-6; 42 USC 285i; 42 USC 285m-3; 42 USC 285o-4; 42 USC 287a-2; 42 USC 287a-3; 42 USC

300cc-41; 42 USC 285a-2; 42 USC 285b-3; 42 USC 285b-4

**CFR Citation:** 42 CFR 52b

**Legal Deadline:** None

**Abstract:** Regulations concerning NCI construction grants will be amended to make them generally applicable to all NIH extramural programs with construction grant authority. Additionally, the regulations will be amended to show new administrative and technical requirements, add new procedures for the recovery of grant

funds for facilities no longer used for biomedical research, show new Public Health Service Act section numbers, and update the listing of other HHS regulations relevant to construction grants.

**Timetable:**

Action	Date	FR Cite
NPRM	07/06/95	60 FR 35266
NPRM Comment Period End	09/05/95	
Final Action	11/00/00	

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Long-Term Actions

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** Previously reported under RIN 0905-AD49.

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

Phone: 301 496-4606  
Email: jm40@nih.gov

**RIN:** 0925-AA04

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

**Proposed Rule Stage**

**1231. 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	05/00/00	
NPRM Comment Period End	07/00/00	

**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)**

**Long-Term Actions**

**1232. STANDARDS OF COMPLIANCE FOR ABORTION-RELATED SERVICES IN FAMILY PLANNING SERVICE PROJECTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 300a-4

**CFR Citation:** 42 CFR 59

**Legal Deadline:** None

**Abstract:** This rule would return the Family Planning Service Program, funded under title X of the Public Health Service Act, to the regulatory

standard operative prior to February 2, 1988, with regard to the statutory provision prohibiting abortion as a method of family planning in projects funded under that title.

**Timetable:**

Action	Date	FR Cite
NPRM	02/05/93	58 FR 7464
NPRM Comment Period End	08/09/93	58 FR 34024
Final Action	To Be Determined	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Additional Information:** Previously reported under RIN 0905-AE03.

**Agency Contact:** Denese Shervington M.D., M.P., Department of Health and Human Services, Office of Public Health and Science, Suite 200, West Tower Bldg., East-West Towers, 4350 East-West Highway, Bethesda, MD 20814  
Phone: 301 594-4001

**RIN:** 0940-AA00

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

**Prerule Stage**

**1233. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (HCFA-3818-F) (SECTION 610 REVIEW)**

**Priority:** Other Significant

**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in

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

**Legal Authority:** 42 USC 1395rr

**CFR Citation:** 42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410;

42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 489; 42 CFR 492

**Legal Deadline:** None

**Abstract:** This rule would revise the current conditions for coverage for end stage renal disease (ESRD) facilities approved to provide ESRD service

## HHS—HCFA

## Prerule Stage

under Medicare. It would update the conditions to reflect developments in technology and equipment, emphasize the total patient experience and develop performance expectations for the facility that result in quality, comprehensive care for the dialysis patient. We will also review for the requirements of Section 610c of the Regulatory Flexibility Act.

**Timetable:**

Action	Date	FR Cite
Begin Review	12/00/99	
End Review	06/00/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Additional Information:** HCFA-3818

**Agency Contact:** Robert Miller, Department of Health and Human Services, Health Care Financing Administration, S3-04-25, Department of Health and Human Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6797

**RIN:** 0938-AG82

### 1234. CRITERIA FOR MEDICARE COVERAGE OF HEART, LIVER, AND LUNG TRANSPLANTS (HCFA-3835-ANPRM)

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395y(a)(1)(A)

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This notice lists various options related to the criteria for Medicare coverage of heart, liver, and

lung transplants and seeks public comment on those options.

**Timetable:**

Action	Date	FR Cite
ANPRM	12/00/99	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** HCFA-3835-PN

**Agency Contact:** Kathy Linstromberg, Department of Health and Human Services, Health Care Financing Administration, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-8279

**RIN:** 0938-AH17

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

## Proposed Rule Stage

### 1235. MEDICARE PROGRAM; QUALIFICATIONS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (HCFA-6002-P)

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

**RIN:** 0938-AH73

### 1236. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (HCFA-4145-P)

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** 42 USC 1320d-2

**CFR Citation:** 45 CFR 142

**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	12/00/99	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Additional Information:** BPO-145

**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

### 1237. STATE CHILD HEALTH; IMPLEMENTING REGULATIONS FOR THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM (HCFA-2006-P)

**Priority:** Economically Significant

**Legal Authority:** PL 105-33; 42 USC 1396

**CFR Citation:** 42 CFR 457

**Legal Deadline:** None

**Abstract:** This proposed regulation will implement all programmatic provisions for the new State Children's Health Insurance Program (CHIP) under title XIX (Medicaid). The CHIP program was established to provide Federal funding to help States to initiate and expand child health assistance to uninsured, low-income children.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/99	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:** Federal, State, Local

**Agency Contact:** Cheryl Austein-Casnoff, Department of Health and Human Services, Health Care Financing Administration, 200 Independence Avenue SW., Washington, DC 20201

Phone: 410 786-4196

**RIN:** 0938-AI28

HHS—HCFA

Proposed Rule Stage

**1238. 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	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**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

**1239. PROSPECTIVE FEE SCHEDULE FOR AMBULANCE SERVICES (HCFA-1002-NR)**

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

**RIN:** 0938-AI72

**1240. MEDICARE PROGRAM; COVERAGE AND ADMINISTRATIVE POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS; INTENT TO FORM NEGOTIATED RULEMAKING COMMITTEE (HCFA-3250-P)**

**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 proposed 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).

**Timetable:**

Action	Date	FR Cite
Notice of Intent to Negotiate	06/03/98	63 FR 30166
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Agency Contact:** Jacqueline Sheridan, Office of Clinical Standards & Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-4635

**RIN:** 0938-AI92

**1241. DECISION ON THE FUNDING FOR THE AIDS HEALTHCARE FOUNDATION START PROGRAM, (HCFA-2041-N)**

**Priority:** Info./Admin./Other

**Legal Authority:** PL 105-33, sec 1110

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This notice announces the award of a grant in the sum of \$2

million to the AIDS Healthcare Foundation of Los Angeles, California, for a demonstration project entitled, "START PROGRAM: Success Through Anti-Retroviral Therapy."

**Timetable:**

Action	Date	FR Cite
NPRM Notice	03/04/99	64 FR 10479
	11/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Wayne Smith Ph.D., CMSO, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786-6762

**RIN:** 0938-AJ43

**1242. PROTECTION FOR WOMEN WHO ELECT RECONSTRUCTION AFTER A MASTECTOMY (HCFA-2040-IFC)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 300gg-6

**CFR Citation:** 45 CFR 146; 45 CFR 148

**Legal Deadline:** None

**Abstract:** This IFC will implement the requirements of the Women's Health and Cancer Rights Act of 1998 (WHCRA). It will provide protection for patients who elect breast reconstruction following a mastectomy.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Michael Bussacca, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850 Phone: 410 786-4602

**RIN:** 0938-AJ44

## HHS—HCFA

## Proposed Rule Stage

**1243. ACCELERATED PAYMENTS TO PROVIDERS FURNISHING SERVICES UNDER MEDICARE PART A AND PART B AND ADVANCE PAYMENTS TO SUPPLIERS FURNISHING ITEMS OR SERVICES UNDER MEDICARE PART B (HCFA-1066-FC)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 91-190; 42 USC 1302; 42 USC 1395g; 42 USC 1395l; 42 USC 1395hh

**CFR Citation:** 42 CFR 412.116; 42 CFR 413.64; 42 CFR 421.214

**Legal Deadline:** None

**Abstract:** This proposed rule would ensure continued payments to providers and suppliers in the event of a national, regional, or a local emergency, such as national disasters including fire, flood, earthquake and the year 2000 computer system difficulties and related breakdowns. The intent of the proposed rule is to give HCFA broad discretion in implementing procedures to provide appropriate payments to providers and suppliers in the event of a national, regional, or a local emergency that may prevent the submission or processing of Medicare claims.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Agency Contact:** Geraldine Nicholson, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6967

**RIN:** 0938-AJ45

**1244. 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 NPRM 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	12/00/99	

**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

**1245. FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (HCFA-2019-FC)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 300gg

**CFR Citation:** 45 CFR 150

**Legal Deadline:** None

**Abstract:** This rule adds more specific requirements for enforcing legislative requirements concerning the portability and availability of health insurance. It specifies the Federal Government's role in enforcing the insurance requirements in States that do not enforce the requirements. It also specifies how the government will impose civil money penalties on health insurance issuers in those states and states appeal rights and procedures.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Rochelle Shevitz, CMSO, Department of Health and

Human Services, Health Care Financing Administration, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-1570

**RIN:** 0938-AJ48

**1246. • MEDICARE PROGRAM: PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITAL SERVICES (HCFA-1069-P)**

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

**RIN:** 0938-AJ55

**1247. • DME SURETY BONDS (HCFA-6006-P)**

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

**RIN:** 0938-AJ64

**1248. • REAPPLICATION OF THE JOINT COMMISSION FOR ACCREDITATION OF HEALTH CARE ORGANIZATIONS JCAHO (HCFA-2058-PN)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395(bb)

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This NPRM announces the receipt of a reapplication from JCAHO for recognition as a national accreditation program for home health agencies (HHA's) that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request for approval describing the nature of the request and providing a 30-day public comment period.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joan Berry, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing

HHS—HCFA

Proposed Rule Stage

Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7233  
Email: jberry@hcfa.gov

RIN: 0938-AJ68

**1249. • REAPPLICATION OF THE COMMUNITY HEALTH ACCREDITATION PROGRAM, INCORPORATED (CHAP FOR CONTINUED APPROVAL OF DEEMING AUTHORITY FOR WHOM HEALTH CARE AGENCIES HCFA-2059-PN)**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395(bb)

CFR Citation: None

Legal Deadline: None

**Abstract:** This NPRM announces the receipt of a reapplication from CHAP for recognition as a national accreditation program for home health agencies (HHA's) that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request for approval describing the nature of the request and providing a 30-day comment period.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joan Berry, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7233  
Email: jberry@hcfa.gov

RIN: 0938-AJ69

**1250. • HHA SURETY BOND (HCFA-6001-P)**

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

RIN: 0938-AJ81

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

**Final Rule Stage**

**1251. ADDITIONAL SUPPLIER STANDARDS (HCFA-6004-F)**

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424.57

Legal Deadline: None

**Abstract:** This rule will establish additional standards for entities seeking to qualify as Medicare suppliers for purposes of submitting claims for durable medical equipment and supplies. This rule is part of HCFA's regulatory reform initiative.

