

Federal Register

Tuesday
November 28, 1995

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary****21 CFR Ch. I****42 CFR Chs. I-V****45 CFR Subtitle A, Chs. II, III, and XIII****Unified Agenda of Regulations**

AGENCY: Office of the Secretary, HHS.

ACTION: Publication of unified agenda of regulations.

SUMMARY: The President's September 30, 1993, Executive order (12866) and the Regulatory Flexibility Act of 1980 require the Department to publish an agenda of significant regulations being developed and an indication of those regulatory actions that are being analyzed for their effect on small businesses. The Department published its last agenda on May 8, 1995.

DATES: Data, information, and views due date: December 5, 1995, for initial suggestions and any date thereafter for additional suggestions.

ADDRESSES: Addresses for submitting comments and information in response to this document are listed at the end.

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

SUPPLEMENTARY INFORMATION:

Department of Health and Human Services' Regulatory Plan

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

Background

On September 30, 1993, President Clinton issued Executive Order 12866 to

make regulations less burdensome, more effective, and in greater alignment with the Administration's priorities and regulatory principles. As part of the Department of Health and Human Services efforts to effectively implement the Executive order, we published a notice in the Federal Register, January 20, 1994, providing a plan for periodic review of existing rules and inviting public comments to assist in determining the best priority for review.

The Executive order and the Administration's effort toward implementation have proven successful by providing real progress in reforming regulations. Building on those successes, in March of 1995, the President announced plans for more immediate, comprehensive reform.

First, the President directed each agency to undertake an exhaustive review of all regulations with an eye toward eliminating or modifying those that are obsolete or which are otherwise in need of reform. Second, the President directed each agency to change the way performance is measured—focusing on results, not process. Third, the President asked his senior executives to convene meetings in order to establish grassroots partnerships which would allow greater collaboration and participation in reinventing the regulatory process. Finally, the President requested that we further our efforts to negotiate more during the rulemaking process.

As a result of the initiative discussed above, this semiannual unified agenda reflects our efforts to reinvent rules identified as needing reform. As we embark on this effort, we continue to invite comments on our unified agenda entries and suggestions for furthering the President's regulatory reinvention strategy.

Comments should be sent to the addresses listed below, depending on the regulations addressed. Comments may be sent to the Office of the Secretary when the responsible division is not known or when the comment covers several regulatory areas crossing agency lines.

Health Care Financing Administration: Mary Ann Troanovitch, Executive for Regulations Management, Health Care Financing Administration,

Room 309G, Hubert H. Humphrey Building, Washington, DC 20201; phone 202-690-7890.

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: Jack McCarthy, Executive Secretariat, Room 4753, Wilbur H. Cohen Building, 330 Independence Avenue SW., Washington, DC 20201; phone 202-619-0441.

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

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

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

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

Centers for Disease Control/Agency for Toxic Substances and Disease Registry: Galen Morris, 1600 Clifton Road NE., Building 1, Room 2050, Atlanta, Georgia 30333; phone 404-639-1548.

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

Food and Drug Administration: Ed Dutra, Director, Regulatory Policy and Management Staff, (HF26), 5600 Fishers Lane, Room 12-A-17, Rockville, Maryland 20857; phone 301-443-3480.

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

Claudia Cooley,

Executive Secretary to the Department.

HHS

Office of the Secretary—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1192 | Revisions to the Civil Money Penalty Provisions Relating to the Misuse of Certain Symbols and Emblems | 0991-AA81 |

Office of the Secretary—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1193 | Civil Money Penalties (CMPs) for Certain Hospital Physician Incentive Plans | 0991-AA45 |
| 1194 | Uniform Administrative Requirements for Grants and Cooperative Agreements | 0991-AA56 |
| 1195 | Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute | 0991-AA66 |
| 1196 | Safe Harbors for Protecting Health Plans | 0991-AA69 |
| 1197 | Revisions to the PRO Sanctions Process | 0991-AA73 |

Office of the Secretary—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1198 | Civil Money Penalties (CMPs) for Certain Practices Relating to Medicare Supplemental Policies | 0991-AA53 |
| 1199 | Civil Money Penalties for Physician Ownership of and Referral to Certain Health Care Entities | 0991-AA65 |
| 1200 | Civil Money Penalties for Notifying a Home Health Agency, or a Home or Community-Based Health Care Center or Provider, of a Standard Survey | 0991-AA79 |
| 1201 | Civil Money Penalties for False Information on Drug Manufacturer Price Surveys and Rebate Agreements | 0991-AA80 |

Office of the Secretary—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1202 | Amendment to Grants Management Common Rule To Raise Threshold for Simplified Small Purchases | 0991-AA77 |
| 1203 | Proposed Amendments to Nonprocurement Debarment and Suspension Common Rule To Achieve Reciprocity With Procurement | 0991-AA78 |

Substance Abuse and Mental Health Services Administration—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1204 | Protection and Advocacy for Individuals With Mental Illness | 0930-AA02 |
| 1205 | Block Grants for Prevention and Treatment of Substance Abuse (Tobacco Provisions) (Reg Plan Seq. No. 26) | 0930-AA03 |

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

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

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1206 | Block Grants for Prevention and Treatment of Substance Abuse | 0930-AA01 |

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Substance Abuse and Mental Health Services Administration—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1207 | Confidentiality of Substance Abuse Patient Records | 0930-AA00 |

Centers for Disease Control and Prevention—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1208 | Respiratory Protective Devices | 0920-AA00 |
| 1209 | National Center for Health Statistics, Special Statistical Services; Grants for Health Education/Risk Reduction; Vaccines Information and Education—Repeal | 0920-AA01 |

Departmental Management—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1210 | Implementation of the Equal Access to Justice Act in Agency Proceedings | 0990-AA02 |

Food and Drug Administration—Prerule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1211 | Reinventing FDA Food Regulations | 0910-AA58 |
| 1212 | Food Standards of Identity, Quality, and Fill of Container; Common or Usual Name Regulations: Request for Comments on Existing Regulations (Reg Plan Seq. No. 27) | 0910-AA67 |

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

Food and Drug Administration—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1213 | Over-the-Counter (OTC) Drug Review | 0910-AA01 |
| 1214 | Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports | 0910-AA04 |
| 1215 | Reporting of Errors and Accidents | 0910-AA12 |
| 1216 | Mammography Quality Standards Act of 1992 (Reg Plan Seq. No. 28) | 0910-AA24 |
| 1217 | Effective Date of Requirement for Submission of Premarket Approval Applications | 0910-AA31 |
| 1218 | Latex Condoms/Gloves: Expiration Date Labeling | 0910-AA32 |
| 1219 | Latex Warning | 0910-AA34 |
| 1220 | Premarket Approval of Medical Devices; Supplemental Applications | 0910-AA35 |
| 1221 | Hearing Aids; Professional and Patient Labeling; Conditions for Sale | 0910-AA39 |
| 1222 | Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals | 0910-AA45 |
| 1223 | Animal Drug Amendments of 1994, Extra-Label Use; Implementation | 0910-AA47 |
| 1224 | Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents (Reg Plan Seq. No. 29) | 0910-AA48 |
| 1225 | Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution | 0910-AA49 |
| 1226 | Habit Forming Drugs | 0910-AA50 |
| 1227 | Bioavailability and Bioequivalence Requirements | 0910-AA51 |
| 1228 | Consolidation of Regulations | 0910-AA53 |
| 1229 | Revocation of Certain Regulations (Reg Plan Seq. No. 30) | 0910-AA54 |
| 1230 | Name of Selling Agent or Distributor | 0910-AA56 |
| 1231 | Streamlining Procedures for Changes in Production of Biologics (Reg Plan Seq. No. 31) | 0910-AA57 |

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Food and Drug Administration—Proposed Rule Stage (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1232 | Dietary Supplement Regulations in Response to DSHEA | 0910-AA59 |
| 1233 | Protection of Human Subjects; Informed Consent (Reg Plan Seq. No. 32) | 0910-AA60 |
| 1234 | OTC Drug Labeling Review | 0910-AA63 |
| 1235 | Medical Device Exemptions From Premarket Notification (Reg Plan Seq. No. 33) | 0910-AA65 |
| 1236 | Substances Approved for Use in the Preparation of Meat and Poultry Products | 0910-AA66 |

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

Food and Drug Administration—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1237 | New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act | 0910-AA02 |
| 1238 | Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection | 0910-AA05 |
| 1239 | Lead in Foods | 0910-AA06 |
| 1240 | Fees for Certification Services; Insulin and Color Additive Certification Programs | 0910-AA07 |
| 1241 | Prescription Drug Marketing Act of 1987; Policy Information, Guidance, and Clarifications | 0910-AA08 |
| 1242 | Implementation of the Safe Medical Devices Act of 1990 | 0910-AA09 |
| 1243 | Final Regulation to Establish Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (Reg Plan Seq. No. 34) | 0910-AA10 |
| 1244 | Bottled Water | 0910-AA11 |
| 1245 | Medical Devices; Protective Restraints; Revocation of Exemptions From 510(k) Premarket Notification Procedures and Current Good Manufacturing Practices Regulations | 0910-AA17 |
| 1246 | Food Labeling Review | 0910-AA19 |
| 1247 | Disqualification of Clinical Investigators | 0910-AA21 |
| 1248 | Investigational Device Exemption; Intraocular Lenses | 0910-AA22 |
| 1249 | Dietary Supplement Label Review | 0910-AA23 |
| 1250 | Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling | 0910-AA25 |
| 1251 | Tamper-Evident Packaging Requirements for Over-the-Counter Human Drug Products | 0910-AA26 |
| 1252 | Certification of Drugs Composed Wholly or Partly of Insulin; Fees for Certification of Drugs Composed Wholly or Partly of Insulin | 0910-AA27 |
| 1253 | Electronic Signatures; Electronic Records | 0910-AA29 |
| 1254 | Financial Disclosure by Clinical Investigators | 0910-AA30 |
| 1255 | Prescription Drug Product Labeling; Medication Guide (Reg Plan Seq. No. 35) | 0910-AA37 |
| 1256 | Human Tissue Intended for Transplantation: Proposed Rule | 0910-AA40 |
| 1257 | Iron Containing Drugs and Supplements | 0910-AA42 |
| 1258 | Public Information; Communications With State and Foreign Government Officials | 0910-AA46 |

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

Food and Drug Administration—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1259 | Policies Concerning Uses of Sulfiting Agents | 0910-AA03 |
| 1260 | Review of Warnings, Use Instructions, and Precautionary Information Under Section 314 of the National Childhood Vaccine Injury Act of 1986 | 0910-AA14 |
| 1261 | General Biological Product Standards; Alternative Procedures and Exceptions | 0910-AA16 |
| 1262 | Medical Foods | 0910-AA20 |
| 1263 | Adverse Experience Reporting Requirements for Human Drug and Licensed Biological Products | 0910-AA28 |
| 1264 | Amalgam Ingredient Labeling | 0910-AA33 |
| 1265 | Classification of Computer Software Programs That Are Medical Devices | 0910-AA41 |
| 1266 | Development of Hazard Analysis Critical Control Points for the Food Industry; Request for Comments | 0910-AA43 |
| 1267 | Drugs Used for Treatment of Narcotic Addicts | 0910-AA52 |

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Food and Drug Administration—Long-Term Actions (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1268 | Export Requirements for Drugs for Investigational Use in Other Countries | 0910-AA61 |
| 1269 | Export Requirements for Medical Devices | 0910-AA62 |

Food and Drug Administration—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1270 | Proposed Labeling for Drug Products Based on False or Fraudulent Data | 0910-AA13 |
| 1271 | Recordkeeping and Reporting: Electronic Products | 0910-AA15 |
| 1272 | Threshold of Regulation Policy for Components of Food Contact Articles | 0910-AA18 |
| 1273 | Medical Devices; Restricted Devices | 0910-AA36 |
| 1274 | Substances Prohibited for Use in Ruminant Feed | 0910-AA38 |
| 1275 | New Drug and Biological Product License Applications; Revisions to Existing Regulations | 0910-AA44 |

Health Resources and Services Administration—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1276 | National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table - II | 0906-AA36 |

Health Resources and Services Administration—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1277 | Organ Procurement and Transplantation Network Rules (Reg Plan Seq. No. 36) | 0906-AA32 |
| 1278 | Technical Amendments to the Health Professions, Nursing, and Allied Health Training Grant Programs Under 42 CFR Parts 57 and 58 | 0906-AA38 |
| 1279 | Removal of Obsolete Regulations of the Title VII Grant for the Construction of Teaching Facilities for Health Professions Personnel | 0906-AA39 |

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

Health Resources and Services Administration—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1280 | Health Education Assistance Loan (HEAL) Program: Lenders'/ Holders' Performance Standards | 0906-AA33 |

Health Resources and Services Administration—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1281 | Grants for the Establishment of Departments of Family Medicine | 0906-AA34 |
| 1282 | Federally Supported Health Centers Assistance Act of 1992 | 0906-AA35 |
| 1283 | National Practitioner Data Bank for Adverse Information on Physicians, Dentists, and Other Health Care Practitioners: Payment of Fees | 0906-AA37 |

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National Institutes of Health—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1284 | National Institutes of Health AIDS Research Loan Repayment Program | 0925-AA02 |
| 1285 | National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds | 0925-AA09 |
| 1286 | Undergraduate Scholarship Program Regarding Professions Needed by the NIH | 0925-AA10 |
| 1287 | Traineeships (Termination Policies) | 0925-AA11 |
| 1288 | Additional DHHS Protection for Pregnant Women and Human Fetuses Involved as Subjects for Research, and Pertaining to Human In Vitro Fertilization | 0925-AA14 |

National Institutes of Health—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1289 | Grants for Research Projects | 0925-AA01 |
| 1290 | Hazardous Substances Basic Research and Training Grants | 0925-AA03 |
| 1291 | National Institutes of Health Construction Grants | 0925-AA04 |
| 1292 | Training Grants | 0925-AA05 |
| 1293 | National Institutes of Health Center Grants | 0925-AA06 |
| 1294 | Grants for National Alcohol Research Centers | 0925-AA08 |

National Institutes of Health—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1295 | Responsibilities of Public Health Service-Funded Institutions for Promoting Objectivity in Research | 0925-AA07 |

Office of Assistant Secretary for Health—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1296 | Standards of Compliance for Abortion-Related Services in Family Planning Service Projects | 0937-AA00 |

Health Care Financing Administration—Prerule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1297 | Ambulance Services (BPD-813-P) | 0938-AH13 |
| 1298 | Changes in Coverage and Payment Policies for Physician Assistant Services (BPD-829-P) | 0938-AH26 |

Health Care Financing Administration—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1299 | New Minimum Standards for Medicare Supplemental (Medigap) Policies (BPD-491-P) | 0938-AD82 |
| 1300 | "Without Fault" and Beneficiary Waiver of Recovery as It Applies to Medicare Overpayment Liability (BPD-719-P) | 0938-AD95 |
| 1301 | Protection of Income and Resources for Community Spouses of Institutionalized Individuals (MB-023-P) | 0938-AE12 |
| 1302 | Coverage of Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Services (BPD-708-P) | 0938-AF00 |
| 1303 | Alternative Sanctions for Psychiatric Hospitals (HSQ-191-P) | 0938-AF32 |
| 1304 | Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (MB-046-F) | 0938-AF42 |
| 1305 | Federally Qualified Health Center Services (Medicaid) (MB-043-P) | 0938-AF90 |

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Health Care Financing Administration—Proposed Rule Stage (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1306 | Revisions to Rules on Health Care Prepayment Plans (OMC-016-P) | 0938-AF97 |
| 1307 | Conditions of Participation for Rural Health Clinics (BPD-764-P) | 0938-AG05 |
| 1308 | Medicare Appeals of Individual Claims (BPD-453-P) | 0938-AG18 |
| 1309 | Appointment of Representatives for Medicare Appeals (BPO-120-P) | 0938-AG30 |
| 1310 | Enforcement Requirements for Renal Dialysis Facilities (HSQ-204-P) | 0938-AG31 |
| 1311 | Disclosure of Confidential PRO Information for Research Purposes (HSQ-208-P) | 0938-AG33 |
| 1312 | Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, and Overpayments (HSQ-215-P) ... | 0938-AG59 |
| 1313 | Medicare Program: Limitations on Medicare Coverage of Cataract Surgery (BPD-797-PN) | 0938-AG65 |
| 1314 | New Payment Methodology for Routine Extended Care Services Provider in a Swing Bed Hospital (BPD-805-P) ... | 0938-AG68 |
| 1315 | Salary Equivalency Guidelines for Physical Therapy, Respiratory Therapy, Speech Pathology, and Occupational Therapy (BPD-808-PN) | 0938-AG70 |
| 1316 | Medicaid: Optional Coverage of TB-Related Services for Individuals Infected with Tuberculosis (MB-082-P) | 0938-AG72 |
| 1317 | Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Expanded to Designated Health Services (BPD-809-P) | 0938-AG80 |
| 1318 | Home Health Agency (HHA) Conditions of Participation (BPD-819-P) (Reg Plan Seq. No. 38) | 0938-AG81 |
| 1319 | End-Stage Renal Disease (ESRD) Conditions of Coverage (BPD-818-P) (Reg Plan Seq. No. 39) | 0938-AG82 |
| 1320 | Distinct Part Requirements for Nursing Homes and Prohibition of Financial Screening of Applicants for Nursing Home Admission (BPD-815-P) | 0938-AG84 |
| 1321 | Medicaid: Nominal Copayments for Institutional Services for Medicaid Recipients (MB-090-P) | 0938-AG90 |
| 1322 | Wage Index Used To Adjust Payment Rates for Hospice Services Under the Medicare Program (BPD-820-P) | 0938-AG93 |
| 1323 | Categorization and Certification Requirements for a New Subcategory of Moderate Complexity Testing (HSQ-222-P) (Reg Plan Seq. No. 40) | 0938-AG98 |
| 1324 | CLIA Program: Categorization of Waived Tests (HSQ-225-P) (Reg Plan Seq. No. 41) | 0938-AG99 |
| 1325 | Medicaid Coverage of Personal Care Services (MB-071-P) | 0938-AH00 |
| 1326 | Liability for Third Parties to Pay for Care and Services (MB-080-P) | 0938-AH01 |
| 1327 | Medicare Program: Coverage of Certified Nurse-Midwife Services (BPD-496-P) | 0938-AH02 |
| 1328 | Medicare Program: Uniform Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies (BPD-788-P) | 0938-AH12 |
| 1329 | Adjustment in Payment Amounts for New Technology Intraocular Lenses (BPD-831-P) | 0938-AH15 |
| 1330 | Schedule of Limits for Skilled Nursing Facility Inpatient Routine Service Costs (BPD-837-NC) | 0938-AH18 |
| 1331 | Additional Supplier Standards (BPD-838-P) | 0938-AH19 |
| 1332 | Delegation of Civil Money Penalties (BPO-135-FC) | 0938-AH22 |
| 1333 | State Plan Amendment (SPA) Reconsideration Process (MB-096-P) | 0938-AH24 |
| 1334 | Evidence of Lawful Permanent Residence (MB-097-P) | 0938-AH25 |
| 1335 | Hospice Care - Conditions of Participation (BPD-844-P) | 0938-AH27 |
| 1336 | Limitations on Payment for Home Oxygen Therapy Based on Inherent Reasonableness Criteria (BPD-845-PN) | 0938-AH28 |
| 1337 | Medicaid: Limitations on Aggregate Payments to Disproportionate Share Hospitals; Federal Fiscal Year 1997 (MB-098-N) | 0938-AH30 |
| 1338 | Medicaid Eligibility Quality Control, Staffing and Training, and Utilization Control: Removal of Obsolete and Restrictive Requirements (MB-099-P) | 0938-AH31 |
| 1339 | Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 1997 Rates (BPD-847-P) (Reg Plan Seq. No. 42) | 0938-AH34 |

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

Health Care Financing Administration—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1340 | Deduction of Incurred Medical Expenses (Spenddown) (MB-020-F) | 0938-AB07 |
| 1341 | Payment for Clinical Diagnostic Laboratory Tests (BPD-309-F) | 0938-AB50 |
| 1342 | Effective Dates for Provider Agreements and Supplier Approvals (HSQ-139-F) | 0938-AC88 |
| 1343 | Changes Concerning Suspension of Medicare Payments and Determinations of Allowable Interest Expense (BPO-118-FC) | 0938-AC99 |
| 1344 | Prohibition on Unbundling of Hospital Outpatient Services (BPD-426-F) | 0938-AD33 |
| 1345 | Changes to Peer Review Organization Regulations (HSQ-135-F) | 0938-AD38 |
| 1346 | Revisions to the Freedom of Information Regulations (OPA-001-P) | 0938-AD60 |
| 1347 | Omnibus Nursing Home Reform Requirements (BPD-488-F) | 0938-AD81 |

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Health Care Financing Administration—Final Rule Stage (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1348 | HMO Organizational Structure and Services (OMC-007-F) | 0938-AE25 |
| 1349 | Hospital Standard for HIV Infectious Blood and Blood Products (BPD-633-F) | 0938-AE40 |
| 1350 | Medicare, Medicaid, and CLIA Programs: Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (HSQ-226-F) (Reg Plan Seq. No. 43) | 0938-AE47 |
| 1351 | Conditions of Coverage for Organ Procurement Organizations (BPD-646-F) | 0938-AE48 |
| 1352 | Resident Assessment in Long-Term Care Facilities (HSQ-180-F) | 0938-AE61 |
| 1353 | Post-Contract Beneficiary Protections and Other Provisions (OMC-003-F) | 0938-AE63 |
| 1354 | Employer Contributions to HMOs (OMC-004-F) | 0938-AE64 |
| 1355 | Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (MB-28-F) | 0938-AE72 |
| 1356 | Payment for Nursing and Allied Health Science Education (BPD-685-F) | 0938-AE79 |
| 1357 | Coverage of Screening Pap Smears (BPD-705-F) | 0938-AE98 |
| 1358 | Medicare Coverage of Clinical Psychologist, Other Psychologist, and Clinical Social Worker Services—Medicare (BPD-706-F) | 0938-AE99 |
| 1359 | Case Management (MB-27-F) | 0938-AF07 |
| 1360 | Payment for Federally Qualified Health Center (FQHC) Services (BPD-728-F) | 0938-AF14 |
| 1361 | Partial Hospitalization Services in Community Mental Health Centers (BPD-736-IFC) | 0938-AF53 |
| 1362 | Medicaid: Outstationed Intake Locations for Certain Low-Income Pregnant Women, Infants and Children Under Age 19 (MB-052-F) | 0938-AF69 |
| 1363 | Medicare and Medicaid Programs: Requirements for Physician Incentive Plans in Prepaid Health Care Organizations (OMC-010-FC) | 0938-AF74 |
| 1364 | Part B Advance Payments to Physicians/Suppliers or Other Entities Furnishing Items or Services Under Medicare Part B (BPO-105-F) | 0938-AF85 |
| 1365 | Retroactive Enrollment and Disenrollment in Risk Health Maintenance Organizations and Competitive Medical Plans (OMC-015-F) | 0938-AF98 |
| 1366 | Payment for Preadmission Services (BPD-731-F) | 0938-AG00 |
| 1367 | Change in Provider Agreement Regulations Related to Federal Employee Health Benefits (BPD-748-F) | 0938-AG03 |
| 1368 | Intermediary and Carrier Functions (BPO-111-F) | 0938-AG06 |
| 1369 | Revised Medicaid Management Information Systems (MB-38-FN) | 0938-AG10 |
| 1370 | End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs (BPD-763-F) | 0938-AG20 |
| 1371 | Medicare Program: Limitations on Medicare Coverage of Intermittent Positive Pressure Breathing Machine Therapy (BPD-781-FN) | 0938-AG44 |
| 1372 | Telephone and Electronic Requests for Review of Part B Initial Claim Determinations (BPO-121-P) | 0938-AG48 |
| 1373 | Schedule of Limits on Home Health Agency Costs Per Visit (BPD-793-N) | 0938-AG54 |
| 1374 | Medicaid Program: Nurse-Midwife Services (MB-085-F) | 0938-AG73 |
| 1375 | Medicaid Program: Fees for Vaccine Administration Under Pediatric Immunization Program (MB-084-FN) | 0938-AG77 |
| 1376 | Revision of Medicare Hospital Conditions of Participation (BPD-745-P) (Reg Plan Seq. No. 44) | 0938-AG79 |
| 1377 | Medicare Program: Changes to the Inpatient Hospital Prospective Payment Systems and Fiscal Year 1996 Rates (BPD-825-FC) | 0938-AG95 |
| 1378 | Medicare Program: Revisions to Payment Policies and Adjustments to the Relative Value Units (RVUs) Under the Physician Fee Schedule for Calendar Year 1996 (BPD-827-FC) (Reg Plan Seq. No. 45) | 0938-AG96 |
| 1379 | Medicare Program: Physician Fee Schedule Update for Calendar Year 1996 & Physician Volume Performance Standard Rates of Increase for Federal Fiscal Year 1996 (BPD-828-FN) | 0938-AH03 |
| 1380 | Part A Premium for 1996 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (OACT-051-N) | 0938-AH06 |
| 1381 | Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rates Beginning January 1, 1996 (OACT-050-N) | 0938-AH07 |
| 1382 | Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1996 (OACT-049-N) | 0938-AH08 |
| 1383 | Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1995 (Medicaid Program) (MB-094-N) | 0938-AH09 |
| 1384 | Reporting of Interest From Zero Coupon Bonds (BPD-647-F) | 0938-AH11 |
| 1385 | Update of the Reasonable Compensation Equivalent Limits for Services Furnished by Physicians (BPD-816-N) | 0938-AH14 |
| 1386 | Criteria and Procedures for Extending Coverage to Certain Devices and Related Services (BPD-841-FC) (Reg Plan Seq. No. 46) | 0938-AH21 |
| 1387 | CLIA Program; Granting and Withdrawal of Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs; Technical Corrections | 0938-AH32 |
| 1388 | Medicare Program; Special Enrollment Periods and Waiting Periods (BPD-752-FC) | 0938-AH33 |

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

HHS

Health Care Financing Administration—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1389 | Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care (BPD-393-F) | 0938-AC58 |
| 1390 | Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology (BPD-432-F) | 0938-AD07 |
| 1391 | Medicare Coverage of Outpatient Occupational Therapy Services (BPD-425-P) | 0938-AD32 |
| 1392 | Medicare Secondary Payer for Disabled Individuals (BPD-482-FC) | 0938-AD73 |
| 1393 | Fee Schedule for Payment of Clinical Psychologist Services (BPD-495-P) | 0938-AD84 |
| 1394 | Survey Requirements and Alternative Sanctions for Home Health Agencies (HSQ-169-F) | 0938-AE39 |
| 1395 | Fire Safety Standards for Hospitals, Long-Term Care Facilities, and Intermediate Care Facilities for the Mentally Retarded (BPD-650-FC) | 0938-AE97 |
| 1396 | Changes to the Long-Term Care Facility Survey Process (HSQ-175-FC) | 0938-AF02 |
| 1397 | OBRA '90 and Miscellaneous Managed Care Technical Amendments (OMC-018-FC) | 0938-AF15 |
| 1398 | Presumptive Limits on Payments to HMOs, CMPs, and HCPPs (OMC-006-F) | 0938-AF16 |
| 1399 | Provider Reimbursement Determinations and Appeals Revisions (BPD-727-P) | 0938-AF28 |
| 1400 | Referral to Child Support Enforcement Agencies of Medicaid Families (MB-051-F) | 0938-AF68 |
| 1401 | Assessing Interest Against Medicare Secondary Payer (MSP) Debts (BPO-108-P) | 0938-AF87 |
| 1402 | General Criteria and Standards for Evaluating Performance of Contract Obligations (HSQ-207-NC) | 0938-AG32 |
| 1403 | Withdrawal of Coverage of Diagnostic Nocturnal Penile Tumescence Testing (Impotence Testing) (BPD-780-FN) .. | 0938-AG43 |
| 1404 | Noncoverage of Electrostimulation of Salivary Glands for the Treatment of Xerostomia (Dry Mouth) (BPD-782-FN) | 0938-AG45 |
| 1405 | Clinical Laboratory Improvement Amendment (CLIA) Fee Schedules (HSQ-219-FC) | 0938-AG87 |
| 1406 | Mandatory Medigap Crossover Claims Transmittal Requirements (BPD-811-P) | 0938-AG94 |
| 1407 | Definition of Skilled Nursing Facility (SNF) and Home Health Agency (HHA) for Coverage of Durable Medical Equipment (DME) (BPD-834-P) | 0938-AH16 |
| 1408 | Medicare Coverage of Liver Transplantation (BPD-835-PN) | 0938-AH17 |
| 1409 | Provisions That Allow Rural Primary Care Hospitals (RPCHs) to Enter Into Swing-Bed Agreements (BPD-839-P) ... | 0938-AH20 |
| 1410 | Transfer of Assets for Less Than Fair Market Value: Medicaid Program (MB-095-P) | 0938-AH23 |