**Timetable:**

Action	Date	FR Cite
NPRM	01/20/98	63 FR 2926
Final Action	11/00/99	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** HCFA-1864

**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-AH19

**1252. REQUIREMENTS FOR ENROLLMENT OF MEDICAID RECIPIENTS UNDER COST EFFECTIVE EMPLOYER-BASED GROUP HEALTH PLANS (HCFA-2047-FC)**

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

**Abstract:** This final rule with comment period amends our regulations to incorporate an optional statutory requirement 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 final rule with comment period 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 final rule with comment period 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	
Final Action	10/00/99	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Additional Information:** MB-047

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

## HHS—HCFA

## Final Rule Stage

**1253. 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 420; 42 CFR 421 to 430; 42 CFR 431 to 440; 42 CFR 442 to 447; 42 CFR 455 to 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 is a technical final rule with comment period that will initiate the rationalization of our system of definitions, correct outdated addresses and formulas, clarify which steps of the appeals process are binding and which are final, remove content that is duplicative or unnecessary, and make other clarifying editorial changes.**Timetable:**

Action	Date	FR Cite
Final With Comment Period	12/00/99	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Additional Information:** BPD-877**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**1254. UTILIZATION CONTROL AND DISCONTINUED REVIEW ACTIVITIES; MEDICAID (HCFA-2101-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 1396a(a)(26); 42 USC 1396a(a)(30); 42

USC 1396a(a)(31); 42 USC 1396a(a)(44); 42 USC 1396b(g)

**CFR Citation:** 42 CFR 400; 42 CFR 431; 42 CFR 456**Legal Deadline:** None**Abstract:** This final rule with comment period amends current regulations to reflect statutory changes under which physician certification, plan of care, and utilization review requirements become State plan requirements and are no longer included in the quarterly "showings" of compliance that States must submit. Those showings are now limited to inspection of care reviews in institutions for mental diseases and intermediate care facilities for the mentally retarded. The rule also reflects the discontinuance of the State-operated claims processing assessment system and of regional office review of a subsample of each State's Medicaid quality control sample.**Timetable:**

Action	Date	FR Cite
Final Action	12/00/99	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** State**Additional Information:** MB-101**Agency Contact:** Pamela Butler, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6776**RIN:** 0938-AH64**1255. UPDATE OF RATESETTING METHODOLOGY, PAYMENT RATES AND THE LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS EFFECTIVE FOR CALENDAR YEAR 2000 (HCFA-1885-F)****Priority:** Other Significant. Major under 5 USC 801.**Legal Authority:** 42 USC 13951(i)(2)(A)**CFR Citation:** 42 CFR 416.61(b); 42 CFR 416.65(a)(4); 42 CFR 416.65(c); 42 CFR 416.120(c)(1); 42 CFR 416.125; 42 CFR 416.130; 42 CFR 416.140(a); 42 CFR 416.140(b); 42 CFR 488.1**Legal Deadline:** None**Abstract:** This final rule discusses several policy changes affecting

coverage of and payment for Ambulatory Surgical Center (ASC) facility services as provided under sections 1833(i)(1A) and (2A) of the Social Security Act. It would include the criteria for identifying procedures that are appropriate and safely performed in an ASC; the method used to set ASC payment rates; and the schedule for publishing and implementing payment and coverage updates.

**Timetable:**

Action	Date	FR Cite
NPRM	06/12/98	63 FR 32290
Final Action	12/00/99	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** BPD-885**Agency Contact:** Joan H. Sanow, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, C4-11-16, Baltimore, MD 21244

Phone: 410 786-5763

**RIN:** 0938-AH81**1256. NATIONAL STANDARD HEALTH CARE PROVIDER IDENTIFIER (HCFA-0045-F)****Regulatory Plan:** This entry is Seq. No. 40 in Part II of this issue of the **Federal Register**.**RIN:** 0938-AH99**1257. MEDICARE PROGRAM; MEDICARE+CHOICE PROGRAM (HCFA-1030-2-F)****Regulatory Plan:** This entry is Seq. No. 41 in Part II of this issue of the **Federal Register**.**RIN:** 0938-AI29**1258. MEDICARE PROGRAM; PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES (HCFA-1005-F)****Regulatory Plan:** This entry is Seq. No. 42 in Part II of this issue of the **Federal Register**.**RIN:** 0938-AI56

**1259. SECURITY AND ELECTRONIC SIGNATURE STANDARDS (HCFA-0049-F)**

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

**RIN:** 0938-AI57

**1260. HEALTH INSURANCE REFORM: STANDARDS FOR ELECTRONIC TRANSACTIONS (HCFA-0149-F)**

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

**RIN:** 0938-AI58

**1261. NATIONAL STANDARD EMPLOYER IDENTIFIER (HCFA-0047-F)**

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

**RIN:** 0938-AI59

**1262. MEDICAID PROGRAM; HOME AND COMMUNITY-BASED SERVICES (HCFA-2010-FC)**

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** This action may affect State, Local or Tribal Governments.

**Legal Authority:** 42 USC 1302; PL 105-33, sec 4743

**CFR Citation:** 42 CFR 440; 42 CFR 441

**Legal Deadline:** None

**Abstract:** This final rule with comment period 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	12/00/99	

**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

**1263. MEDICAID MANAGED CARE; REGULATORY PROGRAM TO IMPLEMENT CERTAIN MEDICAID PROVISIONS OF THE BALANCED BUDGET ACT OF 1997 (HCFA-2001-P)**

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

**RIN:** 0938-AI70

**1264. COVERAGE OF RELIGIOUS NON-MEDICAL HEALTH CARE INSTITUTIONS (HCFA-1909-IFC)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395i-5; 42 USC 1395x(e), (y), and (ss); 42 USC 1395ff; 42 USC 1395oo; 42 USC 1302

**CFR Citation:** 42 CFR 403; 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; 42 CFR 440.170; 42 CFR 488.2; 42 CFR 488.6; 42 CFR 489.102

**Legal Deadline:** Final, Statutory, July 1, 1998, BBA Section 4106.

**Abstract:** This final rule with comment period 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 to be paid 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
Final Action	01/00/00	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**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

**1265. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM (HCFA-1059-P)**

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

**RIN:** 0938-AJ24

**1266. ESTABLISHMENT OF A PROGRAM TO COLLECT SUGGESTIONS FOR IMPROVING MEDICARE PROGRAM EFFICIENCY AND TO REWARD SUGGESTORS (HCFA-4000-FC)**

**Priority:** Other Significant

**Legal Authority:** PL 104-191, sec 203(c)1; 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 420.410

**Legal Deadline:** None

**Abstract:** This rule establishes a suggestion program as a means of (1) encouraging individuals to submit suggestions and (2) rewarding individuals who make suggestions for improving the efficiency of the Medicare program in those instances in which HCFA deems that it is appropriate and when a reward is not otherwise provided by law. The rule describes the program, lists information requirements and eligibility criteria, establishes an upper limit for payments, and outlines the process and time limitations for obtaining a reward.

**Timetable:**

Action	Date	FR Cite
Final Action	12/00/99	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Sam Della Vecchia, CBS, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4481

**RIN:** 0938-AJ30

HHS—HCFA

Final Rule Stage

**1267. • THE CHILDREN'S HEALTH INSURANCE PROGRAM: IMPLEMENTING THE BALANCED BUDGET ACT OF 1997 (HCFA-2006-P)**

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

**RIN:** 0938-AJ75

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

Long-Term Actions

**1268. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (HCFA-1309-F)**

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

**Abstract:** This rule will incorporate provisions of the Deficit Reduction Act of 1984, COBRA '85, OBRA '86, OBRA '87, TMRA '88, OBRA '89, and OBRA '90 regarding payment and "assignment" for diagnostic clinical laboratory tests establishing in regulations the methods for implementing fee schedules. This rule will set forth the methods by which the fee schedules will be updated and will allow certain adjustments for exceptions to the fee schedule. It will also reflect a statutory revision mandated by OBRA '93.

**Timetable:**

Action	Date	FR Cite
NPRM	08/18/93	58 FR 43156
NPRM Comment Period End	10/18/93	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** BPD-3

**Agency Contact:** Cathy Black, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4544

**RIN:** 0938-AB50

**1269. 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 411.15; 42 CFR 431.630; 42 CFR 433.15; 42 CFR 462.1; 42 CFR 462.101; 42 CFR 462.102; 42 CFR 462.106; 42 CFR 462.107; 42 CFR 466.1; 42 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83

**Legal Deadline:** None

**Abstract:** This rule will set forth several changes to regulations that govern Peer Review Organizations (PROs) and is based on statutory changes contained in COBRA '85 and OBRA '86. In addition, several technical changes will be included as a result of experience gained with the PRO program by HCFA. This rule also implements the new quality review requirements for certain Medicaid health maintenance organization contracts.

**Timetable:**

Action	Date	FR Cite
NPRM	03/16/88	53 FR 8654
NPRM Comment Period End	05/16/88	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** HSQ-135

**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

**1270. OMNIBUS NURSING HOME REFORM REQUIREMENTS (HCFA-3488-F)**

**Priority:** Other Significant. Major under 5 USC 801.

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

**Legal Authority:** 42 USC 1395i-3; 42 USC 1395x; 42 USC 1396r; 42 USC 1302

**CFR Citation:** 42 CFR 431; 42 CFR 482; 42 CFR 483; 42 CFR 488

**Legal Deadline:** None

**Abstract:** This rule will implement several provisions of OBRA '87 that concern services to residents of nursing homes. This rule will implement provisions that include Federal standards for evaluating State waivers of nursing facility nurse staffing requirements, use of physical and chemical restraints in nursing facilities, qualifications of facility administrators, notice of Medicaid rights to be given to persons admitted to nursing facilities, and other technical changes.

**Timetable:**

Action	Date	FR Cite
NPRM	02/05/92	57 FR 4516

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Action	Date	FR Cite
NPRM Comment Period End	04/06/92	
Next Action Undetermined		

**Regulatory Flexibility Analysis  
Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** BPD-488

**Agency Contact:** Nancy Archer, Office of Clinical Standards & 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-AD81

**1271. "WITHOUT FAULT" AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (HCFA-1719-P)**

**Priority:** Substantive, Nonsignificant

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

**Legal Authority:** 42 USC 1395gg

**CFR Citation:** 42 CFR 401; 42 CFR 403.310; 42 CFR 405; 42 CFR 410.1; 42 CFR 411.23; 42 CFR 411.28; 42 CFR 413.20; 42 CFR 413.153; 42 CFR 447.31; 42 CFR 466.86; 42 CFR 466.94; 42 CFR 473.14; 42 CFR 493.1834

**Legal Deadline:** None

**Abstract:** This rule would amend the Medicare regulations to clarify our interpretation of "without fault" as it applies to physician, provider, supplier, and beneficiary liability for overpayments. This definition would result in greater uniformity of determinations by carriers and intermediaries. Additionally, this rule would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with HCFA regulations more specific to circumstances involving Medicare overpayments.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** None

**Additional Information:** BPD-71

**Agency Contact:** David Walczak, Center for Health Plans and Providers, Plan & Provider Purchasing Policy Group, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4475

**RIN:** 0938-AD95

**1272. 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:** Next Action Undetermined

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Government Levels Affected:** Local, State

**Additional Information:** HCFA-2023

**Agency Contact:** Roy Trudel, Center for Medicaid & State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-20-15, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3417

**RIN:** 0938-AE12

**1273. SURVEY REQUIREMENTS AND ALTERNATIVE SANCTIONS FOR HOME HEALTH AGENCIES (HCFA-2169-F)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395bbb; 42 USC 1395hh; 42 USC 1302

**CFR Citation:** 42 CFR 488; 42 CFR 489; 42 CFR 498

**Legal Deadline:** None

**Abstract:** These rules will establish periodic, unannounced surveys of home health agencies (HHAs) and other survey requirements and also will specify sanctions that could be used when an HHA is out of compliance with Federal requirements (as an alternative or in addition to terminating an HHA's participation in the Medicare program).