Health Care Financing Administration—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1411 | Clarifications of Medicare's Accrual Basis of Accounting Policy (BPD-366-F) | 0938-AD01 |
| 1412 | Optional Payment System for Low Medicare Volume Skilled Nursing Facilities (BPD-409-F) | 0938-AD02 |
| 1413 | Transfer of Resources for Less Than Fair Market Value (MB-10-P) | 0938-AD18 |
| 1414 | Payment for Durable Medical Equipment and Orthotic and Prosthetic Devices (BPD-494-F) | 0938-AD65 |
| 1415 | Uniform Electronic Cost Reporting System for Hospitals (BPD-689-F) | 0938-AE80 |
| 1416 | Allowing Certifications and Recertifications by Nurse Practitioners and Clinical Nurse Specialists for Certain Services (BPD-709-FC) | 0938-AF01 |
| 1417 | Medicaid Third Party Liability: Cost Effectiveness Waivers (MB-39-F) | 0938-AF11 |
| 1418 | Required Coverage of Nurse Practitioner Services—Medicaid (MB-41-F) | 0938-AF12 |
| 1419 | Physician Ownership of and Referrals to Health Care Facilities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements (BPD-674-FC) | 0938-AF40 |
| 1420 | Medicare and Medicaid Programs; Advance Directives (BPD-718-F) | 0938-AF50 |
| 1421 | Clarification of Resumption of Entitlement Rules for Medicare Patients with End-Stage Renal Disease (BPD-738-F) | 0938-AG19 |
| 1422 | Standards for Quality of Water Used in Dialysis and Revised Guidelines on Reuse of Hemodialyzer Filters for End-Stage Renal Disease Patients (BPD-766-F) | 0938-AG21 |
| 1423 | Community Supported Living Arrangements Services (MB-070-P) | 0938-AG35 |
| 1424 | Conditions for Payment for Physicians' Services in Teaching Settings (BPD-792-P) | 0938-AG53 |
| 1425 | Date for Filing Medicare Cost Reports (BPD-794-F) | 0938-AG55 |
| 1426 | Expansion of the Definition of Eye and Ear Specialty Hospitals (BPD-804-P) | 0938-AG67 |
| 1427 | Categorization of CLIA Tests and Personnel Modifications (HSQ-216-FC) | 0938-AG71 |
| 1428 | Criteria for Medicare Coverage of Lung Transplants (BPD-812-FN) | 0938-AG83 |

HHS

Administration for Children and Families—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1429 | Foster Care, Adoption Assistance, and Child Welfare Services | 0970-AA97 |
| 1430 | Block Grant Programs (Low Income Home Energy Assistance Program —LIHEAP)—FY 1995 and FY 1996 Provisions | 0970-AB47 |
| 1431 | Administrative Flexibility Rule | 0970-AB49 |
| 1432 | Designation of Alternative Agency To Serve Indian Tribal Children | 0970-AB52 |
| 1433 | Construction of Head Start Facilities | 0970-AB54 |
| 1434 | Quality Standards for Head Start Programs (Reg Plan Seq. No. 47) | 0970-AB55 |
| 1435 | Head Start Fellowships Program | 0970-AB56 |
| 1436 | Reporting Overdue Support Information to Consumer Reporting Agencies | 0970-AB57 |
| 1437 | On-Site Foster Care Eligibility Reviews | 0970-AB60 |

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

Administration for Children and Families—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|--|------------------------------|
| 1438 | Amendments to Developmental Disabilities Rules | 0970-AB11 |
| 1439 | Family Violence Prevention and Services | 0970-AB18 |
| 1440 | Child Abuse and Neglect State Grant Program | 0970-AB23 |
| 1441 | Standards for Safe Transportation | 0970-AB24 |
| 1442 | Standards for Purchase of Facilities | 0970-AB31 |
| 1443 | National Voter Registration Act of 1993 Provisions Affecting Public Assistance Agencies | 0970-AB32 |
| 1444 | Child Care—Revised Regulations | 0970-AB33 |
| 1445 | Family Preservation and Support | 0970-AB34 |
| 1446 | Administration of Native Americans 45 CFR Part 1336 | 0970-AB37 |
| 1447 | Reduction of Reporting Requirements for the State Systems Advance Planning Document (APD) Process | 0970-AB46 |
| 1448 | Income and Resource Disregards Related to Interests of Individual Indians in Trust or Restricted Lands | 0970-AB59 |

Administration for Children and Families—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1449 | Income Eligibility Criteria for Indian Tribes | 0970-AB53 |

Administration for Children and Families—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1450 | Block Grant Programs (Low-Income Home Energy Assistance Program —LIHEAP) FY 91 and FY 92 Provisions ... | 0970-AB15 |
| 1451 | Block Grant Programs (Low-Income Home Energy Assistance Program—LIHEAP)—FY 93 and FY 94 Provisions .. | 0970-AB16 |
| 1452 | Statewide Automated Child Welfare Information System | 0970-AB38 |
| 1453 | Refugee Resettlement Program: Miscellaneous, Comprehensive Changes | 0970-AB42 |
| 1454 | Direct Payments to Indian Tribes and Tribal Organizations Under Title IV-B, Subpart 1 | 0970-AB44 |
| 1455 | Repatriation - Advance Approval of Costs | 0970-AB45 |
| 1456 | AFCARS Data Element on Foster Care Payments | 0970-AB58 |
| 1457 | Removal of Keys Amendment Regulations | 0970-AB61 |
| 1458 | Removal of Obsolete Family Assistance Regulation | 0970-AB62 |
| 1459 | Elimination of Obsolete Block Grant Rules | 0970-AB63 |

HHS

Administration on Aging—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|-----------------|---|------------------------------|
| 1460 | Grants for State and Community Programs on Aging, Intrastate Funding Formulas; Training, Research and Discretionary Programs; Vulnerable Elder Rights; and Grants to Indians & Native Hawaiians | 0985-AA00 |

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

Proposed Rule Stage

1192. REVISIONS TO THE CIVIL MONEY PENALTY PROVISIONS RELATING TO THE MISUSE OF CERTAIN SYMBOLS AND EMBLEMS

Priority: Substantive, Nonsignificant
Reinventing Government: This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.
Legal Authority: 42 USC 1320b-10; PL 103-296, Sec 312
CFR Citation: 42 CFR 1003
Legal Deadline: None
Abstract: This final rule will make a number of technical revisions to the

civil money penalty authority relating to the misuse of certain symbols, emblems and names as a result of amendments to section 1140 of the Social Security Act. Among other revisions, this rule (1) eliminates the annual penalty cap, (2) includes the words and letters of the Department and Medicaid under the prohibition, and (3) redefines a violation with regard to bulk mailings and solicitations. In addition, this rule serves to remove references to Social Security and its programs from 42 CFR 1003. Seperate rulemaking addressing violations of the SSA symbols, emblems and names are being developed in conjunction with this final rule.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: None
Government Levels Affected: None

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

RIN: 0991-AA81

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

Final Rule Stage

1193. CIVIL MONEY PENALTIES (CMPS) FOR CERTAIN HOSPITAL PHYSICIAN INCENTIVE PLANS

Priority: Substantive, Nonsignificant
Legal Authority: PL 99-509, Sec 9313(c); PL 101-239, Sec 6003(g)(3); PL 101-508, Sec 4204(a)(3); PL 101-508, Sec 4731(b)(1)
CFR Citation: 42 CFR 1001; 42 CFR 1003
Legal Deadline: None

Abstract: This final rule will prohibit a hospital from knowingly making incentive payments to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of that physician. The rule would also set forth standards governing the imposition of CMPs for each such individual for whom payments are made.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 12/01/94 | 59 FR 61571 |
| NPRM Comment Period End | 01/30/95 | |
| Final Action | 06/00/96 | |

Small Entities Affected: None
Government Levels Affected: None

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

RIN: 0991-AA45

1194. UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS

Priority: Substantive, Nonsignificant
Legal Authority: 5 USC 301

CFR Citation: 45 CFR 74

Legal Deadline: None
Abstract: On 11/29/93 OMB revised circular A-110 which contains administrative requirements for grants to universities, hospitals, and nonprofit organizations. 45 CFR Part 74 is being revised to implement the circular.

Timetable:

Interim Final Rule 08/25/94 (59 FR 43754)
 Comment Period End 10/24/94
 Final Action 10/00/95

Small Entities Affected: None
Government Levels Affected: State, Local

Agency Contact: Charles Gale, Director, Division of Grants Policy and Oversight, Department of Health and Human Services, Office of the Secretary, Rm. 517D, HHH Bldg., 200 Independence Avenue SW., Washington, DC 20201

Phone: 202 690-6377

RIN: 0991-AA56

1195. CLARIFICATION OF THE INITIAL OIG SAFE HARBOR PROVISIONS AND ESTABLISHMENT OF ADDITIONAL SAFE HARBOR PROVISIONS UNDER THE ANTI-KICKBACK STATUTE

Priority: Other Significant

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

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 09/21/93 | 58 FR 49008 |
| NPRM Comment Period End | 11/22/93 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

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

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

RIN: 0991-AA66

1196. SAFE HARBORS FOR PROTECTING HEALTH PLANS

Priority: Other Significant

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

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

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This rule establishes additional "safe harbor" provisions, as authorized by section 14 of PL 100-93. This rule protects certain health care plans, such as health maintenance organizations, that offer incentives to enrollees or that enter into negotiated price reduction agreements with contract health care providers.

Timetable:

| Action | Date | FR Cite |
|------------------------------------|----------|-------------|
| Final Rule With Comment Period | 11/05/92 | 57 FR 52723 |
| Extension of Public Comment Period | 01/07/93 | 58 FR 2989 |
| Interim Final Rule | 11/05/93 | 57 FR 52723 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

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

Phone: 202 619-3270

RIN: 0991-AA69

1197. REVISIONS TO THE PRO SANCTIONS PROCESS

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1302; 42 USC 1320c-5; PL 100-93, sec 6; PL 100-93, sec 8; PL 100-93, sec 10; PL 100-203, sec 4095; PL 101-508, sec 4205

CFR Citation: 42 CFR 1004

Legal Deadline: None

Abstract: This rule will revise and update the procedures governing the imposition and adjudication of sanctions predicated on recommendations of State Peer Review Organizations. These changes are necessitated by statutory revisions resulting from PL 100-93, PL 100-203, and PL 101-508. This rule will also set forth new appeal and reinstatement procedures that are presently codified in 42 CFR part 1004.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 02/28/94 | 59 FR 9452 |
| NPRM Comment Period End | 04/29/94 | |
| Final Action | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0991-AA73

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

Long-Term Actions

1198. CIVIL MONEY PENALTIES (CMPS) FOR CERTAIN PRACTICES RELATING TO MEDICARE SUPPLEMENTAL POLICIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 100-360, Sec 428(b); PL 101-508, Sec 4204(g)(1); PL 101-508, Sec 4351; PL 101-508, Sec 4354(a)(1)(E); PL 101-508, Sec 4354(a)(2); PL 101-508, Sec 4355(a); PL 101-508, Sec 4357

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This rule would authorize CMPs against any individual or entity who knowingly and willfully use misleading or fraudulent practices in the advertisement, solicitation, offering for sale or delivery of Medicare supplemental health insurance (Medigap) policies. Penalties would also be established for failure to (1) meet Medigap policy loss-ratio requirements, (2) comply with policy simplification standards, or (3) obtain Secretarial certification of Medigap policies in States with non-approved regulatory programs. In addition, this rule would also set forth CMPs for the failure of sellers or issuers to solicit information, and to provide notice, about Medicaid status and eligibility before selling or issuing Medigap policies.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0991-AA53

1199. CIVIL MONEY PENALTIES FOR PHYSICIAN OWNERSHIP OF AND REFERRAL TO CERTAIN HEALTH CARE ENTITIES

Priority: Substantive, Nonsignificant

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

duplication, or streamline requirements.

Legal Authority: PL 101-239, Sec 6204; PL 101-508, Sec 4207(e); PL 101-508, Sec 4207(m)(a); PL 103-66, Sec 13562

CFR Citation: 42 CFR 1001; 42 CFR 1003

Legal Deadline: None

Abstract: This revised final rule is designed to implement civil money penalty authority for prohibited physician ownership and referral arrangements set forth in section 1877 of the Social Security Act. This rule addresses comments raised as a result of the final rule with comment period (60 FR 16580), and several technical changes to 42 CFR 1001 and 1003 resulting from Government reinvention efforts.

Timetable:

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

Small Entities Affected: None

Government Levels Affected: None

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

RIN: 0991-AA65

1200. CIVIL MONEY PENALTIES FOR NOTIFYING A HOME HEALTH AGENCY, OR A HOME OR COMMUNITY-BASED HEALTH CARE CENTER OR PROVIDER, OF A STANDARD SURVEY

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1003

Legal Deadline: None

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

scheduled to be conducted by a State or local agency.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0991-AA79

1201. CIVIL MONEY PENALTIES FOR FALSE INFORMATION ON DRUG MANUFACTURER PRICE SURVEYS AND REBATE AGREEMENTS

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 1003

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

HHS—OS

Long-Term Actions

Phone: 202 619-3270

RIN: 0991-AA80

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

Completed Actions

1202. AMENDMENT TO GRANTS MANAGEMENT COMMON RULE TO RAISE THRESHOLD FOR SIMPLIFIED SMALL PURCHASES

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 92

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 04/19/95 | 60 FR 19645 |
| Final Action Effective | 05/19/95 | |

Small Entities Affected: None

Government Levels Affected: State, Local, Tribal

Agency Contact: Charles Gale

Phone: 202 690-6377

RIN: 0991-AA77

1203. PROPOSED AMENDMENTS TO NONPROCUREMENT DEBARMENT AND SUSPENSION COMMON RULE TO ACHIEVE RECIPROCITY WITH PROCUREMENT

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 76

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 06/26/95 | 60 FR 33037 |
| Final Action Effective | 08/25/95 | |

Small Entities Affected: None

Government Levels Affected: None

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

Agency Contact: Neil Steyskal
Phone: 202 690-5729

RIN: 0991-AA78

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

Final Rule Stage

1204. PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 51

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

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

Abstract: Sets requirements for funding State and State-designated systems for protecting and advocating for individuals with mental illness. By law, these requirements must be set out in regulations.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 12/14/94 | 59 FR 64367 |
| NPRM Comment Period End | 02/13/95 | |
| Final Action | 04/00/96 | |

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local

Additional Information: Previously reported under RIN 0905-AD99.

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

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

Phone: 301 443-4640

RIN: 0930-AA02

1205. BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE (TOBACCO PROVISIONS)

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

RIN: 0930-AA03

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

Long-Term Actions

1206. BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE

Priority: Other Significant

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

CFR Citation: 45 CFR 96

Legal Deadline: Final, Statutory, August 25, 1992. Awards to States after January 1, 1993 cannot be made until implementing regulations are published.

Abstract: Sets requirements for block grants for prevention and treatment of substance abuse. The requirements

include criteria for approval of State plans which must by statute be prescribed in regulations. These provisions would replace the existing interim final rule published March 31, 1993. Given the pending reauthorization of SAMHSA and the current Administration's FY 1996

HHS—SAMHSA

Long-Term Actions

legislative proposal to turn the block grant into a "Performance Partnership," publication of this regulation has been put on hold.

Timetable:

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

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: State, Tribal

Additional Information: Previously reported under RIN 0905-AD98.

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

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

Phone: 301 443-4640

RIN: 0930-AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Substance Abuse and Mental Health Services Administration (SAMHSA)

1207. CONFIDENTIALITY OF SUBSTANCE ABUSE PATIENT RECORDS

Priority: Other Significant

CFR Citation: 42 CFR 2

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 05/05/95 | 60 FR 22296 |
| Final Action Effective | 06/05/95 | |

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: State, Local, Tribal, Federal

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

RIN: 0930-AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Centers for Disease Control and Prevention (CDC)

1208. RESPIRATORY PROTECTIVE DEVICES

Priority: Other Significant

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

CFR Citation: 30 CFR 11; 42 CFR 84

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 06/08/95 | 60 FR 30336 |
| Final Action Effective | 07/10/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Richard Metzler
Phone: 304 284-5713

RIN: 0920-AA00

1209. NATIONAL CENTER FOR HEALTH STATISTICS, SPECIAL STATISTICAL SERVICES; GRANTS FOR HEALTH EDUCATION/RISK REDUCTION; VACCINES INFORMATION AND EDUCATION—REPEAL

Priority: Other

Reinventing Government: This rulemaking is part of the Reinventing

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

CFR Citation: 42 CFR 3; 42 CFR 51g; 42 CFR 110

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 07/13/95 | 60 FR 36072 |
| Final Action Effective | 07/13/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Gaylon Morris
Phone: 404 639-3243

RIN: 0920-AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Departmental Management (HHSDM)

1210. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

Priority: Substantive, Nonsignificant

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

CFR Citation: 45 CFR 13

Legal Deadline: None

Abstract: The Equal Access to Justice Act generally requires agencies to pay attorney fees to parties prevailing against the Government in certain types of administrative proceedings. It requires each agency to issue rules implementing the Act as it applies to these proceedings. As originally enacted, the Act had a sunset clause. A statutory amendment eliminated the

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

HHS—HHSDM

Final Rule Stage

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 06/19/87 | 52 FR 23311 |
| NPRM Comment Period End | 08/17/87 | |
| Final Action | 02/00/96 | |
| Final Action Effective | 03/00/96 | |

Small Entities Affected: None**Government Levels Affected:** None**Agency Contact:** Leslie L. Clune, Acting Associate General Counsel, Business and Administrative Law Division, Department of Health and Human Services, Room 5362, HHSCohen Building, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619-0150**RIN:** 0990-AA02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Prerule Stage

Food and Drug Administration (FDA)

1211. ● REINVENTING FDA FOOD REGULATIONS**Priority:** Substantive, Nonsignificant**Reinventing Government:** This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371**CFR Citation:** 21 CFR 101; 21 CFR 102; 21 CFR 103; 21 CFR 131; 21 CFR 133; 21 CFR 135; 21 CFR 136; 21 CFR 137; 21 CFR 139; 21 CFR 145; 21 CFR 146; 21 CFR 150; 21 CFR 152; 21 CFR 155; 21 CFR 156; ...**Legal Deadline:** None**Abstract:** In response to President Clinton's memorandum to heads of departments, and agencies entitled "Regulatory Reinvention Initiative," FDA will be initiating rulemaking to retain, revise, or revoke certain of its

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

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

NPRM 09/00/96

Food Additives, Color Additives, and GRAS Petition Review

NPRM 03/00/96

Food Standards and Other Regulations for Food

ANPRM 10/00/95

Notification Procedures for Independent GRAS Determinations

NPRM 02/00/96

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

Phone: 202 205-4561

Fax: 202 401-7739

RIN: 0910-AA58**1212. ● FOOD STANDARDS OF IDENTITY, QUALITY, AND FILL OF CONTAINER; COMMON OR USUAL NAME REGULATIONS: REQUEST FOR COMMENTS ON EXISTING REGULATIONS****Regulatory Plan:** This entry is Seq. No. 27 in Part II of this issue of the Federal Register.**RIN:** 0910-AA67

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Proposed Rule Stage

Food and Drug Administration (FDA)

1213. 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 repropounded as "Poison Treatment Products." NPRM for "Astringent (Wet Dressings) Products" was included in the NPRM for "Skin

Protectant Products." NPRM for "Diaper Rash Products" was included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." "Poison Ivy/Oak/Sumac Prevention" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Mercurial (Topical) Products" was

HHS—FDA

Proposed Rule Stage

included in revised NPRM for "Antimicrobial Products." NPRM for "Alcohol (Topical) Products" was included in revised NPRM for "Antimicrobial Products." The NPRM for "Antimicrobial Products" was updated and split into two sections: first aid products and health care products.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:**Acne (Topical) Products**

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

Alcohol (Oral) in OTC Drug Products

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

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

ANPRM 05/21/82 (47 FR 22324)

Anorectal Products

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

Antacid Drug Products

ANPRM 04/05/73 (38 FR 8714)
NPRM 11/12/73 (38 FR 31260)
Final Action 06/04/74 (39 FR 9862)
NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)
Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)
NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)
NPRM (Amendment)(Sodium Bicarb.) 02/02/94 (59 FR 5060)
Final Action (Technical Amendment) 11/25/94 (59 FR 60555)
Final Action (Amendment) (Testing) 11/00/95

Anthelmintic Products

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

Antibiotic First Aid Products

ANPRM 04/01/77 (42 FR 17642)
NPRM 07/09/82 (47 FR 29986)
Final Action 12/11/87 (52 FR 47312)
NPRM (Amendment) 08/18/89 (54 FR 34188)
Final Action 03/15/90 (55 FR 9721)
NPRM (Amendment) 05/11/90 (55 FR 19868)
NPRM (Amendment) 06/08/90 (55 FR 23450)
Final Action (Amendment) 10/03/90 (55 FR 40379)
Final Action (Amendment) 12/05/90 (55 FR 50171)
NPRM (Amendment) (Warning) 11/00/95

Anticaries Products

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

Antidiarrheal Products

ANPRM 03/21/75 (40 FR 12924)
NPRM 04/30/86 (51 FR 16138)
Final Action 12/00/95

Antidotes, Toxic Ingestion Prdts (New Poison Treatment Prdts)

ANPRM 01/05/82 (47 FR 444)

Antiemetic Products

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

Antiflatulent Drug Products

NPRM 11/12/73 (38 FR 31260)
Final Action 06/04/74 (39 FR 19877)
NPRM (Amendment) 01/29/88 (53 FR 2716)
Final Action (Amendment) 12/00/95

Antifungal (Topical) Products

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

Antimicrobial Products

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

Antiperspirant Products

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

Antiseptic First Aid

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

Antiseptic Products (Professional Use)

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

Aphrodisiac Products

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

Aspirin (Heart Labeling)

NPRM 10/20/93 (58 FR 54224)

Aspirin (Reye Syndrome)

NPRM 10/20/93 (58 FR 54228)

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

ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products

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

Boil Ointments

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

Camphorated Oil Drug Products

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

Cholecystokinetic Products

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

Corn and Callus Remover Products

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

Cough/Cold (Anticholinergic) Products

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

Cough/Cold (Antihistamine) Products

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

Cough/Cold (Antitussive) Products

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

HHS—FDA

Proposed Rule Stage

Cough/Cold (Bronchodilator) Products

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

Cough/Cold (Combination) Products

ANPRM 09/09/76 (41 FR 38312)
 NPRM 08/12/88 (53 FR 30522)
 NPRM (Amendment)(DPH Combinations) 02/23/95 (60 FR 10286)
 Final Action Theophylline 07/27/95 (60 FR 38636)
 Final Action 03/00/96

Cough/Cold (Diphenhydramine) Products

Final Action/Enforcement Policy 12/00/95

Cough/Cold (Expectorant) Products

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

Cough/Cold (Expectorant/Ipecac) Products

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

Cough/Cold (Nasal Decongestant) Products

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

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products

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

Daytime Sedatives

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

Diaper Rash Products (Merged w/other rulemg)

ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products

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

Emetic Products

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

Exocrine Pancreatic Insufficiency Products

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

External Analgesic Products

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

Fever Blister Products (Internal)

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

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

ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention Products

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

Hormone (Topical) Products

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

Hypo/Hyperphosphatemia Products

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

Ingrown Toenail Relief Products

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

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

ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal)

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

Internal Analgesic Products

ANPRM 07/08/77 (42 FR 35346)
 NPRM 11/16/88 (53 FR 46204)
 NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66762)
 NPRM (Amdt.)(Sodium Bicarbonate) 02/02/94 (59 FR 5068)
 NPRM (Amendment)(Alcohol Warning) 12/00/95
 Final Action (Cardio/Cerebrvasclar) 02/00/96
 NPRM (Labeling-revised indications) 03/00/96
 NPRM (Prof. Labeling)(Acute MI) 03/00/96

Internal Analgesic Products (Overindulgence)

Final Action 00/00/00

Internal Deodorant Products

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

Labeling of Drug Products for OTC Use

NPRM 04/05/93 (58 FR 17553)
 Final Action 01/28/94 (59 FR 3998)
 NPRM (Do not mix drugs) 08/03/94 (59 FR 39499)
 NPRM (Amendment) (Do not mix drugs) 10/04/95 (60 FR 52058)
 NPRM (Unless a doctor tells you) 11/00/95
 NPRM (Format/Examples) 02/00/96
 NPRM (Calcium/Magnesium/Potassium) 03/00/96

Laxative Products

ANPRM 03/21/75 (40 FR 12902)
 NPRM 01/15/85 (50 FR 2124)
 NPRM (Amendment) 10/01/86 (51 FR 35136)
 NPRM (Amendment) 09/02/93 (58 FR 46589)
 Final Action 03/00/96

Leg Muscle Cramps (Nocturnal Relief) Products

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

Male Genital Desensitizer Products

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

Menstrual Products

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

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

ANPRM 01/05/82 (47 FR 436)

Nailbiting/Thumbsucking Deterrent Products

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

Nighttime Sleep Aid Products

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

NDA Labeling Exclusivity

NPRM 11/09/93 (58 FR 59622)

Ophthalmic Products

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

Oral Discomfort (Relief) Products

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

Oral Health Care Products

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

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

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

Oral Wound Healing Products

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

HHS—FDA

Proposed Rule Stage

Otic Products (Dry Water-Clogged Ears)

NPRM (Amendment) 02/00/96

Otic Products (Earwax)

NPRM 07/09/82 (47 FR 30012)

Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear)

NPRM 07/30/86 (51 FR 27366)

Final Action 02/15/95 (60 FR 8916)

Final Action Partial Stay 08/16/95 (60 FR 42435)

Overindulgence Remedies

ANPRM 10/01/82 (47 FR 43540)

NPRM 12/24/91 (56 FR 66742)

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

Overindulgence Remedies/Prevention of Inebriation

ANPRM 10/01/82 (47 FR 43540)

Final Action 07/19/83 (48 FR 32872)

Pediculicide Products

ANPRM 06/29/82 (47 FR 28312)

NPRM 04/03/89 (54 FR 13480)

Final Action 12/14/93 (58 FR 65452)

Phenylpropanolamine Products (Labeling)

NPRM 01/00/96

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

ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products

NPRM 01/15/85 (50 FR 2244)

Final Action 03/00/96

Quinine for Malaria

NPRM 04/19/95 (60 FR 19650)

Reporting of Adverse Reactions

NPRM 12/00/95

Skin Bleaching Products

ANPRM 11/03/78 (43 FR 51546)

NPRM 09/03/82 (47 FR 39108)

NPRM (Reproposed) 03/00/96

Skin Protectant Products

ANPRM 08/04/78 (43 FR 34628)

NPRM 02/15/83 (48 FR 6820)

NPRM (Amendment) (Astringent) 04/03/89 (54 FR 13490)

NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40808)

NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3362)

NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25204)

Final Action (Astringent) 10/21/93 (58 FR 54466)

Final Action (Witch Hazel) 06/03/94 (59 FR 28767)

Final Action (Poison Ivy) 03/00/96

Final Action 03/00/96

Smoking Deterrent Products

ANPRM 01/05/82 (47 FR 490)

NPRM 07/03/85 (50 FR 27552)

Final Action 06/01/93 (58 FR 31236)

Sodium Labeling

NPRM 04/25/91 (56 FR 19222)

Final Action 12/00/95

Status of Certain Category II and III Ingredients

NPRM 05/16/90 (55 FR 20434)

Final Action 11/07/90 (55 FR 46914)

NPRM 08/25/92 (57 FR 38568)

Final Action 05/10/93 (58 FR 27636)

Stimulant (Overindulgence) Products

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

Stimulant Products

ANPRM 12/08/75 (40 FR 57292)

NPRM 06/13/78 (43 FR 25544)

Final Action 02/29/88 (53 FR 6100)

Stomach Acidifier Products

ANPRM 10/19/79 (44 FR 60316)

NPRM 01/15/85 (50 FR 2184)

Final Action 08/17/88 (53 FR 31270)