**Timetable:**

Action	Date	FR Cite
NPRM	08/02/91	56 FR 37054
NPRM Comment Period End	10/01/91	
Next Action Undetermined		

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Small Entities Affected:** Businesses, Governmental Jurisdictions

**Government Levels Affected:** Local, State, Federal

**Additional Information:** HSQ-169

Pending completion of RIN 0938-AG81 (HCFA-3819-P)

**Agency Contact:** Patricia Miller, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-19-14, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-6780

**RIN:** 0938-AE39

**1274. 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

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## Long-Term Actions

**Abstract:** Section 1905(r) of the Social Security Act, added by section 6403 of OBRA '89, defines the following EPSDT services: screening services, vision services, dental services and hearing services. EPSDT services also are defined to include such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects, illnesses and conditions discovered by the screening services whether or not the services are covered under the State plan. Section 1902(a)(43) of the Act requires States to report to the Secretary certain information about EPSDT services provided under the plan during each fiscal year. This rule would set forth requirements to implement these statutory provisions.

**Timetable:**

Action	Date	FR Cite
NPRM	10/01/93	58 FR 51288
NPRM Comment Period End	11/30/93	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Local, State

**Additional Information:** MB-028

**Agency Contact:** Cindy Ruff, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, C4-16-08, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-5916

**RIN:** 0938-AE72

**1275. 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:** Final, Statutory, June 30, 1990.

**Abstract:** This rule will set forth our policy for the payment of the costs of approved nursing and allied health science programs, as directed by section 6205(b)(2) of OBRA '89. For the most part, the provisions set forth in this rule restate or clarify our current

policies governing these costs, which were previously set forth in the provider reimbursement manual and other documents, but have never been included in the regulations. In addition, we are amending the list of approved programs and clarifying payment rules for certified registered nurse anesthetist programs. This rule will also address section 4004 of OBRA '90 which provides that, effective with cost reporting periods beginning on or after October 1, 1990, under certain conditions, costs incurred by a hospital or educational institution related to the hospital for clinical training are treated as pass-through costs and paid on the basis of reasonable cost even though the hospital does not operate the education programs.

**Timetable:**

Action	Date	FR Cite
NPRM	09/22/92	57 FR 43659
NPRM Comment Period End	11/23/92	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** HCFA-1685

**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

**1276. 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

Action	Date	FR Cite
NPRM Comment Period End	01/24/94	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** BPD-705

**Agency Contact:** Joyce Eng, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4619

**RIN:** 0938-AE98

**1277. CHANGES TO THE LONG-TERM CARE FACILITY SURVEY PROCESS (HCFA-3175-FC)**

**Priority:** Substantive, Nonsignificant

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

**Legal Authority:** PL 101-239, sec 6901(a); 42 USC 1395i-3; 42 USC 1395aa(d); 42 USC 1396r

**CFR Citation:** 42 CFR 442; 42 CFR 488

**Legal Deadline:** None

**Abstract:** This rule will amend the Medicare and Medicaid regulations by removing obsolete long-term care survey forms, guidelines, and procedures used by State agencies when they evaluate a Medicare skilled nursing facility or a Medicaid nursing facility for compliance with Federal certification requirements. Effective October 1, 1990, the application of new Federal participation requirements for these facilities with an increased focus on actual or potential resident outcomes has made the survey forms and process in existing regulations outdated. Retention of the outdated items can cause confusion in connection with directions State survey agencies must follow in determining facility compliance. This rule is part of the Administration's reinventing government and regulatory reform initiatives. Publication of this regulation is dependent upon court approval which has been sought.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

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## Long-Term Actions

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** HSQ-175

This regulation may be published only with the concurrence of the U.S. District Court in *Smith v. Shalala*.

**Agency Contact:** Helene Fredeking, Director, Division of Outcomes and Improvements, Department of Health and Human Services, Health Care Financing Administration, S2-21-28, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-7304

**RIN:** 0938-AF02

#### 1278. REQUIREMENTS FOR CERTAIN HEALTH INSURING ORGANIZATIONS AND OBRA '90 TECHNICAL AMENDMENTS (HCFA-1018-F)

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

**Abstract:** This final rule amends the Medicaid regulations to apply Medicaid regulations governing prepaid health plans to those health insuring organizations that provide or arrange for health care services to Medicaid recipients but are not subject to the requirements for health maintenance organizations (HMOs) set forth in section 1903(m)(2)(A) of the Social Security Act. It also incorporates technical amendments relating to HMO and/or competitive medical plan enrollment, disenrollments, guaranteed eligibility, and provisional status included in OBRA '90 and the Balanced Budget Act of 1997.

**Timetable:**

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

Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Organizations

**Government Levels Affected:** None

**Additional Information:** OMC-018

**Agency Contact:** Betty Stanton, Center for Medicaid and State Operations,

Department of Health and Human Services, Health Care Financing Administration, S2-25-13, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3247

**RIN:** 0938-AF15

#### 1279. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (HCFA-1727-P)

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** BPD-727

**Agency Contact:** Morton Marcus, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-26-22, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4477

**RIN:** 0938-AF28

#### 1280. ALTERNATIVE SANCTIONS FOR PSYCHIATRIC HOSPITALS (HCFA-2191-P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395cc; 42 USC 1396a

**CFR Citation:** 42 CFR 488

**Legal Deadline:** None

**Abstract:** This proposed rule would provide an alternative to terminating a psychiatric hospital's participation in the Medicare and Medicaid programs for facilities found to be out of compliance with participation requirements. Alternative sanctions could be imposed instead of, or in addition to, terminating a psychiatric hospital's participation in the Medicare and Medicaid programs when deficiencies do not pose immediate jeopardy to the health and safety of psychiatric hospital patients. These amendments are necessary to conform HCFA regulations to changes made by OBRA '89 and OBRA '90. The statutory and regulatory revisions are intended to encourage correction of deficiencies that do not jeopardize patient health and safety before termination of a facility becomes necessary.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** State, Federal

**Additional Information:** HSQ-191

**RIN:** 0938-AF32

#### 1281. 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 final rule with comment period will incorporate section 4401 of

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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	
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Additional Information:** HCFA-2046-FC

**Agency Contact:** Peggy Rahn, Department of Health and Human Services, Health Care Financing Administration, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-3284

**RIN:** 0938-AF42

**1282. 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	
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State

**Additional Information:** HCFA-2051

**Agency Contact:** Robert Nakielnny, 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

**1283. MEDICAID: OUTSTATIONED INTAKE LOCATIONS FOR CERTAIN LOW-INCOME PREGNANT WOMEN, INFANTS, AND CHILDREN UNDER AGE 19 (HCFA-2052-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1396a(a)(55)

**CFR Citation:** 42 CFR 435.901; 42 CFR 435.902; 42 CFR 435.903; 42 CFR 435.904; 42 CFR 435.907; 42 CFR 436.2; 42 CFR 436.3; 42 CFR 435.3

**Legal Deadline:** None

**Abstract:** This rule will finalize the interim final rule that requires State Medicaid agencies to provide for receipt and initial processing of Medicaid applications filed by certain low-income pregnant women, infants, and children under age 19, at locations which are other than those used for receipt and processing of applications for cash assistance under title IV-A of the Social Security Act. The rule is based on section 1902(a)(55) of the Social Security Act, as added by section 4602 of OBRA '90, PL 101-508.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	09/23/94	59 FR 48805
Effective Date	10/24/94	
Comment Period End	11/22/94	
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State

**Additional Information:** HCFA-2052

**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-AF69

**1284. ASSESSING INTEREST AGAINST MEDICARE SECONDARY PAYER (MSP) DEBTS (HCFA-6108-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 31 USC 3711; 42 USC 1395y(b)(2)(B)

**CFR Citation:** 42 CFR 405.378; 42 CFR 411.24(m); 42 CFR 411.39

**Legal Deadline:** None

**Abstract:** This proposed rule would amend the regulations concerning interest charges on amounts owed to the Federal government when an overpayment occurs because Medicare was billed and made payment as the primary payer, rather than as the secondary payer. We also propose to clarify the date of determination that an overpayment has occurred so that all parties would have a clear understanding of the period subject to payment of interest charges.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** BP0-108

**Agency Contact:** John W. Albert, Office of Financial Management, Department of Health and Human Services, Health Care Financing Administration, S3-02-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-7457

**RIN:** 0938-AF87

**1285. REVISED MEDICAID MANAGEMENT INFORMATION SYSTEMS (HCFA-2038-FN)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1396b(r)

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

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## Long-Term Actions

**Abstract:** This notice sets forth revised general functional requirements for the Medicaid Management Information Systems (MMIS). The MMIS consists of software and hardware used to process Medicaid claims and to retrieve and produce utilization and management information about services that are required by the Medicaid agency or Federal Government for administrative or audit purposes. The revised requirements allow States more flexibility to exercise variations in the implementation.

**Timetable:**

Action	Date	FR Cite
Proposed Notice	11/22/93	58 FR 61692
Comment Period End	01/21/94	
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State

**Additional Information:** MB-038

**Agency Contact:** Richard H. Friedman, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4451

**RIN:** 0938-AG10

### 1286. ALTERNATIVE SANCTIONS FOR RENAL DIALYSIS FACILITIES (HCFA-3204-P)

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

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

authorized to impose alternative sanctions only when an ESRD facility failed to cooperate in the goals and activities of the ESRD network for the area in which the facility is located.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Additional Information:** HSQ-204

**Agency Contact:** Judith Kari, Center for Medicaid and State Operations, Division of Outcomes and Improvements, Department of Health and Human Services, Health Care Financing Administration, S2-19-26, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-6829

**RIN:** 0938-AG31

### 1287. DESCRIPTION OF HCFA'S EVALUATION METHODOLOGY FOR THE PEER REVIEW ORGANIZATIONS FIFTH SCOPE OF WORK CONTRACTS (HCFA-3207-N)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1320c; 42 USC 1320c-(2)(h)(2)

**CFR Citation:** 42 CFR 462

**Legal Deadline:** None

**Abstract:** This notice with a comment period would provide general criteria and standards that will be used to evaluate the effective and efficient performance of Utilization and Quality Control Peer Review Organizations (known as PROs) for contracts entered into on or after April 1, 1996.

**Timetable:**

Action	Date	FR Cite
NPRM	07/02/97	62 FR 35824
NPRM Comment Period End	09/02/97	
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** HSQ-207-NC

**Agency Contact:** Heidi Gelzer, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S1-08-24, 7500

Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-9352

**RIN:** 0938-AG32

### 1288. 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 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

**Government Levels Affected:** None

**Additional Information:** HSQ-208

**Agency Contact:** 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-AG33

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## Long-Term Actions

**1289. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF INTERMITTENT POSITIVE PRESSURE BREATHING MACHINE THERAPY (HCFA-3781-FN)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395x(n); 42 USC 1395y(a)(1)(A)**CFR Citation:** 45 CFR 500**Legal Deadline:** None

**Abstract:** Intermittent positive pressure breathing (IPPB) machine therapy is currently covered under Medicare as durable medical equipment for patients whose ability to breathe is severely impaired. Based on an Office of Health Technology Assessment recommendation, we will place limitations on Medicare coverage of IPPB machine therapy.