Sunscreen Products

ANPRM 08/25/78 (43 FR 38206)

NPRM 05/12/93 (58 FR 28194)

NPRM (Amendment) 06/08/94 (59 FR 29706)

Sweet Spirits of Nitre

ANPRM 02/22/80 (45 FR 11846)

Final Action 06/27/80 (45 FR 43400)

Topical Drug Products Containing Benzoyl Peroxide (Labeling)

NPRM 02/17/95 (60 FR 9554)

Vaginal Contraceptive Products

ANPRM 12/12/80 (45 FR 82014)

NPRM 02/03/95 (60 FR 6892)

Vaginal Drug Products

ANPRM 10/13/83 (48 FR 46694)

Withdrawal 02/03/95 (60 FR 5226)

Vitamin/Mineral Products

ANPRM 03/16/79 (44 FR 16126)

Withdrawal 11/27/81 (46 FR 57914)

Wart Remover Products

ANPRM 10/03/80 (45 FR 65609)

NPRM 09/03/82 (47 FR 39102)

NPRM (Amendment) 03/27/87 (52 FR 9992)

Final Action 08/14/90 (55 FR 33246)

NPRM (Amendment)(Directions) 01/28/94 (59 FR 4015)

Final Action (Amdt.)(Directions) 11/23/94 (59 FR 60315)

Water Soluble Gums

NPRM 10/30/90 (55 FR 45782)

Final Action 08/26/93 (58 FR 45194)

Weight Control Products

ANPRM 02/26/82 (47 FR 8466)

NPRM 10/30/90 (55 FR 45788)

Final Action 08/08/91 (56 FR 37792)

NPRM (Amendment) 01/00/96

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

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

Agency Contact: William E. Gilbertson, Director, Monograph Review Staff, Office of OTC Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-810), 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 594-5000

RIN: 0910-AA01**1214. INFANT FORMULA: GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, NOTIFICATION REQUIREMENTS, AND RECORDS AND REPORTS****Priority:** Other Significant**Legal Authority:** 21 USC 350a**CFR Citation:** 21 CFR 107; 21 CFR 106**Legal Deadline:** None**Abstract:** The agency published on December 24, 1991, a final rule implementing certain aspects of the Infant Formula Act of 1986. The rule establishes infant formula record and record retention requirements. The agency is preparing a proposed rule that will establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and reports for the production of infant formulas.**Timetable:****Current Good Mfg. Practices; Qual Control Proc**

NPRM 05/00/96

NPRM (Comment Period End) 08/00/96

Infant Form Cons Comp, Micro Test & Recd Retention Req

NPRM 01/26/89 (54 FR 3783)

NPRM (Comment Period End) 03/27/89

Final Rule 12/24/91 (56 FR 66566)

Small Entities Affected: None**Government Levels Affected:** None**Additional Information:** Previously reported under RIN 0905-AC46.**Agency Contact:** Carolyn W. Miles, Nutritionist, Regulatory Branch, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-456), 200 C Street SW., Washington, DC 20204
Phone: 202 205-5372**RIN:** 0910-AA04**1215. REPORTING OF ERRORS AND ACCIDENTS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360i; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262 to 264**CFR Citation:** 21 CFR 600; 21 CFR 606**Legal Deadline:** None**Abstract:** All licensed manufacturers are required to notify FDA promptly of

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

Timetable:

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

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD67.

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

RIN: 0910-AA12

1216. MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

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

RIN: 0910-AA24

1217. EFFECTIVE DATE OF REQUIREMENT FOR SUBMISSION OF PREMARKET APPROVAL APPLICATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360e

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

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

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

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| Notice | 05/06/94 | 59 FR 23731 |
| NPRM | 09/07/95 | 60 FR 46718 |
| NPRM Comment Period End | 01/05/96 | |
| Final Action | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE34.

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

Phone: 301 594-4765

RIN: 0910-AA31

1218. LATEX CONDOMS/GLOVES: EXPIRATION DATE LABELING

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352

CFR Citation: 21 CFR 801

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE37.

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

Phone: 301 594-4765

RIN: 0910-AA32

1219. LATEX WARNING

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 352

CFR Citation: 21 CFR 801

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/96 | |

Small Entities Affected: Undetermined

HHS—FDA

Proposed Rule Stage

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE40.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA34

1220. PREMARKET APPROVAL OF MEDICAL DEVICES; SUPPLEMENTAL APPLICATIONS

Priority: Substantive, Nonsignificant

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

Legal Authority: 21 USC 360e

CFR Citation: 21 CFR 814.39

Legal Deadline: None

Abstract: FDA has become aware of several situations in which a supplement to an approved premarket approval application (PMA) was not submitted for a change to the device even though FDA believed that a supplement was required. Therefore, FDA would propose to revise its regulation to clarify when a supplement is required. This would result in fewer unapproved changes in devices.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE41.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA35

1221. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE

Priority: Other Significant

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

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360d; 21 USC 371; 21 USC 360j(e)

CFR Citation: 21 CFR 801.420; 21 CFR 801.421

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|-----------------------------|----------|-------------|
| ANPRM | 11/10/93 | 58 FR 59695 |
| ANPRM Comment Period End | 01/10/94 | |
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AE46.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA39

1222. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; PROPOSED AMENDMENT OF CERTAIN REQUIREMENTS FOR FINISHED PHARMACEUTICALS

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 210.3; 21 CFR 211.22; 21 CFR 211.68; 21 CFR 211.82; 21 CFR 211.84; 21 CFR 211.101; 21 CFR 211.103; 21 CFR 211.110; 21 CFR 211.111; 21 CFR 211.113; 21 CFR 211.115; 21 CFR 211.160; 21 CFR 211.166; 21 CFR 211.192; 21 CFR 211.220; ...

Legal Deadline: None

Abstract: FDA is proposing revisions to the current good manufacturing practice (CGMP) regulations at 21 CFR parts 210 and 211 regarding finished pharmaceuticals. The new regulations either codify current agency policies or current industry practices. Among other things, the proposal would create or clarify requirements for process and methods validation, appropriate laboratory testing procedures, and protection against contamination. The proposal is designed to update the CGMP regulations in response to technological changes and the Agency's experience with the regulations.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: Federal

Additional Information: Previously reported under RIN 0905-AE63.

Agency Contact: Thomas Kuchenberg, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1046

RIN: 0910-AA45

1223. ANIMAL DRUG AMENDMENTS OF 1994, EXTRA-LABEL USE; IMPLEMENTATION

Priority: Substantive, Nonsignificant

Legal Authority: PL 103-396

CFR Citation: None

Legal Deadline: Final, Statutory, October 22, 1996.
Two years after bill was signed into law (10/22/94).

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

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| NPRM | 12/00/95 | |
| Final Action | 10/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE66.

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

RIN: 0910-AA47

1224. • REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS TO PROTECT CHILDREN AND ADOLESCENTS

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

RIN: 0910-AA48

1225. • REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 207

Legal Deadline: None

Abstract: Revises and clarifies these regulations to reduce burden to manufacturers, packers, distributors, and to consolidate and streamline the requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 06/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Howard Muller, Regulatory Counsel, Division of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA49

1226. • HABIT FORMING DRUGS

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 329

Legal Deadline: None

Abstract: Revise and clarify these regulations and to be consistent with the Drug Enforcement Administration regulation and the Controlled Substances Act; to streamline requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 06/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Division of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049
Fax: 301 827-0901

RIN: 0910-AA50

1227. • BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 320

Legal Deadline: None

Abstract: Revisions and clarification of these requirements to eliminate duplication and inconsistencies and streamline requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Erica L. Keys, Regulatory Counsel, Division of Health and Human Services, Food and Drug Administration, Center for Drug

HHS—FDA

Proposed Rule Stage

Evaluation and Research (HFD-362),
7500 Standish Place Rockville, MD
20855
Phone: 301 594-1046
Fax: 301 827-0901

RIN: 0910-AA51

1228. • CONSOLIDATION OF REGULATIONS

Priority: Other

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

Legal Authority: 21 USC 371

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

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Mary E. Catchings, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-366), 7500 Standish Place Rockville, MD 20855
Phone: 301 594-2041
Fax: 301 827-0901

RIN: 0910-AA53

1229. • REVOCATION OF CERTAIN REGULATIONS

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

RIN: 0910-AA54

1230. • NAME OF SELLING AGENT OR DISTRIBUTOR

Priority: Other Significant

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

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

CFR Citation: 21 CFR 610

Legal Deadline: None

Abstract: This proposed rule proposes to allow distributors' and selling agents' names to be prominently displayed on biological product containers, package labels, and labeling, while retaining current product manufacturer labeling information. The proposed rule modifies the current requirement giving precedence to the name of the manufacturer by deleting the requirement for prominence of the name of the manufacturer. The proposed rule is intended to remove an impediment to flexible manufacturing, packaging, and distribution arrangements and to harmonize with the drug regulations (21 CFR 201).

Timetable:

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

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0910-AA56

1231. • STREAMLINING PROCEDURES FOR CHANGES IN PRODUCTION OF BIOLOGICS

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

RIN: 0910-AA57

1232. • DIETARY SUPPLEMENT REGULATIONS IN RESPONSE TO DSHEA

Priority: Routine and Frequent

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: On January 4, 1994, FDA published final rules relative to nutrition labeling, nutrient content claims and health claims for dietary supplements. The Dietary Supplement Health and Education Act (DSHEA) was enacted on October 25, 1995, modifying the provisions for labeling of dietary supplements. FDA is initiating rulemaking to modify its regulations for dietary supplements accordingly. One proposal would modify the nutrition labeling and ingredient declaration requirements. A second proposal would modify the provisions for nutrient content claims and health claims for the disclaimer to accompany statements of nutritional support. A third proposal would define the terms high potency and antioxidant.

Timetable:

| | |
|--|---------------|
| High Potency and Antioxidant terms; Dietary Supplements | NPRM 12/00/95 |
| Nutrition Content and Health Claims; Dietary Supplements | NPRM 12/00/95 |
| Nutrition Labeling and Ingredient Labeling; Dietary Supplements | NPRM 12/00/95 |

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW, Washington, DC 20204
Phone: 202 205-4561
Fax: 202 205-4594

RIN: 0910-AA59

HHS—FDA

Proposed Rule Stage

1233. ● PROTECTION OF HUMAN SUBJECTS; INFORMED CONSENT

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

RIN: 0910-AA60

Services, Food and Drug Administration, Office of Policy (HF-23) 5600 Fishers Lane, Rm. 15-74 Rockville, MD 20857 Phone: 301 827-3380 Fax: 301 443-6906

RIN: 0910-AA63

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

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

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

RIN: 0910-AA66

1234. ● OTC DRUG LABELING REVIEW

Priority: Substantive, Nonsignificant

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 200

Legal Deadline: None

Abstract: As part of the Food and Drug Administration's ongoing process to improve the labeling of over-the-counter (OTC) drug products, the agency will seek public comment on a standardized uniform format for OTC labeling. This action is intended to improve the communication of important information about OTC products to consumers.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ilisa B. G. Bernstein, Department of Health and Human

1235. ● MEDICAL DEVICE EXEMPTIONS FROM PREMARKET NOTIFICATION

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

RIN: 0910-AA65

1236. ● SUBSTANCES APPROVED FOR USE IN THE PREPARATION OF MEAT AND POULTRY PRODUCTS

Priority: Other Significant

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

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 348; 21 USC 355 to 357; 21 USC 360; 21 USC 360b to 360f; 21 USC 360h to 360j; 21 USC 361; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 262

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Food and Drug Administration (FDA)

1237. NEW ANIMAL DRUG APPROVAL PROCESS; IMPLEMENTATION OF TITLE I OF THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT

Priority: Substantive, Nonsignificant

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

Legal Authority: 21 USC 360b; 21 USC 371

CFR Citation: 21 CFR 514

Legal Deadline: Final, Statutory, November 16, 1989.

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

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

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

Timetable:

New Animal Drug Approval Process

NPRM 12/17/91 (56 FR 65544)
NPRM 08/00/96

Reporting Requirements for Marketed Animal Drugs

NPRM 12/17/91 (56 FR 65581)
Final Action 02/00/96

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AA96.

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

Agency Contact: Andrew J. Beaulieu, Deputy Director, Office of New Animal Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine (HFV-101), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1620

RIN: 0910-AA02

1238. CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS; NOTIFICATION OF CONSIGNEES RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK FOR TRANSMITTING HIV INFECTION

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351 to 360k; 21 USC 374; 42 USC 262 to 264

CFR Citation: 21 CFR 606; 21 CFR 610

Legal Deadline: None

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

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

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 06/30/93 | 58 FR 34962 |
| Final Action | 12/00/95 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AC90.

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

RIN: 0910-AA05

1239. LEAD IN FOODS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 342(a); 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 371

CFR Citation: 21 CFR 109; 21 CFR 182; 21 CFR 189

Legal Deadline: None

Abstract: In light of the public health concerns raised by continuing findings concerning the effects of low levels of exposure to lead, particularly exposure by pregnant women, infants, and children, the agency is undertaking a comprehensive effort to further reduce lead levels in food where controllable

or avoidable sources of lead addition to food can be identified. The goal of FDA is to reduce consumers' exposure to lead in the diet to the lowest level that can be practicably obtained.

Timetable:

Lead From Ceramic Pitchers

NPRM 06/01/89 (54 FR 23485)
NPRM Comment Period End 07/31/89
Withdrawal of NPRM 00/00/00

Prohibit Use of Lead-Soldered Food Cans

NPRM 06/21/93 (58 FR 33860)
Final Action 06/27/95 (60 FR 33106)

Prohibit Use of Tin-Coated Lead Foil

Capsules on Wine Bottles
NPRM 11/25/92 (57 FR 55485)
Final Action 12/00/95

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AC91.

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

RIN: 0910-AA06

1240. FEES FOR CERTIFICATION SERVICES; INSULIN AND COLOR ADDITIVE CERTIFICATION PROGRAMS

Priority: Routine and Frequent

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

Legal Authority: 21 USC 356; 21 USC 379e(e)

CFR Citation: 21 CFR 80; 21 CFR 429

Legal Deadline: None

Abstract: Insulin Certification Program:

In the Federal Register of October 4, 1991 (56 FR 50248), FDA issued an interim rule effective on November 4, 1991 with opportunity for public comment, revising the fee schedule for insulin certification services. The fees are intended to recover the full costs of operation of FDA's insulin certification program, including the unfunded liability of the Civil Service Retirement Fund and appropriate overhead costs of the Public Health Service and Department of Health and

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Human Services. FDA is publishing a new interim rule lowering the fees, to reflect lower costs involved in administering the insulin certification program.