**Timetable:**

Action	Date	FR Cite
Proposed Notice	06/29/94	59 FR 33520
Comment Period End	08/29/94	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Additional Information:** BPD-781

**Agency Contact:** Francine Spencer, Office of Clinical Standards and Quality, Coverage and Analysis Group, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4614

**RIN:** 0938-AG44**1290. TELEPHONE REQUESTS FOR REVIEW OF PART B INITIAL CLAIM DETERMINATIONS (HCFA-4121-F)****Priority:** Substantive, Nonsignificant

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

**Legal Authority:** 42 USC 1302; 42 USC 1395ff(b); 42 USC 1395hh; 42 USC 1395ii; 42 USC 1395u(b)(3)(C)**CFR Citation:** 42 CFR 405.802; 42 CFR 405.807**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	07/10/95	60 FR 35544
NPRM Comment Period End	09/08/95	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Additional Information:** BPO-121

**Agency Contact:** Rosalind Little, Center for Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, S1-05-18, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-6972

**RIN:** 0938-AG48**1291. 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 1395f(b); 42 USC 1395g(a); 42 USC 1395hh; 42 USC 1395ii; 42 USC 1395oo; 42 USC 1395xx; 42 USC 1395x(v); 42 USC 1395l; 42 USC 405; 42 USC 1395ww**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:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** Undetermined**Additional Information:** HSQ-215

**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**1292. 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 tuberculosis related services. The rule would incorporate and interpret provisions of section 13603 of OBRA '93.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Local**Additional Information:** HCFA-2082

**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

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Phone: 410 786-4461

RIN: 0938-AG72

**1293. 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 final 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	03/20/98	
Period End		
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Additional Information:** HCFA-3745

**Agency Contact:** Doris Jackson, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-05-18, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4656

RIN: 0938-AG79

**1294. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—EXPANDED TO DESIGNATED HEALTH SERVICES (HCFA-1809-F)**

**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 455.109

**Legal Deadline:** None

**Abstract:** This rule provides that a physician who has (or whose immediate family member has) a financial relationship with a health care entity may not make referrals to that entity for certain services (designated health services) under the Medicare program except under specified circumstances. In the Medicaid context, this rule would deny payment to a State for expenditures for designated health services furnished on the basis of a physician referral that, all things being equal, would result in denial of payment under Medicare. The provisions of the rule are based on sections 13562 and 13624 of OBRA '93 and section 152 of SSAA '94.

**Timetable:**

Action	Date	FR Cite
NPRM	01/09/98	63 FR 1659
NPRM Comment	05/11/98	
Period End		
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Additional Information:** BPD-1809-

**Agency Contact:** Joanne Sinsheimer, Technical Assistant, CHPPS, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4620

RIN: 0938-AG80

**1295. 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 1395bb

**CFR Citation:** 42 CFR 484

**Legal Deadline:** None

**Abstract:** This final 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 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. In addition, this final rule will require that HHAs use a standard core assessment data set, the "Outcome and Assessment Information Set" (OASIS), when evaluating adult, non-maternity patients receiving home health care.

**Timetable:**

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment	06/09/97	
Period End		
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Additional Information:** HCFA-3819

**Agency Contact:** 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

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**1296. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION OF 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 proposed 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 proposed 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 2-month deposit before admission to ensure that sufficient funds are available to pay for care which the individual may receive before discharge.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** BPD-815

**Agency Contact:** Nancy Archer, Office of Clinical Standards & 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**1297. 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 493.7; 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; 42 CFR 493.39; 42 CFR 493.45; 42 CFR 493.47; 42 CFR 493.49; 42 CFR 493.53; 42 CFR 493.1775

**Legal Deadline:** None

**Abstract:** As part of the CLIA program (see RIN: 0938-AE47), 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	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** HSQ-225

**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**1298. 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 433.135 to 433.152**Legal Deadline:** None

**Abstract:** This rule would incorporate provisions of OBRA '93 by amending the regulations governing third party liability. It would add ERISA plans, service benefit plans, and health maintenance organizations to the definition of liable third parties. It would require States to prohibit any health insurer from taking into account, when enrolling or making payments, that an individual is eligible for or receiving Medicaid. It would also require States to enact a law under which the State is deemed to have

acquired a individual's right to payment by a third party.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** Federal, State**Additional Information:** MB-08

**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**1299. DEFINITION OF SKILLED NURSING FACILITY (SNF) FOR COVERAGE OF DURABLE MEDICAL EQUIPMENT (DME) AND HOME HEALTH (HCFA-1834-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395x(n); 42 USC 1395i-3(a)(1); 42 USC 1396r(a)(1)**CFR Citation:** 42 CFR 409; 42 CFR 410**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** BPD-834

**Agency Contact:** Thomas E. Hoyer, Center for Health Plans and Providers,

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Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4605

RIN: 0938-AH16

### 1300. 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 proposed rule would revise and streamline the State Plan Amendment (SPA) reconsideration process. Currently, when a State requests reconsideration of a denied SPA, a hearing is held in all cases, even when the only dispute is over the interpretation of the statute. Under the proposed regulation, the State and HCFA could avoid the cost and delay of the hearing process when the only issue is interpretation of the statute by permitting the State expedited judicial review, without a full administrative hearing, after HCFA has a brief opportunity to reconsider its decision.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Additional Information:** HCFA-2096

**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

### 1301. 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 proposed rule would revise the Medicare conditions of participation for hospices to help ensure the provision of quality care through an emphasis on patient-centered outcomes. Areas of change would include, among others, assessment of patient needs, clarification of physician roles, coordination of care for hospice patients residing in nursing homes, clarification of nursing roles, patient rights, and provision of services.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Additional Information:** HCFA-3844

**Agency Contact:** Lynn Merritt-Nixon, Office of Clinical Standard & Quality, Department of Health and Human Services, Health Care Financing Administration, S3-04-25, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4652

RIN: 0938-AH27

### 1302. CLIA PROGRAM; CYTOLOGY PROFICIENCY TESTING (HCFA-2233-N)

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 493.855

**Legal Deadline:** None

**Abstract:** This notice announces the withdrawal of a proposed rule on cytology proficiency testing that was published in the Federal Register November 30, 1995, and instead, announces a supplement to the

rulemaking record of a final rule published February 28, 1992. In publishing the proposed rule, HHS complied with a Federal court order requiring publication of a proposal that would require that cytology proficiency testing be conducted to the extent practicable, under normal working conditions. As required, we proposed to revise regulations to require that proficiency testing be conducted at a pace corresponding to the maximum workload rate for individuals examining slides. We also solicited comments on the use of computer facsimile representations of cytology specimens, as an alternative to glass-slide proficiency testing. After the proposed rule was published, the appeals court revised the lower court's order, allowing us to withdraw the proposed rule and supplement the record to the final rule.

#### Timetable:

Action	Date	FR Cite
NPRM	11/30/95	60 FR 61509
NPRM Comment Period End	01/29/96	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

**Agency Contact:** Rhonda S. Whalen, Senior Health Scientist, Department of Health and Human Services, Health Care Financing Administration, MS F, 4770 Buford Highway NE, 11, Atlanta, GA 30341-3724  
Phone: 770 488-8155

RIN: 0938-AH35

### 1303. 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 proposed rule would implement SSA '94 provisions to

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Additional Information:** BPD-843

**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

#### 1304. PAYMENT AMOUNT IF CUSTOMARY CHARGES ARE LESS THAN REASONABLE COSTS (HCFA-1860-FC)

**Priority:** Other Significant

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

**Legal Authority:** 42 USC 1395f(b); 42 USC 1395l(a); 42 USC 1395m(a)

**CFR Citation:** 42 CFR 413.13

**Legal Deadline:** None

**Abstract:** In accordance with HCFA's regulatory burden reduction program, this technical regulation modifies or removes from regulations language that reference the following aspects of the Medicare program:

o The Lower of Cost or Charges (LCC) carryover provision; this provision was removed from HCFA regulations several years ago.

o The application of the LCC principle to durable medical equipment (DME) furnished by home health agencies (HHAs); these items are now paid in accordance with a fee schedule.

o Other content that was previously removed. This final regulation also clarifies several portions of section 413.13 and removes obsolete provisions.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Additional Information:** BPD-86

**Agency Contact:** Ward Pleines, Chronic Care Purchasing Policy Group, Division of Cost Reporting, Department of Health and Human Services, Health Care Financing Administration, C5-02-23, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4528

**RIN:** 0938-AH49

#### 1305. LIMITATIONS ON LIABILITY (HCFA-4859-FC)

**Priority:** Substantive, Nonsignificant

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

**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1395pp

**CFR Citation:** 42 CFR 411.404

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** BPD-85

**Agency Contact:** Denis M. Garrison, Division of Beneficiary Protections, Department of Health and Human Services, Health Care Financing Administration, C4-06-21, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5643

**RIN:** 0938-AH51

#### 1306. MEDICARE SECONDARY PAYER CLARIFICATIONS AND AMENDMENTS (HCFA-1865-P)

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 411

**Legal Deadline:** None

**Abstract:** This proposed rule would codify in regulations policies regarding liability insurance, such as structured liability settlements, future medical expenses, provider malpractice, wrongful death, and Federal Tort Claims Act policy. It would also clarify the rules dealing with group health plan bankruptcies, religious orders, and foreign group health plans, and make numerous other changes.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Additional Information:** BPD-865

**Agency Contact:** Herb Pollock, Center for Health Plans & Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-08-27, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4474

**RIN:** 0938-AH52

#### 1307. REVISION TO ACCRUAL BASIS OF ACCOUNTING POLICY (HCFA-1876-F)

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 413.100

**Legal Deadline:** None

**Abstract:** The proposed rule would specify the providers' share of the costs of FICA and other employee payroll taxes that will be allowable under Medicare when the payroll period ends subsequent to the end of the reporting period. The proposed rule would provide that if payment would be made to an employee during a cost reporting period but for the fact that the regularly scheduled payment date is after the end of the period, that portion of employees FICA or other taxes that have accrued

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up to the end of the reporting period will be treated as allowable costs in the current reporting period.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** HCFA-1876

**Agency Contact:** John Eppinger Jr., Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C5-03-18, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4518

**RIN:** 0938-AH61

**1308. MEDICAID; ESTATE RECOVERIES (HCFA-2083-P)**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 433.36

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** State

**Additional Information:** HCFA-2083

**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

**1309. MEDICAID HOSPICE CARE (HCFA-2016-P)**

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Governmental Jurisdictions, Organizations

**Government Levels Affected:** State, Local

**Additional Information:** HCFA-2016

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

Phone: 410 786-3295

**RIN:** 0938-AH65

**1310. PROVIDER AND SUPPLIER BILLING WHEN MEDICARE IS SECONDARY PAYOR TO LIABILITY INSURANCE (HCFA-1848-P)**

**Priority:** Other Significant

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

**Legal Authority:** 42 USC 1302; 42 USC 1395cc; 42 USC 1395dd; 42 USC 1395hh; 42 USC 1395ww; 42 USC 1395x; 42 USC 1395aa

**CFR Citation:** 42 CFR 411; 42 CFR 489

**Legal Deadline:** None

**Abstract:** This proposed rule would revise current regulations to require

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** BPD-848

**Agency Contact:** Anita Heygster, Center for Health Plans & Providers, Department of Health and Human Services, Health Care Financing Administration, C4-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4486

**RIN:** 0938-AH66

**1311. MEDICARE TECHNICAL CONFORMING AMENDMENTS (HCFA-1858-FC)**

**Priority:** Substantive, Nonsignificant

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

**Legal Authority:** 42 USC 1302; 42 USC 1395k

**CFR Citation:** 42 CFR 409.50; 42 CFR 409.61; 42 CFR 410.152

**Legal Deadline:** None

**Abstract:** This final rule with comment period will update our regulations to reflect that payment for durable medical equipment is on the basis of a fee schedule.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Additional Information:** BPD-858

**Agency Contact:** Martha Kuespert, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Boulevard, Baltimore, MD 21244-1850