Color Certification Program:

In the Federal Register of November 29, 1994, FDA issued an interim rule effective December 29, 1994, which amended the color additive regulations by increasing the fees for certification services. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act.

On February 13, 1995, FDA received comments from only one interested party, the International Association of Color Manufacturers (IACM). Those comments, which stated IACM's opposition to an automatic annual escalator provision in the interim rule, will be incorporated into a final rule. The final rule is expected to be published in the Federal Register by early 1996. FDA expects to eliminate the automatic annual escalator provision in response to IACM's concerns.

Timetable:

Color Additives

Interim Final Rule 11/29/94 (59 FR 60898)
Final Action 11/00/95

Insulin

Interim Final Rule 10/04/91 (56 FR 50248)
Interim Final Rule 11/00/95

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD34.

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

RIN: 0910-AA07

1241. PRESCRIPTION DRUG MARKETING ACT OF 1987; POLICY INFORMATION, GUIDANCE, AND CLARIFICATIONS

Priority: Substantive, Nonsignificant

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 Period End | 08/01/94 | |
| Final Action | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD44.

Agency Contact: Lee D. Korb, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855
Phone: 301 594-1049

RIN: 0910-AA08

1242. IMPLEMENTATION OF THE SAFE MEDICAL DEVICES ACT OF 1990

Priority: Other Significant

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

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

Legal Deadline:

NPRM, Statutory, August 28, 1991, for Medical Device Tracking.
Final, Statutory, November 28, 1991, for Exemption of Humanitarian Devices, etc.
Other, Statutory, December 1, 1991, for Classification of Transitional Devices Notice.
Final, Statutory, August 28, 1993, for Medical Device Tracking.

Abstract: The Safe Medical Devices Act of 1990 (SMDA), enacted November 28, 1990, was intended to assure marketed devices are safe and effective, FDA learns quickly of device problems, and has authority to remove defective devices from the market. The act directs or authorizes FDA to develop these regulations: Medical Device Reporting--This rule will require healthcare facilities and distributors to report deaths and serious injuries/illnesses related to medical devices. Medical Device Tracking--This regulation requires manufacturers to track certain devices to the user. Classification of Transitional Devices--FDA issued a notice to require submission of adverse safety and effectiveness data on transitional devices. FDA will now propose to keep each device in class III, or reclassify it in class I or II. Good Manufacturing Practices for Medical Devices--FDA proposed to add preproduction design validation in existing CGMP regulations. Exemption of Humanitarian Devices--The proposed rule gives procedures for applications for certain premarket review exemptions for humanitarian devices.

Summaries of Safety and Effectiveness for Premarket Notification--The final rule sets forth information to be included in data summaries on which substantial equivalence determinations are made. Recall of Medical Devices--A proposed rule sets forth procedures for using its authority to order device recalls and notifications. Reports of Removal and Corrections--FDA

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proposed procedures for manufacturers to report to FDA health-related market removals and corrections of devices. Civil Money Penalties--A final rule established procedures for a hearing to which persons are entitled before the imposition of civil money penalties. Procedural Changes in Medical Device Regulations--This final rule made revisions in regulations necessary because of procedural changes made by the SMDA. Premarket Review of Combination Products--FDA published a final rule establishing procedures for determining which FDA center will review premarket approval applications for products that are a combination of a device and a drug or biologic.

Timetable:

| Action | Date | FR Cite |
|--|----------|---------------|
| Final Action | 00/00/00 | |
| Assignment of Agency Component for Review of Premarket Applctns | | |
| Notice (Public Hearing) | 07/12/91 | (56 FR 31951) |
| Final Action | 11/21/91 | (56 FR 31951) |
| Civil Money Penalties | | |
| NPRM | 05/26/93 | (58 FR 30680) |
| Final Action | 07/27/95 | (60 FR 38612) |
| Classification of Transitional Devices | | |
| Notice | 11/14/91 | (56 FR 57960) |
| Notice(Extension of Comment Period) | 03/10/92 | (57 FR 8462) |
| Notice (Extension of Deadline) | 11/30/92 | (57 FR 56586) |
| Final Rule (Contact Lenses) | 03/04/94 | (59 FR 10283) |
| CGMPs for Medical Devices | | |
| ANPRM (Revisions;Request for Cmnts) | 06/15/90 | (55 FR 24544) |
| ANPRM (Suggested Changes;Availblty) | 11/30/90 | (55 FR 49644) |
| ANPRM (Extension of Comment Period) | 02/14/91 | (56 FR 5965) |
| Notice (Open Public Advsy Cmte Mtg) | 04/17/91 | (56 FR 15626) |
| NPRM | 11/23/93 | (58 FR 61952) |
| NPRM | 07/24/95 | (60 FR 37856) |
| Final Action | 03/00/96 | |
| Exemption of Humanitarian Devices | | |
| NPRM | 12/21/92 | (57 FR 60491) |
| Final Action | 12/00/95 | |
| Medical Device Recall Authority | | |
| NPRM | 06/14/94 | (59 FR 30656) |
| NPRM (Correction) | 06/23/94 | (59 FR 32489) |
| Final Action | 12/00/95 | |
| Medical Device Reporting | | |
| Notice (Public Conf ;Rqst for Info) | 03/28/91 | (56 FR 12934) |
| NPRM | 11/26/91 | (56 FR 60024) |
| Final Rule (Distributor Reporting) | 09/01/93 | (58 FR 46514) |
| Final Action | 11/00/95 | |

Medical Device Tracking

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

Miscellaneous Procedural Changes in Medical Device Regulations

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

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

Notice 05/06/94 (59 FR 23731)

Reports of Removals and Corrections of Medical Devices

NPRM 06/04/94 (59 FR 13828)

Final Action 12/00/95

Safe Medical Devices Act of 1990; Implementation Plans

Notice 04/05/91 (56 FR 14111)

Summaries of Safety & Effectiveness for Premarket Notification

Final Action 04/28/92 (57 FR 18062)

Notice (Stay of Effective Date) 06/01/92
 (57 FR 23059)

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

Temporary Suspension of a Premarket Approval Application

NPRM 10/12/93 (58 FR 52729)

Final Action 12/00/95

Small Entities Affected: None**Government Levels Affected: None****Additional Information:** Previously reported under RIN 0905-AD59.

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

Phone: 301 594-4765

RIN: 0910-AA09

1243. FINAL REGULATION TO ESTABLISH PROCEDURES FOR THE SAFE AND SANITARY PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS

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

RIN: 0910-AA10

1244. BOTTLED WATER

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 103; 21 CFR 165

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

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

Timetable:**Beverages; Bottled Water**

NPRM 01/05/93 (58 FR 393)

Final Action 11/00/95

Microbiological Quality Standard

NPRM 10/06/93 (58 FR 25042)

Final Action 00/00/00

Quality Standard for Lead and Copper

NPRM 01/05/93 (58 FR 389)

Final Action 05/25/94 (59 FR 26933)

Quality Standards for 24 Contaminants

NPRM 08/04/93 (58 FR 41612)

Final Action 02/00/96

Quality Standards for 35 Contaminants

NPRM 01/05/93 (58 FR 382)

Final Action 12/01/94 (59 FR 61529)

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

Additional Information: Previously reported under RIN 0905-AD65.

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

Phone: 202 205-4681

RIN: 0910-AA11

1245. MEDICAL DEVICES; PROTECTIVE RESTRAINTS; REVOCATION OF EXEMPTIONS FROM 510(K) PREMARKET NOTIFICATION PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES REGULATIONS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360y; 21 USC 371

CFR Citation: 21 CFR 880.6760; 21 CFR 890.3910

Legal Deadline: None

Abstract: FDA has become aware through various sources of numerous reports of complications including permanent physical injuries, severe psychological disabilities, other serious injuries and deaths that have been attributed to incorrect supervision, handling or application of protective restraint devices by medical or paramedical personnel. Complications associated with protective restraint devices frequently result from misuse of the devices. To address potential misuse, manufacturers should include specific directions for use, to the extent that such directions are not currently available or not attached to or kept with the garment. Revocation of the premarket notification exemptions will allow FDA to collect information about the current availability and actual employment of directions for use and to monitor the introduction into commerce of new and changed protective restraints. Revocation of the exemption from the current good manufacturing practice regulation will allow FDA to require the necessary controls over labeling. FDA is also considering educational programs to address this problem. FDA anticipates total first year costs of \$930,000 for this regulation. These costs will be offset by the saving of lives and reduced product liability exposure.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 06/19/92 | 57 FR 27397 |
| NPRM Comment Period End | 08/18/92 | |
| Final Action | 12/00/95 | |

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD84.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765

RIN: 0910-AA17

1246. FOOD LABELING REVIEW

Priority: Routine and Frequent

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

USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

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

Legal Deadline: None

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

Timetable:

Misleading Containers; Nonfunctional Slack Fill
NPRM 01/06/93 (58 FR 2957)
Final Action 12/06/93 (58 FR 64123)

Nutrient Content Claims and Health Claims; Restaurant Foods
NPRM 06/15/93 (58 FR 33055)
Final Action 00/00/00

Nutrient Content, Definition of the Term, Healthy
NPRM 01/06/93 (58 FR 2944)
Final Action 05/10/94 (59 FR 24232)

Placement of Nutrition Facts Panel

NPRM 08/18/93 (58 FR 44091)
Final Action 04/05/95 (60 FR 17202)
Final Action Effective 05/05/95
Final Action Correction 06/12/95 (60 FR 30788)

Protein Hydrolysates; Broth in Tuna; and/or Labeling

NPRM (Declaration of Ingredients) 01/06/93 (58 FR 2950)
Final Action (Dec. of Ingredients) 00/00/00

Reference Daily Intakes

NPRM 01/04/94 (59 FR 427)
Final Action 02/00/96

Small Business Exemption, Nutrition Labeling

NPRM 03/14/94 (59 FR 11872)
Final Action 11/00/95

Voluntary Guidelines for Nutrition Labeling Produce

NPRM 07/18/94 (59 FR 36379)
Final Action 01/00/96

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD89.

Agency Contact: F. Edward Scarbrough, Director, Office of Food Labeling, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-150), 200 C Street SW., Washington, DC 20204
Phone: 202 205-4561
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RIN: 0910-AA19

1247. DISQUALIFICATION OF CLINICAL INVESTIGATORS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360j(g)

CFR Citation: 21 CFR 812

Legal Deadline: None

Abstract: The rule would amend the investigational device exemption (IDE) regulations to provide for a procedure for disqualification of clinical investigators in cases of fraud or other serious violations of the regulations. Persons whose disqualification is proposed would be entitled to an opportunity for hearing.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 10/06/93 | 58 FR 52144 |
| Final Action | 12/00/95 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD94.

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Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765
RIN: 0910-AA21

1248. INVESTIGATIONAL DEVICE EXEMPTION; INTRAOCULAR LENSES

Priority: Other

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

Legal Authority: 21 USC 360j(g)

CFR Citation: 21 CFR 813; 21 CFR 812

Legal Deadline: None

Abstract: The rule would revoke the separate investigational device exemption regulation for intraocular lenses (IOL's). IOL's would then be subject to the same IDE regulation (21 CFR Part 812) as all other devices. The IOL-IDE regulation was originally created as an interim measure.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 10/06/93 | 58 FR 52142 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD95.

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-84), 2098 Gaither Road, Rockville, MD 20850
Phone: 301 594-4765
RIN: 0910-AA22

1249. DIETARY SUPPLEMENT LABEL REVIEW

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 101

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

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

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

Timetable:

Health Claims and Label Statements; Dietary Supplements

NPRM Folic Acid and Neural Tube Def 10/14/93 (58 FR 53254)
Final Action 01/04/94 (59 FR 433)
Final Action Effective 07/01/94
Final Action 03/00/96

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

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

Health Claims; Dietary Supplements

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

Nutrient Content Claims; Dietary Supplements

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

Nutrition Labeling; Dietary Supplements

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

Regulation of Diet. Supp.

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

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD96.

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

RIN: 0910-AA23

1250. SPECIFIC REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS; ADDITION OF "GERIATRIC USE" SUBSECTION IN THE LABELING

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: On November 1, 1990 (55 FR 46134), the Agency proposed to amend its regulations governing the content and format of labeling for human prescription drug products to require a subsection in the labeling that would include information on the use of a drug in the elderly. This proposal reflects growing recognition by FDA and others of the special concerns associated with prescription drug use in this age group. FDA believes that providing access to this information is necessary for the safe and effective use of prescription drugs in older populations. The Agency is reviewing the public comments submitted in response to the proposed rule and preparing a final rule.

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Timetable:

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

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE26.

Agency Contact: Erica L. Keys, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855

Phone: 301 594-1046

RIN: 0910-AA25

1251. TAMPER-EVIDENT PACKAGING REQUIREMENTS FOR OVER-THE-COUNTER HUMAN DRUG PRODUCTS

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 211

Legal Deadline: None

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

Timetable:

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

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE27.

Agency Contact: Tamar S. Nordenberg, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855

Phone: 301 594-1049

RIN: 0910-AA26

1252. CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN; FEES FOR CERTIFICATION OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

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 356; 21 USC 371

CFR Citation: 21 CFR 429.55

Legal Deadline: None

Abstract: The Food and Drug Administration intends to issue an interim rule, with opportunity for public comment, to revise the fee schedule for insulin certification services to reflect lower agency costs for the program.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|---------|
| Interim Final Rule | 10/00/95 | |
| NPRM | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE28.

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855

Phone: 301 594-1049

RIN: 0910-AA27

1253. ELECTRONIC SIGNATURES; ELECTRONIC RECORDS

Priority: Other Significant

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

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

CFR Citation: 21 CFR 11

Legal Deadline: None

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

Timetable:

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

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

Additional Information: Previously reported under RIN 0905-AE31.

Agency Contact: Paul J. Motise, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-323), 7500 Standish Place, Rockville, MD 20855
 Phone: 301 594-1089
 Fax: 301 594-2202
 Email: Motise@FDACD.BITNET
RIN: 0910-AA29

1254. FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

Priority: Other Significant

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

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

Legal Deadline: None

Abstract: This final regulation addresses the problem of certain financial arrangements and interests of clinical investigators that have the potential to bias the outcome of clinical trials. The problem is significant because clinical research data provide the basis for FDA's evaluation of drugs, biologics and devices for marketing. The regulation requires the sponsor of a product that is the subject of a marketing application to submit either a statement certifying that the clinical investigator is not a party to any problematic financial interests and arrangements or a statement disclosing problematic interests and arrangements to which the investigator is a party. This information would enable FDA to subject the relevant clinical research data to an appropriate level of scrutiny to test its reliability. Alternatives are to prohibit investigators from holding certain financial interests altogether or to require divestiture by the investigator of a prohibited interest. The estimated costs to industry associated with preparation, submission, and retention of the information required by this final rule are well below the \$100 million threshold that defines a significant regulatory action. The final rule is not

expected to impose a significant resource burden on FDA because the submission of statements is limited to clinical data submitted in support of marketing applications, ruling out data from the large number of studies that do not lead to applications, and FDA estimates that sponsors will be able to certify for the majority of their clinical investigators, so that most submitted data will not require intensified scrutiny. The final rule will strengthen the FDA review process.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 09/22/94 | 59 FR 47807 |
| NPRM Comment Period End | 12/21/94 | |
| Final Action | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

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

Additional Information: Previously reported under RIN 0905-AE32.

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

RIN: 0910-AA30

1255. PRESCRIPTION DRUG PRODUCT LABELING; MEDICATION GUIDE

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

RIN: 0910-AA37

1256. HUMAN TISSUE INTENDED FOR TRANSPLANTATION: PROPOSED RULE

Priority: Other Significant

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

CFR Citation: 21 CFR 1270

Legal Deadline: None

Abstract: FDA is issuing a final rule requiring certain infectious disease testing, donor screening, and

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

Timetable:

| Action | Date | FR Cite |
|-----------------------------------|----------|-------------|
| Interim Rule; Opport. for Comment | 12/14/93 | 58 FR 65514 |
| Interim Rule; Comment Period End | 03/14/94 | |
| Final Action | 01/00/96 | |
| NPRM | 04/00/96 | |
| NPRM Comment Period End | 07/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AE49.

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

RIN: 0910-AA40

1257. IRON CONTAINING DRUGS AND SUPPLEMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 342; 21 USC 343; 21 USC 351; 21 USC 352

CFR Citation: 21 CFR 101; 21 CFR 111; 21 CFR 310

Legal Deadline: None

Abstract: On October 6, 1994, FDA published a proposal responding to three citizen petitions that were submitted in response to an increase in deaths and poisonings in small children due to accidental ingestion of iron containing drugs and dietary supplements. The petitions requested that FDA require label warning

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Final Rule Stage

statements for these products and special packaging to ensure the safe use of these products. Because of recent changes in the laws regulating dietary supplements brought about by the Dietary Supplement Health and Education Act (Pub. L. 103-417), FDA published a supplemental proposal on February 16, 1995, that set forth its revised legal authority a supplemental proposal that sets forth its revised legal authority.

Timetable:

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

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE59.

Agency Contact: Linda Kahl, Acting Director, Division of Programs and Enforcement Policy, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-455), 200 C Street SW., Washington, DC 20204

Phone: 202 205-5365

RIN: 0910-AA42

1258. PUBLIC INFORMATION; COMMUNICATIONS WITH STATE AND FOREIGN GOVERNMENT OFFICIALS

Priority: Other

Legal Authority: 5 USC 552; 18 USC 1905; 19 USC 2531 to 2582; 21 USC 321 to 393; 42 USC 241; 42 USC 242; 42 USC 242a; 42 USC 242i; 42 USC 242n; 42 USC 243; 42 USC 262; 42 USC 263; 42 USC 263b to 263n; 42 USC 264; 42 USC 265

CFR Citation: 21 CFR 20

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations governing communications with officials of State and foreign governments. This proposal will permit FDA to disclose to, and receive from, these officials certain nonpublic information without being compelled to disclose the information to the public generally. This proposal addresses the nonpublic exchange of two types of information. First, it allows the disclosure of nonpublic safety, effectiveness, or quality information concerning FDA-regulated products to State government officials. Second, it allows the disclosure of draft proposed rules and other nonpublic

predecisional documents concerning regulatory requirements or activities between FDA and either State or foreign government officials. This action is necessary to enhance cooperation in regulatory activities, to eliminate unfounded contradictory regulatory requirements, and to minimize redundant application of similar requirements.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 01/27/95 | 60 FR 5530 |
| NPRM Comment Period End | 04/27/95 | |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: State, Local, Federal

Additional Information: Previously reported under RIN 0905-AE65.

42 USC 300u-300u-5 42 USC 300aa-1

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

Phone: 301 827-3344

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Email: LHorton@Bangate.FDA.GOV

RIN: 0910-AA46

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Food and Drug Administration (FDA)

1259. POLICIES CONCERNING USES OF SULFITING AGENTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

CFR Citation: 21 CFR 182.3616; 21 CFR 182.3637; 21 CFR 182.3739; 21 CFR 182.3766; 21 CFR 182.3798; 21 CFR 182.3862; 21 CFR 100; 21 CFR 130.9

Legal Deadline: None

Abstract: Acceptable evidence and information exist to show that a subgroup of asthmatics is at moderate to severe risk for a severe reaction upon exposure to sulfites. The agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use

labeling to inform those persons who need or want to avoid the ingredient. The agency issued a final rule, effective January 7, 1987, that requires that when a sulfiting agent is present in a finished food at 10 parts per million or greater, the sulfiting agent must be declared on the label. In addition, FDA issued a final rule, effective August 8, 1986, prohibiting the use of sulfiting agents on raw fruits and vegetables intended to be served or sold raw to consumers (e.g., in salad bars). On December 10, 1987, FDA announced its tentative conclusion that there is no longer a basis to find that the use of sulfiting agents on "fresh" potatoes served or sold un packaged to consumers is GRAS. On December 19, 1988, FDA proposed to affirm, with specific limitations, that certain other uses of

sulfiting agents are GRAS and to establish labeling requirements for sulfiting agents in standardized foods.

On March 15, 1990 (55 FR 9826), FDA issued a final rule prohibiting the use of sulfiting agents on "fresh" potatoes (55 FR 9826) and requested data and information concerning the use of sulfiting agents on frozen potatoes (55 FR 9834).

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

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court invalidating on procedural grounds FDA's final rule revoking the GRAS status of the use of sulfiting agents on fresh potatoes.

FDA's repropoed rule will include the GRAS status of sulfiting agents on both minimally processed (formerly fresh) and frozen potatoes was left in place.

Timetable:

Food Labeling; Declaration of Sulfiting Agents

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

GRAS Status of the Use of Sulfiting Agents on Fresh Potatoes

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

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

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

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

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

Status of the Use of Sulfiting Agents on Shrimp

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

Status of Use of Sulfit Agents on Minimally Procd & Froz Potatoes

NPRM 00/00/00

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AB52.

Agency Contact: JoAnn Ziyad, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-207), 200 C Street SW., Washington, DC 20204
 Phone: 202 254-3116

Phone: 202 254-3116

RIN: 0910-AA03

1260. REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION UNDER SECTION 314 OF THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

Priority: Other Significant

Legal Authority: PL 99-660, sec 314

CFR Citation: None

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

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

Timetable:

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

Small Entities Affected: None

Government Levels Affected: State

Additional Information: Previously reported under RIN 0905-AD72.

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

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

RIN: 0910-AA14

1261. GENERAL BIOLOGICAL PRODUCT STANDARDS; ALTERNATIVE PROCEDURES AND EXCEPTIONS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 262

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

Legal Deadline: None

Abstract: The Food and Drug Administration is amending its regulations governing biological products. This amendment would authorize the Director, Center for Biologics Evaluation and Research, to approve an exception or alternative to any regulation in 21 CFR governing

biological products. The regulation will provide flexibility needed to accommodate rapid changes in biotechnology and to assure the continued availability of biological products.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 12/00/96 | |

Small Entities Affected: None

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AD82.

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

RIN: 0910-AA16

1262. 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 | 00/00/00 | |

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Additional Information: Previously reported under RIN 0905-AD91.

Agency Contact: Robert Moore, Regulatory Branch, Division of Programs and Enforcement Policy,

HHS—FDA

Long-Term Actions

Office of Spec Nut., Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-456), 200 C Street SW., Washington, DC 20204

Phone: 202 205-5372

RIN: 0910-AA20

1263. ADVERSE EXPERIENCE REPORTING REQUIREMENTS FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS

Priority: Substantive, Nonsignificant

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

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

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

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 10/27/94 | 59 FR 54046 |
| NPRM Comment Period End | 01/25/95 | |
| Final Action | 12/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE29.

Agency Contact: Howard P. Muller, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place, Rockville, MD 20855

Phone: 301 594-1049

RIN: 0910-AA28

1264. AMALGAM INGREDIENT LABELING

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 352

CFR Citation: 21 CFR 801

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE39.

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

Phone: 301 594-4765

RIN: 0910-AA33

1265. CLASSIFICATION OF COMPUTER SOFTWARE PROGRAMS THAT ARE MEDICAL DEVICES

Priority: Other Significant

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

CFR Citation: None

Legal Deadline: None

Abstract: FDA is announcing its intention to classify stand-alone computer software products that fit the

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE58.

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

Phone: 301 594-4765

RIN: 0910-AA41

1266. DEVELOPMENT OF HAZARD ANALYSIS CRITICAL CONTROL POINTS FOR THE FOOD INDUSTRY; REQUEST FOR COMMENTS

Priority: Other Significant

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

CFR Citation: None

Legal Deadline: None

Abstract: FDA announced on April 4, 1994, its plans to consider developing regulations that would establish requirements for a new comprehensive food safety assurance program for both domestically produced and imported foods that would be based on the principles of Hazard Analysis Critical Control Points (HACCP). The new food safety program would respond to new challenges, such as new food

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processing and packaging technologies, new food distribution and consumption patterns, exposure to industrial chemicals and chemical waste, the increasing importation of foods, new microbial pathogens, and resource constraints. The most serious of these challenges is presented by food pathogens. The number of recognized food-borne pathogens has broadened considerably, as has awareness of long-term complications from certain food-borne illnesses—such as arthritis, heart disease, and kidney and neurological damage. To meet such challenges, FDA intends to shift the focus of its food safety assurance program away from periodic visual inspection and end-product testing and toward prevention of food safety risks and problems, utilizing the HACCP state-of-the-art preventive approach.

Timetable:

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

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Additional Information: Previously reported under RIN 0905-AE60.

Agency Contact: John E. Kvenberg, Strategic Manager, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-10), 200 C Street SW., Washington, DC 20204

Phone: 202 205-4010

RIN: 0910-AA43

1267. • DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 291

Legal Deadline: None

Abstract: Revise these regulations to reduce burden, to streamline requirements, to consolidate various sections.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/97 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Wayne H. Mitchell, Regulatory Counsel, Division of Regulatory Affairs, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-362), 7500 Standish Place Rockville, MD 20855

Phone: 301 594-1049

Fax: 301 827-0901

RIN: 0910-AA52

1268. • EXPORT REQUIREMENTS FOR DRUGS FOR INVESTIGATIONAL USE IN OTHER COUNTRIES

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: FDA is considering whether to amend its regulations on investigational new drugs to streamline requirements for exports of unapproved drugs for investigational use in other countries. FDA is considering whether to exempt, or reduce requirements for exports of such drugs to highly developed countries such as Australia, Canada, Japan, and countries that are members of the European Union or the European Free Trade Area. The proposal carries out the President's and Vice President's "National Performance Review" for drugs and devices and is consistent with recent Congressional initiatives.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

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

RIN: 0910-AA61

1269. • EXPORT REQUIREMENTS FOR MEDICAL DEVICES

Priority: Substantive, Nonsignificant

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

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

CFR Citation: 21 CFR 812.18

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations for investigational devices to describe streamlined requirements for exports of unapproved medical devices. Under the proposed rule, an approved investigational device exemption (IDE) would constitute an agency determination that the export of the unapproved device is not contrary to the public health or safety. Countries could notify FDA that they do not object to the importation of unapproved devices with an approved IDE into their countries. Thus, for devices with an FDA-approved IDE, the proposal would eliminate the need for FDA to make independent determinations either that exportation is not contrary to the public health or safety or that an importing country does not object to the importation of a specific device. The proposed rule is intended to codify and to simplify export requirements for certain unapproved devices pursuant to the President's and Vice-President's

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“National Performance Review,” as reflected in the April 1995 report titled, “Reinventing Drug & Medical Device Regulations.” It is also consistent with recent Congressional initiatives.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

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

RIN: 0910-AA62

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Food and Drug Administration (FDA)

1270. PROPOSED LABELING FOR DRUG PRODUCTS BASED ON FALSE OR FRAUDULENT DATA

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 201

Completed:

| Reason | Date | FR Cite |
|-----------|----------|---------|
| Withdrawn | 08/14/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Howard Muller
Phone: 301 594-1049

RIN: 0910-AA13

1271. RECORDKEEPING AND REPORTING: ELECTRONIC PRODUCTS

Priority: Substantive, Nonsignificant

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

CFR Citation: 21 CFR 1000; 21 CFR 1002

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 09/19/95 | 60 FR 48374 |

Small Entities Affected: None

Government Levels Affected: None

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

RIN: 0910-AA15

1272. THRESHOLD OF REGULATION POLICY FOR COMPONENTS OF FOOD CONTACT ARTICLES

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 170; 21 CFR 171; 21 CFR 174

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 07/17/95 | 60 FR 36582 |
| Final Action Effective | 08/16/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Edward J. Machuga
Phone: 202 418-3085

RIN: 0910-AA18

1273. MEDICAL DEVICES; RESTRICTED DEVICES

Priority: Other Significant

CFR Citation: 21 CFR 801; 21 CFR 899

Completed:

| Reason | Date | FR Cite |
|-----------|----------|---------|
| Withdrawn | 08/16/95 | |

Small Entities Affected: Businesses

Government Levels Affected: None

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

RIN: 0910-AA36

1274. SUBSTANCES PROHIBITED FOR USE IN RUMINANT FEED

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 589.2000

Completed:

| Reason | Date | FR Cite |
|--------|------|---------|
|--------|------|---------|

Withdrawn - No action planned in the next 12 months.