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## Long-Term Actions

Phone: 410 786-4605

RIN: 0938-AH67

**1312. 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

**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 462.107; 42 CFR 466.71; 42 CFR 466.73

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** HSQ-235-FC

**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-AH68

**1313. DETERMINATION OF SUBSTANDARD CARE IN SNFS AND NFS (HCFA-2240-P)**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 488.301

**Legal Deadline:** None

**Abstract:** This proposed rule would revise the definition of "substandard

quality of care" as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program. "Substandard quality of care" is one type of noncompliance with Federal participation requirements that carries with it statutory consequences to facilities providing such care. The purpose of this proposed revision is to improve the definition of substandard quality of care so that the process can make a more meaningful distinction between facility noncompliance that warrants the consequences mandated by the statute for a finding of substandard quality of care and noncompliance that does not.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:** Federal, State, Local

**Additional Information:** HSQ-24

**Agency Contact:** Patricia Miller, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-19-14, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-6780

RIN: 0938-AH69

**1314. WAIVER OF STAFFING REQUIREMENTS FOR END STAGE RENAL DISEASE (ESRD) FACILITIES PARTICIPATING IN AN EXPERIMENT (HCFA-2236-GNC)**

**Priority:** Other Significant

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

**Legal Authority:** 42 USC 1302; 42 USC 1320; 42 USC 1395x; 42 USC 1395y; 42 USC 1395hh; 42 USC 1395rr

**CFR Citation:** 42 CFR 405.2136; 42 CFR 405.2161; 42 CFR 405.2162; 42 CFR 405.2163

**Legal Deadline:** None

**Abstract:** This general notice with comment period announces our intention to conduct a demonstration

that would grant selected ESRD facilities a 2-year waiver of staffing requirements. The ESRD staffing requirements pertain to: the governing body and management, director of a facility, on-duty licensed health care professionals, and providing adequate laboratory, social, and dietetic services. Facilities would be given flexibility to deviate from specified regulation requirements, provided assurances are in place ensuring that quality of care standards are not being compromised.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** HSQ-236

**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-AH72

**1315. INDIVIDUAL MARKET HEALTH INS. REFORM PORTABILITY FROM GROUP TO INDIV. COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIV. MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (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 final rule will address comments received on the interim final rule published on April 8, 1997 and further clarifies the Departmental position on HIPAA requirements in the individual market.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	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	

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## Long-Term Actions

**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations**Government Levels Affected:** Federal, State, Local**Additional Information:** BPD-882**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**1316. 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 proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement. The focus would be to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements where possible.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** BPD-887**Agency Contact:** Judy Goldfarb, Office of Clinical Standards & Quality, Department of Health and Human Services, Health Care Financing Administration, S2-199.06, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-6747**RIN:** 0938-AH83**1317. 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**CFR Citation:** 42 CFR 466.70(a); 42 CFR 476.101; 42 CFR 476.107; 42 CFR 476.132; 42 CFR 476.133(b)(4)**Legal Deadline:** None**Abstract:** This proposed rule would change our policy regarding the disclosure of peer review organization (PRO) information in responding to beneficiary complaints about physicians, other practitioners, and other institutional and non-institutional providers of health care, including Health Maintenance Organizations and Competitive Medical Plans. Under the proposal, we would permit the disclosure of PRO information about physicians and other individual practitioners without their permission to the extent necessary to comply with section 1154(a)(14) of the Social Security Act. This section requires PROs to conduct reviews of beneficiary complaints about the quality of services that do not meet professionally recognized standards of health care and inform each beneficiary of the final disposition of his or her complaint.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** HSQ-241**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-AH85**1318. 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 1396r(b)**CFR Citation:** 42 CFR 405; 42 CFR 431; 42 CFR 433; 42 CFR 441; 42 CFR 483**Legal Deadline:** None**Abstract:** This proposed rule would make changes to the preadmission screening and annual resident review program in accordance with the provisions of Public Law 104-315, which were included in the Reinventing Government effort. The rule would repeal the Medicaid program requirement for an annual review of nursing facility (NF) residents with mental illness or mental retardation. This proposed rule also would add the requirement for NFs to notify the State when there is a significant change in the physical or mental condition of a resident and add a statutory requirement that the State conduct a review promptly after notification of the resident's change in condition.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses, Governmental Jurisdictions**Government Levels Affected:** State**Additional Information:** HCFA-2107**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**1319. 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

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## Long-Term Actions

**Legal Deadline:** None

**Abstract:** This interim final rule with comment period will revise our rules to allow States to include individuals who are described as categorically needy to be covered as medically needy. The State must specify the income and resources criteria for the medically needy group in the State plan. If an individual is also described as categorically needy, the individual would receive Medicaid as categorically needy if the State elected to cover the categorically needy group into which the individual fits. If the State has not elected to cover that group, the individual would be medically needy. This change will allow more individuals to become eligible for Medicaid as medically needy and eliminate an inequity in current regulations. This revision also allows some individuals who would otherwise lose their Medicaid benefits to retain their eligibility.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State

**Additional Information:** MB-1

**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  
Email: jwilder@hfca.gov

**RIN:** 0938-AH92

**1320. 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 proposed rule would incorporate and interpret in regulations coverage and payment requirements for services furnished by a federally qualified health center (FQHC) under the Medicaid program. This rule will include changes in the payment

provisions to FQHCS made by section 4712 of the Balanced Budget Act of 1997 PL-105-33.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Governmental Jurisdictions

**Government Levels Affected:** State, Tribal

**Additional Information:** MB-43

**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

**1321. REVISION TO THE DEFINITION OF AN UNEMPLOYED PARENT (HCFA-2106-FC)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 607; 42 USC 1396u-1

**CFR Citation:** 45 CFR 233

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
Final Rule With Comment Period	08/07/98	63 FR 42270
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State

**Additional Information:** HCFA-2106-FC

**Agency Contact:** Judith Rhoades, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-08-05, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4462

**RIN:** 0938-AH98

**1322. 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 final 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 with respect to group health plans and health insurance issuers offering group health insurance coverage. A group health plan or health insurance issuer offering group health coverage may provide greater rights to participants and beneficiaries than those currently provided. This rule 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	
Next Action Undetermined		

Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

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## Long-Term Actions

**Government Levels Affected:** Federal

**Additional Information:** BPD-890-IFC

**Agency Contact:** Dave Holstein, Insurance Standards Team, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1564

**RIN:** 0938-AI08

**1323. MEDICARE PROGRAM;  
MEDICARE INTEGRITY PROGRAM  
(HCFA-7020-F)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** PL 104-191

**CFR Citation:** 42 CFR 400; 42 CFR 421

**Legal Deadline:** None

**Abstract:** This rule implements section 1893 of the Social Security Act (added by section 202 of the Health Insurance Portability and Accountability Act of 1996) by establishing the Medicare Integrity Program to carry out Medicare payment integrity activities. Under this program HCFA may enter into new contracts with entities to perform these activities. This rule will identify the services to be procured; competitive requirements; procedures for identification, evaluation, and resolution of conflicts of interest; and rules regarding contractor liability. In addition, this rule will revise the list of intermediary and carrier functions set forth in existing regulations to make them consistent with sections 1816, 1842, and 1893 of the Social Security Act.

**Timetable:**

Action	Date	FR Cite
NPRM	05/19/98	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Additional Information:** OFH-020-P, PL 104-191, sec. 202

**Agency Contact:** Brenda Thew, OICS, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4889

**RIN:** 0938-AI09

**1324. 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 proposed rule would establish new administrative review requirements for Medicare beneficiaries enrolled in health maintenance organizations (HMOs), competitive medical plans (CMPs), and health care prepayment plans. This rule would implement section 1876(c)(5) of the Social Security Act, which specifies the appeal and grievance rights of Medicare enrollees in HMOs and CMPs. This rule would reduce time lines for nonurgent denials of care and make other improvements. We will also address related requirements of the Balanced Budget Act of 1997.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Beverly Sgroi, Department of Health and Human Services, Health Care Financing Administration, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, Baltimore, MD 21244-1850  
Phone: 410 786-7638

**RIN:** 0938-AI11

**1325. MEDICARE PROGRAM;  
PHYSICIAN FEE SCHEDULE  
CONVERSION FACTOR FOR  
CALENDAR YEAR 1998 AND  
SUSTAINABLE GROWTH RATE FOR  
FISCAL YEAR 1998 (HCFA-1893-FN)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** 42 USC 1395w-4

**CFR Citation:** 42 CFR ch IV

**Legal Deadline:** None

**Abstract:** This notice announces the calendar year 1998 Medicare physician fee schedule conversion factor and the fiscal year 1998 sustainable growth rate for expenditures for physicians' services under the Medicare Supplementary Medical Insurance (part

B) program as required by sections 1848(d) and (f) of the Social Security Act.

**Timetable:**

Action	Date	FR Cite
ANPRM	10/31/97	62 FR 59261
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Terrence Kay, Center for Health Plans and Providers, Division of Practitioner and Ambulatory C, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, C4-10-26, Baltimore, MD 21244  
Phone: 410 786-4497

**RIN:** 0938-AI16

**1326. 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

**Legal Deadline:** None

**Abstract:** This proposed rule would require States to provide assurances satisfactory to the Secretary that the State has in effect laws relating to medical child support. This requirement would implement section 13623 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66), commonly cited as OBRA 1993. The medical child support laws that the States must have in effect are set forth in section 1908 of the Social Security Act (the Act). These laws would impose requirements on insurers, employers, and State Medicaid agencies 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

**Additional Information:** HCFA-2081

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## Long-Term Actions

**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

**1327. MEDICARE PROGRAM: PHYSICIANS' REFERRALS; ISSUANCE OF ADVISORY OPINIONS (HCFA-1902-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395nn(g)(6); 42 USC 1302; 42 USC 1395hh

**CFR Citation:** 42 CFR 411.370 to 411.389

**Legal Deadline:** None

**Abstract:** This final rule will set forth the procedures HCFA will use to issue written advisory opinions to outside parties concerning whether a physician's referral of a Medicare beneficiary for certain designated health services is prohibited under section 1877 of the Social Security Act.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	01/09/98	63 FR 1646
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Joanne Sinsheimer, Technical Assistant, CHPPS, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4620

**RIN:** 0938-AI38

**1328. 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 proposed 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:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**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

**1329. SURETY BOND REQUIREMENTS FOR COMPREHENSIVE OUTPATIENT REHAB. FACILITIES, REHAB. 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

**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 proposed 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:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**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

**1330. 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 proposed rule would establish in regulations 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 proposed rule would implement section 4724(g) of the Balanced Budget Act of 1997.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Governmental Jurisdictions

**Government Levels Affected:** State

**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

**1331. RECOGNITION OF THE COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP) AND JOINT COMMISSION FOR ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO) FOR HOSPICES (HCFA-2029-PN)**

**Priority:** Routine and Frequent

**Legal Authority:** 42 USC 1395bb

**CFR Citation:** 42 CFR ch IV

**Legal Deadline:** Other, Statutory, September 8, 1998, The statute requires us to publish a notice within 60 days of receipt of a completed application.

**Abstract:** This notice announces the receipt of an application from the

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## Long-Term Actions

Community Health Accreditation Program, Inc. (CHAP) and Joint Commission for Accreditation of Healthcare Organizations (JCAHO) for recognition as a national accreditation program for hospices that wish to participate in the Medicare program.

**Timetable:**

Action	Date	FR Cite
NPRM	09/11/98	63 FR 48735
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Joan Berry, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7233  
Email: jberry@hcfa.gov

**RIN:** 0938-AI69

### 1332. ELIMINATION OF APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2111-IFC)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302

**CFR Citation:** 42 CFR 435

**Legal Deadline:** None

**Abstract:** This interim final rule with comment period eliminates the requirement that Federal financial participation income limits be applied when States use less restrictive income and resource methodologies to determine eligibility for aged, blind and disabled individuals, as well as for the optional categorically needy and the medically needy. This rule conforms the application of the FFP limits to the policy that the use of less restrictive income methodologies are not subject to FFP limits. This change will give States additional flexibility in setting Medicaid eligibility requirements.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**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  
Email: jwilder@hcfa.gov

**RIN:** 0938-AI73

### 1333. MEDICAID PROGRAM; CHANGES TO ELIGIBILITY OF NON-U.S. CITIZENS (HCFA-2108-P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1302; PL 104-193, sec 401 to 403

**CFR Citation:** 42 CFR 435; 42 CFR 436; 42 CFR 440

**Legal Deadline:** None

**Abstract:** The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 created changes in Federal law making most non-U.S. citizens ineligible for Supplemental Security Income (SSI). In most States, receipt of SSI confers automatic Medicaid eligibility. Although many States have elected optional eligibility groups that provide a basis for covering persons who do not receive SSI, some States have not done so. In these States, these individuals would be left without access to Medicaid (including emergency services). To conform with the new law, we are proposing regulations that would result in the loss of Medicaid for qualified aliens in those States that cover only SSI recipients. We are also seeking comments on whether there remains any statutory basis to continue Medicaid coverage for these individuals.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** 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-AI74

### 1334. 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 proposed 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 also would 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:** Next Action Undetermined

**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

### 1335. MEDICARE HOSPICE CARE (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 proposed rule would implement section 4441(a), 4442-4446, and 4448 of the Balanced Budget Act

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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 programs in non-urbanized areas, and extending the period for physician certification of an individual's terminal illness. Additionally, the proposed rule would also clarify other current policies.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** 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-AI77

### 1336. 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 proposed 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 all providers.

**Timetable:**

Action	Date	FR Cite
NPRM	08/11/98	63 FR 42797
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** 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

### 1337. SOLVENCY STANDARDS FOR PROVIDER-SPONSORED ORGANIZATIONS (HCFA-1011-F)

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395w-21 to 1395w-27; 42 USC 1395hh

**CFR Citation:** 42 CFR 422

**Legal Deadline:** None

**Abstract:** This final rule establishes solvency standards for provider-sponsored organizations (PSOs) under the new Medicare+Choice Program.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	05/07/98	63 FR 25360
Interim Final Rule Effective	05/07/98	
Interim Final Rule Comment Period End	07/06/98	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Greg Snyder, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-0329

**RIN:** 0938-AI83

### 1338. 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 final 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

**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

### 1339. HEALTH INSURANCE REFORM UNIVERSAL HEALTH CARE IDENTIFIER (HCFA-0048-NOI)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1320d-2

**CFR Citation:** 42 CFR ch IV

**Legal Deadline:** Final, Statutory, February 28, 1998, BBA Section 4106.

**Abstract:** This notice announces our intent to publish a proposed rule on requirements for a unique health identifier for individuals. These requirements are mandated by law and are part of a national framework for

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health data standards and health information privacy that will support the efficient electronic exchange of specified administrative and financial health care transactions. This notice discusses the options for the identifier that have been put forward for consideration and asks for public comments.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**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-AI91

**1340. PEER REVIEW ORGANIZATION CONTRACTS: SOLICITATION OF STATEMENTS OF INTEREST FROM IN-STATE ORGANIZATIONS (HCFA-3009-N)**

**Priority:** Other Significant

**Legal Authority:** 44 USC 35

**CFR Citation:** 42 CFR ch IV

**Legal Deadline:** None

**Abstract:** This notice, in accordance with section 1153(i) of the Social Security Act, gives at least 6 months' advance notice of the expiration dates of contracts with out-of-state utilization and quality control peer review organizations. It also specifies the period of time in which in-state organizations may submit a statement of interest so that they may be eligible to compete for these contracts.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**Agency Contact:** Udo Nwachukwu, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing

Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-7234

**RIN:** 0938-AI99

**1341. REPLACEMENT OF REASONABLE CHARGE METHODOLOGY BY FEE SCHEDULES (HCFA-1010-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 13945u

**CFR Citation:** 42 CFR 414

**Legal Deadline:** None

**Abstract:** We are proposing to implement fee schedules to be used for payment of services, excluding ambulance services, still subject to the reasonable charge payment methodology.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Joel Kaiser, Center for Health Plan and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4499

**RIN:** 0938-AJ00

**1342. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (HCFA-2015-P)**

**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 proposed rule would amend the regulation to conform with the provisions of section 4705 of the Balanced Budget Act of 1997. It would require 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 by these managed care organizations and performance through annual external, independent reviews conducted by accrediting organizations that are approved by HCFA.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State

**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

**1343. HHS' RECOGNITION OF NAIC MODEL STANDARDS FOR REGULATION OF MEDIGAP POLICY (HCFA-2025-N)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395ss

**CFR Citation:** 42 CFR ch IV

**Legal Deadline:** None

**Abstract:** This notice describes changes made by the Balanced Budget Act of 1997 and the Health Insurance Portability and Accountability Act of 1996 to section 1882 of the Social Security Act, which governs Medicare supplemental insurance. It also provides notice that the model regulation adopted by the National Association of Insurance Commissioners (NAIC) on April 29, 1998, and reprinted in its entirety as an addendum to this notice, constitutes the applicable NAIC model regulation that is incorporated by reference in section 1882.

**Timetable:**

Action	Date	FR Cite
Notice	09/30/98	63 FR 67078
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Larry Cutler, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5903

**RIN:** 0938-AJ07

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**1344. 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 interim final rule with comment period requires electronic reporting of data from the Outcome and Assessment Information Set (OASIS) as a condition of participation for 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 interim final 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		

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

**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  
Phone: 410 786-3398

**RIN:** 0938-AJ10**1345. 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:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** None

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

**Agency Contact:** 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**1346. 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 proposed 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, prohibit commercial use, the use of space equipment, and other resources of an RHC by another entity. The rule also requires establishment of a quality assessment and performance improvement program.

**Timetable:** Next Action Undetermined**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**1347. 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 proposed 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:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Organizations**Government Levels Affected:** None

**Agency Contact:** Mary Collins, OCSQ, Department of Health and Human

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## Long-Term Actions

Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3189

RIN: 0938-AJ29

**1348. MEDICARE PROGRAM; PROCEDURES FOR MAKING MEDICAL SERVICES NATIONAL COVERAGE DECISIONS (HCFA-3432-GN)**

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

**Legal Authority:** 42 USC 1302; 40 USC 1395hh

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This notice withdraws the proposed rule that we published in the Federal Register on January 30, 1989 (54 FR 4302), in which we proposed to establish in regulations generally applicable criteria and procedures for HCFA decisions regarding whether and under what circumstances specific health care technologies could be considered "reasonable" and "necessary" and, therefore, covered under Medicare. We are withdrawing the proposed rule and announcing our intention to issue a new notice of proposed rulemaking concerning the criteria to be used in making national coverage decisions.

This notice also describes the procedures we use for making national decisions regarding the coverage of a payment for specific medical items and services under Medicare.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Ron Milhourn, Office of Clinical Standards & 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-AJ31

**1349. MEDICARE PROGRAM; SPECIAL PAYMENT LIMITS FOR CERTAIN DURABLE MEDICAL EQUIPMENT AND PROSTHETIC DEVICES (HCFA-1050-PN)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395m; 42 USC 1395u

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This notice proposes special payment limits, for five items of durable medical equipment and one prosthetic device, to replace the current fee schedule amounts for these items.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Kaiser, Center for Health Plan and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4499

RIN: 0938-AJ34

**1350. 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 proposed 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 proposed rule would clarify other current policies.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** 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

**1351. EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) (HCFA-1063-FC)**

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1395cc, sec 1866; 42 USC 1395dd

**CFR Citation:** 42 CFR 489.24

**Legal Deadline:** None

**Abstract:** This final rule with comment period clarifies the extent of the Emergency Medical Treatment and Labor Act (EMTALA) application.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** George Morey, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4653

RIN: 0938-AJ39

**1352. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 2000 RATES (HCFA-1053-P) (SECTION 610 REVIEW)**

**Priority:** Economically Significant. Major under 5 USC 801.

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

**CFR Citation:** 42 CFR 412; 42 CFR 413; 42 CFR 483; 42 CFR 485

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**Legal Deadline:** NPRM, Statutory, April 1, 1999.  
Final, Statutory, August 1, 1999.

**Abstract:** We are proposing to revise the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement changes arising from our continuing experience with the systems. In addition, in the addendum to this proposed rule, we are describing proposed changes in the amounts and factors necessary to determine rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes would be applicable to discharges occurring on or after October 1, 1999. We are also

setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital unites excluded from the prospective payment systems. Finally, we are proposing changes to the policies governing payment to hospitals for the direct costs of graduate medical education. We will also review for the requirements of Section 610c of the Regulatory Flexibility Act.

**Timetable:**

Action	Date	FR Cite
NPRM	05/07/99	64 FR 24715
NPRM Comment Period End	07/06/99	

Action	Date	FR Cite
Final Action	07/30/99	64 FR 41490
Next Action	Undetermined	

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

**Agency Contact:** Tzvi Hefter, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1304  
**RIN:** 0938-AJ50

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

## Completed Actions

**1353. CASE MANAGEMENT (HCFA-2027-F)****Priority:** Other Significant

**CFR Citation:** 42 CFR 431.51(c); 42 CFR 431.54; 42 CFR 440.169; 42 CFR 440.250; 42 CFR 441.10; 42 CFR 441.18; 42 CFR 447.327

**Completed:**

Reason	Date	FR Cite
Withdrawn	09/01/99	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** Local, State**RIN:** 0938-AF07**1354. ADJUSTMENT IN PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES (HCFA-3831-F)****Priority:** Economically Significant**CFR Citation:** 42 CFR 416**Completed:**

Reason	Date	FR Cite
Final Action	06/16/99	64 FR 32198

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

**Agency Contact:** Claude Mone  
Phone: 410 786-5666

**RIN:** 0938-AH15**1355. MEDICARE AND MEDICAID PROGRAMS; QUARTERLY LISTING OF PROGRAM ISSUANCES AND COVERAGE DECISIONS—SECOND QUARTER, 1998 (HCFA-9002-N)****Priority:** Routine and Frequent**CFR Citation:** 42 CFR ch IV**Completed:**

Reason	Date	FR Cite
NOTICE	12/09/98	63 FR 67899

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

**Agency Contact:** Kristy Nishimoto  
Phone: 410 786-8517

Email: knishimotochcfa.gov

**RIN:** 0938-AI13**1356. GME: INCENTIVE PAYMENTS UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS (HCFA-1001-F)****Priority:** Other Significant**CFR Citation:** 42 CFR 413**Completed:**

Reason	Date	FR Cite
Interim Final Rule	08/18/99	64 FR 44841
Interim Final Rule Comment Period End	10/18/99	

**Regulatory Flexibility Analysis Required:** Yes**Government Levels Affected:** Federal, State, Local

**Agency Contact:** Marc Hartstein  
Phone: 410 786-4539

**RIN:** 0938-AI27**1357. MEDICARE PROGRAM; PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES. (HCFA-1913-IFC)****Priority:** Economically Significant

**CFR Citation:** 42 CFR 409; 42 CFR 410; 42 CFR 411; 42 CFR 413; 42 CFR 483; 42 CFR 489

**Completed:**

Reason	Date	FR Cite
Final Action	07/30/99	64 FR 41644
Final Action Effective	09/28/99	

**Regulatory Flexibility Analysis Required:** Yes**Government Levels Affected:** Federal

**Agency Contact:** Laurence Wilson  
Phone: 410 786-4603

**RIN:** 0938-AI47**1358. MEDICARE AND MEDICAID PROGRAMS; QUARTERLY LISTING OF PROGRAM ISSUANCES — FIRST QUARTER 1998 (HCFA-9879-N)****Priority:** Routine and Frequent**CFR Citation:** 42 CFR ch IV**Completed:**

Reason	Date	FR Cite
Notice	09/16/98	63 FR 49598

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## Completed Actions

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

Agency Contact: Kristy Nichimoto  
Phone: 410 786-8517

RIN: 0938-AJ12

**1359. MEDICARE PROGRAM STATE ALLOTMENTS FOR PAYMENTS OF MEDICARE PART B PREMIUM FOR QUALIFYING INDIVIDUALS: FEDERAL FISCAL YEAR FOR 1999 (HCFA-2032-N)**Priority: Economically Significant.  
Major under 5 USC 801.

CFR Citation: Not Yet Determined

**Completed:**

Reason	Date	FR Cite
Notice	03/29/99	64 FR 14931

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: Federal, State

Agency Contact: Miles McDermott  
Phone: 410 786-3722  
Email: mmcdermott@hcfa.gov

RIN: 0938-AJ28

**1360. MEDICAID PROGRAM; CIVIL MONEY PENALTIES FOR NURSING HOMES (SNF/NF), CHANGE IN NOTICE REQUIREMENTS, AND EXPANSION OF DISCRETIONARY REMEDY (HCFA-2035-FC)**

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 488.402; 42 CFR 488.408; 42 CFR 488.430; 42 CFR 488.432; 42 CFR 488.434; 42 CFR 488.438; 42 CFR 488.440; 42 CFR 488.442; 42 CFR 488.454; 42 CFR 435.1001(c)

**Completed:**

Reason	Date	FR Cite
Final Rule with Comment	03/28/99	64 FR 13354

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

Agency Contact: Fred Galdden  
Phone: 410 786-3033

RIN: 0938-AJ35

**1361. MEDICARE AND MEDICAID PROGRAMS; QUARTERLY LISTING OF PROGRAM ISSUANCES — THIRD QUARTER, 1998 (HCFA-9000-N)**

Priority: Routine and Frequent

CFR Citation: None

**Completed:**

Reason	Date	FR Cite
Notice	05/11/99	64 FR 25351

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

Agency Contact: Kristy Nishimoto  
Phone: 410 786-8517  
Email: knishimotohcfa.gov

RIN: 0938-AJ37

**1362. RECOGNITION OF THE JOINT COMMISSION FOR ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO) FOR HOSPICES (HCFA-2039-FN)**

Priority: Routine and Frequent

CFR Citation: 42 CFR ch IV

**Completed:**

Reason	Date	FR Cite
Notice	06/18/99	64 FR 32881

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

Agency Contact: Joan C. Berry  
Phone: 410 786-7233  
Email: jberry@hcfa.gov

RIN: 0938-AJ41

**1363. RECOGNITION OF THE COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP) FOR HOSPICES (HCFA-2029-FN)**

Priority: Routine and Frequent

CFR Citation: 42 CFR ch IV

**Completed:**

Reason	Date	FR Cite
Notice	04/20/99	64 FR 19376

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

Agency Contact: Joan C. Berry  
Phone: 410 786-7233  
Email: jberry@hcfa.gov

RIN: 0938-AJ42

**1364. • PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR HOME HEALTH AGENCIES (HCFA-1059-P)**

Priority: Other Significant

Legal Authority: PL 105-33

CFR Citation: None

Legal Deadline: None

**Abstract:** This proposed rule will establish requirements for the new prospective payment system from home health agencies as governed by section 4603 of the Balanced Budget Act of 1997.**Timetable:**

Action	Date	FR Cite
Duplicate of 0938-AJ24	10/20/99	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Robert Wardell, Chief, Home &amp; Community Based Waiver Branch, Department of Health and Human Services, Health Care Financing Administration, 4th Floor, EHR, 6325 Security Boulevard, Baltimore, MD 21207

Phone: 301 966-5659

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

Phone: 410 786-3254

RIN: 0938-AJ51

**1365. • MEDICARE AND MEDICAID PROGRAMS: HOSPITAL CONDITIONS OF PARTICIPATION; PATIENTS' RIGHTS (HCFA-3018-IFC)**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 99-509, sec 9343(c)

CFR Citation: 42 CFR 409.10; 42 CFR 410.2; 42 CFR 410.27; 42 CFR 410.410.28; 42 CFR 410.30; 42 CFR 411.15; 42 CFR 412.50; 42 CFR 413.118; 42 CFR 413.122; 42 CFR 413.124; 42 CFR 413.130; 42 CFR 413; 42 CFR

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## Completed Actions

489.20; 42 CFR 1003.101 to 102; 42 CFR 1003.105

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

**Abstract:** The Balanced Budget Act of 1997 (BBA) (Public Law 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 inpatient who have no Part A coverage) furnished on or after January 1, 1999. 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 in regulations the requirements for designating certain entities as provider based or as a department of a hospital.

**Timetable:**

Action	Date	FR Cite
NPRM	09/06/98	63 FR 47551
NPRM Comment Period End	07/30/99	
Duplicate of 0938- A156	10/20/99	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Janet Wellham, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4510

**RIN:** 0938-AJ56

**1366. • MEDICARE PROGRAM: PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES UPDATE**

**Priority:** None

**Legal Deadline:** None

**Abstract:** 0938-AJ58

**Timetable:**

Action	Date	FR Cite
Withdrawn	10/28/99	

**Regulatory Flexibility Analysis Required:**

**RIN:** 0938-AJ58

**1367. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2000 (HCFA-1065-P)**

**Priority:** Other Significant. Major under 5 USC 801.

**Legal Authority:** 42 USC 1395w(4); PL 105-33, sec 4103; PL 105-33, sec 4505; PL 105-33, sec 4511; PL 105-33, sec 4512; PL 105-33, sec 4513

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

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

**Abstract:** This final rule will update physician payments by Medicare as required by section 1848 of the Social Security Act (the Act). It includes a provision to change the method of determining malpractice insurance relative value units (RVUs) from the current charge-based system to a resource-based system and continues the refinement of the practice expense RVUs that are transitioning from charge-based to resource-based. New and revised procedure codes for 2000 are also addressed. Provisions of the Balanced Budget Act of 1997 (BBA) concerning the coverage of prostate screening tests and removal of the x-ray requirement as a prerequisite for chiropractic manipulation, and policy changes concerning discontinuous anesthesia time, payment for diagnostic tests, physician pathology services and independent laboratories and nurse practitioner qualifications are also included in this rule. A discussion of the next 5 year review of work RVUs is also included.

**Timetable:**

Action	Date	FR Cite
NPRM	07/22/99	64 FR 39608
NPRM Comment Period End	09/20/99	
Final Action	11/02/99	64 FR 59739

**Regulatory Flexibility Analysis Required:** No

**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-AJ61

**1368. • MEDICAID MANAGED CARE; REGULATORY PROGRAM TO IMPLEMENT CERTAIN MEDICAID PROVISIONS OF THE BALANCED BUDGET ACT OF 1997**

**Priority:** Other Significant

**Legal Authority:** PL 105-33; 42 USC 1396w

**CFR Citation:** 42 CFR 438

**Legal Deadline:** None

**Abstract:** This final rule establishes rules for Medicaid managed care programs. It implements certain provisions in sections 4710 of the Balanced Budget Act of 1997 (Pub. L. 105-33).

**Timetable:**

Action	Date	FR Cite
Duplicate of 0938- A170	10/20/99	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations

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

**Agency Contact:** David Cade, Family & Children's Health Programs Group, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3870

**RIN:** 0938-AJ73

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

## Proposed Rule Stage

**1369. BONUS TO REWARD HIGH PERFORMANCE STATES UNDER THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES BLOCK GRANT**

**Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** 42 USC 603(a)(4)

**CFR Citation:** 45 CFR 270 (New)

**Legal Deadline:** None

**Abstract:** The Administration for Children and Families, in consultation with the National Governor's Association and the American Public Human Services Association (formerly the American Public Welfare Association), will propose specific performance measures and a funds allocation formula for measuring State performance under the Temporary Assistance for Needy Families Block Grant as the basis for payment of a bonus to high performing States.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State

**Agency Contact:** Howard Rolston, Director, Office of Planning, Research and Evaluation, Department of Health and Human Services, Administration for Children and Families, 7th Floor West, 370 L'Enfant Promenade SW, Washington, DC 20447  
Phone: 202 401-9220

**RIN:** 0970-AB66

**1370. 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	05/00/00	

**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: 202 401-5635  
Email: phbiava@acf.dhhs.gov

**RIN:** 0970-AB73

**1371. 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	02/00/00	

**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

**RIN:** 0970-AB90

**1372. 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, May 16, 2000.

**Abstract:** Joint DHHS/DOL regulations mandating use of a national medical support notice and including

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	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

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

**Agency Contact:** 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

**1373. PROGRAM PERFORMANCE STANDARDS FOR THE OPERATION OF HEAD START PROGRAMS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 9831 et seq; sec 641A of the Head Start Act

**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	05/00/00	

**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

**RIN:** 0970-AB99

## HHS—ACF

## Proposed Rule Stage

**1374. SAFEGUARDING CHILD SUPPORT AND EXPANDED FPLS INFORMATION****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 652; 42 USC 653; 42 USC 653A; 42 USC 654; 42 USC 654A; 42 USC 663**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	06/00/00	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Local**Agency Contact:** Eileen C. Brooks, Program Specialist, DHHS/OCSE, 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

**1375. TITLE IV-E FOSTER CARE ELIGIBILITY REVIEWS AND CHILD AND FAMILY SERVICES STATE PLAN REVIEWS, MEPA IMPLEMENTATION, AND ASFA IMPLEMENTATION****Priority:** Other Significant**Legal Authority:** 42 USC 622; 42 USC 671; 42 USC 1302; 42 USC 1320a-2a**CFR Citation:** 45 CFR 1355; 45 CFR 1356; 45 CFR 1357**Legal Deadline:** Final, Statutory, July 1, 1995.**Abstract:** This rule will contain requirements that implement the Social Security Act Amendments of 1994 on review of State programs under parts B and E of the Social Security Act for conformity with State Plan requirements as well as Adoption and Safe Families Act requirements related to State plan issues. It will contain requirements that govern on-site eligibility reviews that the Administration for Children and Families conducts to assure State agencies' compliance with the statutory requirements under title IV-E of the Social Security Act for the eligibility of foster care providers and the eligibility of children in foster care. The rule will provide for enforcement of the prohibition on race-based discrimination in foster care and adoptive placements.**Timetable:**

Action	Date	FR Cite
NPRM	09/18/98	63 FR 50058
NPRM Comment Period End	12/17/98	
Final Action	12/00/99	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Additional Information:** This action was previously reported under RIN 0970-AB60.**Agency Contact:** Kathleen McHugh, ACYF/Children's Bureau, Department of Health and Human Services, Administration for Children and Families, Washington, DC 20013  
Phone: 202 401-5789  
Email: kmchugh@acf.dhhs.gov**RIN:** 0970-AA97

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	08/00/00	

**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**RIN:** 0970-AB24**1376. STANDARDS FOR SAFE TRANSPORTATION****Priority:** Other Significant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1310**Legal Deadline:** None**Abstract:** This rule establishes Head Start Performance Standards for the safe transportation of Head Start children, including vehicle requirements, driver qualifications and training and safety rules for children**1377. CONSTRUCTION OF HEAD START FACILITIES****Priority:** Other Significant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1309**Legal Deadline:** None**Abstract:** This rule establishes procedures to be used by Head Start agencies in requesting to use Head Start grant funds to construct or renovate a Head Start facility.

## HHS—ACF

## Final Rule Stage

**Timetable:**

Action	Date	FR Cite
NPRM	02/08/99	64 FR 6013
NPRM Comment Period End	04/09/99	
Final Action	06/00/00	

**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

RIN: 0970-AB54

**1378. METHODOLOGY FOR DETERMINING WHETHER AN INCREASE IN A STATE'S CHILD POVERTY RATE IS THE RESULT OF THE TANF PROGRAM****Priority:** Other Significant**Legal Authority:** 42 USC 613(i)**CFR Citation:** 45 CFR 284 (New)**Legal Deadline:** None**Abstract:** This rule will set forth a methodology to determine whether an increase in a State's child poverty rate is the result of the TANF Program.**Timetable:**

Action	Date	FR Cite
NPRM	09/23/98	63 FR 50837
NPRM Comment Period End	11/23/98	
Final Action	04/00/00	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Agency Contact:** Howard Rolston, Director, Office of Planning, Research and Evaluation, Department of Health and Human Services, Administration for Children and Families, 7th Floor West, 370 L'Enfant Promenade SW, Washington, DC 20447  
Phone: 202 401-9220

RIN: 0970-AB65

**1379. REQUIREMENTS FOR THE TRIBAL PROGRAMS****Priority:** Other Significant**Legal Authority:** 42 USC 612**CFR Citation:** 45 CFR 286 (New); 45 CFR 287 (New)**Legal Deadline:** None**Abstract:** This rule sets forth a process for: the completion and submission of tribal TANF plans; the determination of funding levels for tribal TANF grants; the establishment of criteria to determine minimum work participation requirements and time limits for tribal TANF programs; and the review and approval of tribal TANF plans. This rule sets forth program requirements for the application of penalties and for data collection and reporting.

The rule also sets forth procedures for planning and operating a program to make work activities available to tribal members. Funds for this program are available to Indian tribes and Alaska Native organizations that operated a Job Opportunities and Basic Skills Training (JOBS) program in fiscal year 1995. This tribal work activities program is called the Native Employment Works (NEW) Program.

**Timetable:**

Action	Date	FR Cite
NPRM	07/22/98	63 FR 39366
NPRM Comment Period End	11/20/98	
Final Action	01/00/00	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** Federal, State, Tribal**Agency Contact:** John Bushman, Director, Division of Tribal Services, Department of Health and Human Services, Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade SW, Washington, DC 20447  
Phone: 202 401-2418  
Email: jbushman@acf.dhhs.gov

RIN: 0970-AB78

**1380. 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 304; 45 CFR 305; 45 CFR 301; 45 CFR 302; 45 CFR 303**Legal Deadline:** None**Abstract:** This rule eliminates child support enforcement program regulations rendered obsolete or inconsistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.**Timetable:**

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

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Agency Contact:** Marilyn R. Cohen, 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: 202 401-5366  
Email: mcohen@acf.dhhs.gov

RIN: 0970-AB81

**1381. REFUGEE RESETTLEMENT PROGRAM: REFUGEE CASH AND MEDICAL ASSISTANCE PROGRAMS****Priority:** Other Significant**Legal Authority:** 8 USC 1522(a)(9)**CFR Citation:** 45 CFR 400**Legal Deadline:** None**Abstract:** This regulation will give States flexibility to establish the refugee cash assistance program as a public/private partnership between States and local resettlement agencies, make several revisions to the Refugee Medical Assistance Program, and other technical changes.**Timetable:**

Action	Date	FR Cite
NPRM	01/08/99	64 FR 1159
NPRM Comment Period End	03/09/99	
Final Action	02/00/00	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Agency Contact:** Gayle Smith, Division of Refugee Self-Sufficiency, Department

## HHS—ACF

## Final Rule Stage

of Health and Human Services,  
Administration for Children and  
Families, 370 L'Enfant Promenade SW,  
Washington, DC 20447  
Phone: 202 401-9250

RIN: 0970-AB83

### 1382. 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 proposes to  
implement 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 would also implement  
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 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, Division  
of Policy and Planning, Department of  
Health and Human Services,  
Administration for Children and  
Families, MS OCSE, DPP, 370 L'Enfant  
Promenade SW, Washington, DC 20447  
Phone: 202 401-5374  
Email: jpitts@acf.dhhs.gov

RIN: 0970-AB85

### 1383. HEAD START APPEAL TIMELINES

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 9801 et seq

**CFR Citation:** 45 CFR 1303

**Legal Deadline:** None

**Abstract:** This amendment to part 1303  
will provide timelines and selected  
procedural changes for conducting  
administrative hearings on adverse  
actions taken against Head Start  
agencies.

**Timetable:**

Action	Date	FR Cite
NPRM	06/30/98	63 FR 35554
NPRM Comment Period End	08/31/98	
Final Action	01/00/00	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Governmental  
Jurisdictions, Organizations

**Government Levels Affected:** State,  
Local, Tribal

**Additional Information:** RFA: N

**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

RIN: 0970-AB87

### 1384. WELFARE-TO-WORK DATA COLLECTION

**Priority:** Other Significant

**Legal Authority:** 42 USC 611

**CFR Citation:** 45 CFR 276

**Legal Deadline:** None

**Abstract:** This final rule specifies the  
data elements that grantees must report  
for the Welfare-to-Work program.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	10/29/98	63 FR 57919
Final Action	05/00/00	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State

**Agency Contact:** Howard Rolston,  
Director, Office of Planning, Research  
and Evaluation, Department of Health  
and Human Services, Administration  
for Children and Families, 7th Floor  
West, 370 L'Enfant Promenade SW,  
Washington, DC 20447  
Phone: 202 401-9220

RIN: 0970-AB92

### 1385. STATE SELF ASSESSMENTS TO DETERMINE COMPLIANCE WITH FEDERAL REGULATIONS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 654(15)(A)

**CFR Citation:** 45 CFR 306

**Legal Deadline:** None

**Abstract:** The rule would require States  
to conduct annual reviews on certain  
aspects of the State Title IV-D Programs  
and provide a report to the Secretary.

**Timetable:**

Action	Date	FR Cite
NPRM	10/08/99	64 FR 55102
Final Action	10/00/00	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Jan Rothstein,  
Program Specialist, Office of Child  
Support Enforcement/DHHS,  
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: 202 401-5073  
Email: jrothstein@acf.dhhs.gov

RIN: 0970-AB96

### 1386. PRIORITY FOR PREVIOUSLY SELECTED HEAD START AGENCIES

**Priority:** Other Significant

**Legal Authority:** 42 USC 9801 et seq

**CFR Citation:** 45 CFR 1302.12

**Legal Deadline:** None

**Abstract:** The final rule proposes to  
amend 45 CFR part 1302 by removing  
section 1302.12 for clarification  
purposes.

**Timetable:**

Action	Date	FR Cite
NPRM	03/24/99	64 FR 14202
NPRM Comment Period End	05/24/99	
Final Action	02/00/00	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Local,  
Tribal

**Agency Contact:** James Kolb, Head  
Start Bureau, ACYF, Department of

HHS—ACF

Final Rule Stage

Health and Human Services,  
Administration for Children and  
Families, 330 C Street SW, Washington,  
DC 20201  
Phone: 202 205-8580

RIN: 0970—AB98

**1387. TECHNICAL REVISION OF HEAD  
START REGULATIONS TO MAKE  
THEM CONFORM TO RECENT  
STATUTORY REVISIONS**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9831 et seq

CFR Citation: 45 CFR 1301; 45 CFR  
1302; 45 CFR 1303; 45 CFR 1308

Legal Deadline: None

Abstract: This rule will correct several  
Head Start regulations which define  
Head Start programs as “non-profit”  
agencies. Recent statutory changes now  
allow “for-profit” agencies to receive  
Head Start grant funds.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	06/00/00	

**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

RIN: 0970—AC00

**1388. ASSETS FOR INDEPENDENCE  
RESERVE ACCOUNT**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 604 Note

CFR Citation: 45 CFR Part 1000

Legal Deadline: None

Abstract: The Office of Community  
Services (OCS) is administering a new  
demonstration project that will  
establish, support, and participate in  
the evaluation of Individual  
Development Accounts (IDA) for lower

income individuals and families, as  
enacted in Title IV, Human Services  
Reauthorization Act of 1998 (P.L. 105-  
285). Section 407(b)(2) of Title IV,  
Human Services Reauthorization Act of  
1998 (P.L. 105-285), states that the  
Secretary is to prescribe regulations on  
accounting for amounts in the IDA  
reserve fund. This regulation would  
address that requirement.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	02/00/00	

**Regulatory Flexibility Analysis  
Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Richard Saul,  
Program Specialist, Department of  
Health and Human Services,  
Administration for Children and  
Families, 5th Floor, OCS, 370 L'Enfant  
Promenade SW, Washington, DC 20447  
Phone: 202 401-9341  
Email: rsaul@acf.dhhs.gov

RIN: 0970—AC02

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

Completed Actions

**1389. TEMPORARY ASSISTANCE FOR  
NEEDY FAMILIES (TANF)**

Priority: Other Significant

CFR Citation: 45 CFR 260 to 265 (New)

**Completed:**

Reason	Date	FR Cite
Final Rule	04/12/99	64 FR 17720

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** Federal,  
State, Tribal

**Agency Contact:** Mack A. Storrs  
Phone: 202 401-9289  
Email: mstorrs@acf.dhhs.gov

RIN: 0970—AB77

**1390. BONUS TO REWARD  
DECREASE IN ILLEGITIMACY RATIO**

Priority: Other Significant

CFR Citation: 45 CFR 283 (New)

**Completed:**

Reason	Date	FR Cite
Final Rule	04/14/99	64 FR 18484

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** State

**Agency Contact:** Kelleen Kaye  
Phone: 202 401-6634  
Email: kkaye@osaspe.dhhs.gov

RIN: 0970—AB79

**1391. IMPLEMENTATION OF AFCARS  
CORRECTIVE ACTION AND  
PENALTIES AND CAPTA  
AMENDMENTS**

Priority: Other Significant

CFR Citation: 45 CFR 1355; 45 CFR  
1356; 45 CFR 1340

**Completed:**

Reason	Date	FR Cite
Withdrawn	10/01/99	

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** State

**Agency Contact:** Kathleen McHugh  
Phone: 202 401-5789  
Email: kmchugh@acf.dhhs.gov

RIN: 0970—AB94

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

Proposed Rule Stage

**1392. 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 1324; 45 CFR 1326; 45 CFR 1327; 45 CFR 1328

**Legal Deadline:** None

**Abstract:** The Administration on Aging in consultation with the Office of Management and Budget, has determined that it is no longer necessary to pursue final action on rules 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	12/00/99	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Governmental Jurisdictions

**Government Levels Affected:** State, Tribal

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