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: John P. Honstead
Phone: 301 594-1728

RIN: 0910-AA38

1275. NEW DRUG AND BIOLOGICAL PRODUCT LICENSE APPLICATIONS; REVISIONS TO EXISTING REGULATIONS

Priority: Other Significant

CFR Citation: 21 CFR 314.51; 21 CFR 314.60; 21 CFR 314.61; 21 CFR 314.71; 21 CFR 314.100; 21 CFR 314.110; 21 CFR 314.120; 21 CFR 600.3; 21 CFR 601.2; 21 CFR 601.3; 21 CFR 611

Completed:

| Reason | Date | FR Cite |
|--------|------|---------|
|--------|------|---------|

Withdrawn 08/14/95

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Thomas Hassall
Phone: 301 594-6740

RIN: 0910-AA44

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

Proposed Rule Stage

1276. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE - II

Priority: Other Significant

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

CFR Citation: 42 CFR 100

Legal Deadline: None

Abstract: The Secretary has made findings as to the illnesses and conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines. Based on these

findings, the Secretary proposes to amend the Vaccine Injury Table by regulation pursuant to section 313 of the National Childhood Vaccine Injury Act of 1986 and section 2114(c) of the Public Health Service Act. These proposed regulations would have effect only for petitions for compensation under the National Vaccine Injury Compensation Program (VICP) filed after the new regulations become effective.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE52.

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

Phone: 301 443-6593

RIN: 0906-AA36

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

Final Rule Stage

1277. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK RULES

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

RIN: 0906-AA32

1278. TECHNICAL AMENDMENTS TO THE HEALTH PROFESSIONS, NURSING, AND ALLIED HEALTH TRAINING GRANT PROGRAMS UNDER 42 CFR PARTS 57 AND 58

Priority: Other

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

Legal Authority: 42 USC 293; 42 USC 293c; 42 USC 293d; 42 USC 293j; 42 USC 293k; 42 USC 293l; 42 USC 293m; 42 USC 293n; 42 USC 294; 42 USC 294b; 42 USC 294i; 42 USC 294o

CFR Citation: 42 CFR 57; 42 CFR 58

Legal Deadline: None

Abstract: This final rule amends various Public Health Service (PHS) health professions, nursing, and allied health training grant regulations, codified at 42 CFR parts 57 and 58, to bring these programs into conformity with statutory amendments made by the Health Professions Extension Amendments of 1992 to the various sections of the PHS Act under titles VII and VIII. Technical changes being made to the regulations are: (1) the

renumbering of PHS section numbers and their corresponding United States Code numbers within the regulations; (2) the removal of the reference to the National Advisory Council on Health Professions Education and the requirements for the Council's review of title VII grants; (3) the removal of the reference to section 705 of the PHS Act concerning audit and inspection requirements, which is redundant to the requirements that are covered under 45 CFR part 74; (4) the removal of repealed and inactive title VII and VIII health professions, nursing, and allied health training grant program regulations; and (5) other technical changes which are clarifying or editorial changes in nature.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE54.

Agency Contact: Betty B. Hambleton, Chief, Planning, Evaluation and Legislation Branch, Office of Research & Planning/BHP, Department of Health and Human Services, Health Resources and Services Administration, Room 8-67, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
 Phone: 301 443-1590

RIN: 0906-AA38

1279. • REMOVAL OF OBSOLETE REGULATIONS OF THE TITLE VII GRANT FOR THE CONSTRUCTION OF TEACHING FACILITIES FOR HEALTH PROFESSIONS PERSONNEL

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 292 et seq

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

Legal Deadline: None

Abstract: The purpose of this action is to remove regulations rendered obsolete by P.L. 102-408, which rescinded the authority for a health professions training facilities construction grant program that the now obsolete regulations governed.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

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

RIN: 0906-AA39

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

Long-Term Actions

1280. HEALTH EDUCATION ASSISTANCE LOAN (HEAL) PROGRAM: LENDERS'/ HOLDERS' PERFORMANCE STANDARDS
Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 292 to 292o
CFR Citation: 42 CFR 60
Legal Deadline: NPRM, Statutory, October 13, 1993.
Abstract: This Final rule amends the existing regulations governing the HEAL Program to establish standards for lenders and holders as required by

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

Timetable:

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

Small Entities Affected: None
Government Levels Affected: None
Additional Information: Previously reported under RIN 0905-AD87.
Agency Contact: Michael Heningburg, Director, Division of Student Assistance, Bureau of Health Professions, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Bldg. Room 8-48, Rockville, MD 20857
 Phone: 301 443-1173
RIN: 0906-AA33

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

Completed Actions

1281. GRANTS FOR THE ESTABLISHMENT OF DEPARTMENTS OF FAMILY MEDICINE
Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 57, subpart R
Completed:

| Reason | Date | FR Cite |
|--|----------|-------------|
| Final Action | 05/30/95 | 60 FR 28065 |
| Correction Notice - 7/31/95, 60 FR 38970 | | |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Enrique Fernandez, M.D., M.Ed.
 Phone: 301 443-6190
RIN: 0906-AA34

1282. FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT OF 1992
Priority: Other Significant
CFR Citation: 42 CFR 6
Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/08/95 | 60 FR 22530 |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Libby Merrill, Legislative Analyst
 Phone: 301 594-4060
RIN: 0906-AA35

1283. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS, DENTISTS, AND OTHER HEALTH CARE PRACTITIONERS: PAYMENT OF FEES
Priority: Other
CFR Citation: 45 CFR 60
Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/26/95 | 60 FR 27898 |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Thomas C. Croft
 Phone: 301 443-2300
RIN: 0906-AA37

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

Proposed Rule Stage

1284. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM
Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 288-1
CFR Citation: 42 CFR 68
Legal Deadline: None
Abstract: Section 634 of PL 100-607 creates a new program through which health professionals can obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees. The new regulations will cover this program.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 10/00/95 | |

Small Entities Affected: Undetermined
Government Levels Affected: Undetermined
Additional Information: Previously reported under RIN 0905-AD18.
Agency Contact: Marc Horowitz, Director, NIH AIDS Research Loan Repayment Program, Department of Health and Human Services, National Institutes of Health, Office of AIDS Research, 9000 Rockville Pike, Bethesda, MD 20892

Phone: 301 496-0357
 Fax: 301 402-0169
 Email: MOOREJ@OD31EMI.NIH.GOV
RIN: 0925-AA02

1285. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS
Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 216; 42 USC 288-5
CFR Citation: 42 CFR 68a
Legal Deadline: None

HHS—NIH

Proposed Rule Stage

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE56.

Agency Contact: Marc Horowitz, Dir., Clinical Research Loan Repayment Prog., Individuals from Disadvantaged Backgrounds, Department of Health and Human Services, National Institutes of Health, Office of AIDS Research, 9000 Rockville Pike, Bethesda, MD 20892
Phone: 301 402-0852
Fax: 301 402-0169
Email: MOOREJ@OD31EMI.NIH.GOV

RIN: 0925-AA09

1286. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NIH

Priority: Other

Legal Authority: 42 USC 288-4; 42 USC 216

CFR Citation: 42 CFR 68b

Legal Deadline: None

Abstract: Section 487D of the PHS Act, as added by the NIH Revitalization Act of 1993, creates a program offering scholarships, in an amount not to exceed \$20,000 per year of academic study, to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for

careers in professions needed by the NIH. For each year of scholarship support, the recipient agrees to service (employment), after graduation at the NIH, for one year. Additionally, the individual agrees to at least ten consecutive weeks of service (employment) at the NIH during which the individual is attending the institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE57.

Agency Contact: Marc Horowitz, Dir., NIH AIDS Research Loan Repayment Program, Department of Health and Human Services, National Institutes of Health, Office of AIDS Research, NIH, 9000 Rockville Pike, Bethesda, MD 20892
Phone: 301 402-0852

RIN: 0925-AA10

1287. TRAINEESHIPS (TERMINATION POLICIES)

Priority: Other

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

CFR Citation: 42 CFR 63

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AE62.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, Bldg 31, Rm 1B25, Center DR MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606

RIN: 0925-AA11

1288. • ADDITIONAL DHHS PROTECTION FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED AS SUBJECTS FOR RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION

Priority: Other

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46, supart B

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0925-AA14

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

Final Rule Stage

1289. GRANTS FOR RESEARCH PROJECTS

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing

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

Legal Authority: 42 USC 216

CFR Citation: 42 CFR 52

Legal Deadline: None

Abstract: Regulations covering grants for research projects will be amended to show changes necessitated by

enactment of Public Laws 99-158, 99-660, 100-607, 101-549, 101-613, 102-222, 102-321, and 102-588, and to show their applicability to various programs administered by the Centers for Disease Control and Prevention and the Food and Drug Administration previously omitted from the regulations.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| NPRM | 08/02/94 | 59 FR 39312 |
| NPRM Comment Period End | 10/03/94 | |
| Final Action | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AC02.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, Room 1B25, Center DR MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
Fax: 301 402-0169
Email: MOOREJ@OD31EMI.NIH.GOV
RIN: 0925-AA01

1290. HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Priority: Other

Legal Authority: 42 USC 9660; 42 USC 216

CFR Citation: 42 CFR 65a

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| NPRM | 03/07/95 | 60 FR 12525 |
| NPRM Comment Period End | 05/08/95 | 60 FR 12525 |
| Final Action | 10/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD46.

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

RIN: 0925-AA03

1291. NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

Priority: Other

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

Legal Authority: 42 USC 216; 42 USC 285a-2; 42 USC 285a-3; 42 USC 285b-3; 42 USC 285b-4; 42 USC 285d-6; 42 USC 285i; 42 USC 285m-3; 42 USC 287a-2; 42 USC 287a-3; 42 USC 300cc-41

CFR Citation: 42 CFR 52b

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| NPRM | 07/06/95 | 60 FR 35266 |
| NPRM Comment Period End | 09/05/95 | 60 FR 35266 |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD49.

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

Institutes of Health, 9000 Rockville Pike, Bldg. 31, Rm 1B25, Center DR MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
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Email: MOOREJ@OD31EMI.NIH.GOV

RIN: 0925-AA04

1292. TRAINING GRANTS

Priority: Other

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

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

CFR Citation: 42 CFR 63a

Legal Deadline: None

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

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|------------|
| NPRM | 01/24/95 | 60 FR 4742 |
| NPRM Comment Period End | 03/27/95 | 60 FR 4742 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information: Previously reported under RIN 0905-AD56.

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, Bldg. 31, Rm 1B25, Center DR MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
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RIN: 0925-AA05

HHS—NIH

Final Rule Stage

1293. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Other

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

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

CFR Citation: 42 CFR 52a

Legal Deadline: None

Abstract: NIH Center Grants regulations will be amended to show their applicability to the Drug Abuse Research Centers Program authorized by PHS Act, section 464N, as added by section 123 of the ADAMHA Reorganization Act, P.L. 102-321, and several new centers authorized under the NIH Revitalization Act of 1993. Additionally, in accordance with the President's Reinventing Government effort, NIH is merging the regulations governing Grants for National Alcohol Research Centers codified at 42 CFR Part 54a with the Center Grants regulations and removing 42 CFR Part 54a from the CFR.

Timetable:

| Action | Date | FR Cite |
|--------|----------|------------|
| NPRM | 02/17/95 | 60 FR 9560 |

| Action | Date | FR Cite |
|----------------------------|----------|------------|
| NPRM Comment Period End | 04/18/95 | 60 FR 9560 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

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

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, 9000 Rockville Pike, Bldg 31, Rm 1B25, Center DR MSC 2075, Bethesda, MD 20892-2075
Phone: 301 496-4606
Fax: 301 402-0169
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RIN: 0925-AA06

1294. GRANTS FOR NATIONAL ALCOHOL RESEARCH CENTERS

Priority: Other

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

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

CFR Citation: 42 CFR 54a

Legal Deadline: None

Abstract: In accordance with the President's Reinventing Government effort, regulations governing grants for alcohol abuse and alcoholism prevention, treatment, and rehabilitation services, and National Alcohol Research Centers are being merged with the regulations governing NIH center grants codified at 42 CFR Part 52. Part 54a is being removed from the CFR.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| NPRM | 08/19/94 | 59 FR 42793 |
| NPRM Comment Period End | 10/18/94 | 59 FR 42793 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

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

Agency Contact: Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Bldg. 31, Rm. 3B-11, 9000 Rockville Pike, Bethesda, MD 20892
Phone: 301 496-2832
Fax: 301 402-0169
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RIN: 0925-AA08

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

Completed Actions

1295. RESPONSIBILITIES OF PUBLIC HEALTH SERVICE-FUNDED INSTITUTIONS FOR PROMOTING OBJECTIVITY IN RESEARCH

Priority: Other Significant

CFR Citation: 42 CFR 50, subpart F; 42 CFR 94

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 07/11/95 | 60 FR 35810 |
| Final Action Effective | 10/01/95 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Dr. George J. Galasso
Phone: 301 496-5356

RIN: 0925-AA07

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Office of Assistant Secretary for Health (OASH)
Long-Term Actions
1296. STANDARDS OF COMPLIANCE FOR ABORTION-RELATED SERVICES IN FAMILY PLANNING SERVICE PROJECTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 300a-4

CFR Citation: 42 CFR 59

Legal Deadline: None

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

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

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 02/05/93 | 58 FR 7464 |
| NPRM Comment Period End | 08/09/93 | 58 FR 34024 |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: State

Additional Information: Previously reported under RIN 0905-AE03.

Agency Contact: Felicia Stewart, M.D., Deputy Assistant Secretary for Population Affairs, Department of Health and Human Services, Office of Assistant Secretary for Health, East-West Towers, Suite 200, West Bldg., 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 594-4000

RIN: 0937-AA00

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)
Prerule Stage
1297. ● AMBULANCE SERVICES (BPD-813-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 1861(s)(7)

CFR Citation: 42 CFR 410.40

Legal Deadline: None

Abstract: This proposed rule would revise HCFA's policy on Medicare coverage of ambulance services. It focuses on the medical necessity for ambulance service, redefines an ambulance as an "emergency vehicle" and revises the policy on coverage of non-emergency ambulance transportation for beneficiaries with end-stage renal disease. These changes would prevent use of non-emergency vehicles and the use of ambulance transportation in non-emergency situations where the medical need has not clearly been determined. These changes require the use of emergency vehicles as ambulances and would focus on the medical treatment rather

than transportation as the primary concern for furnishing ambulance services, as required by Title XVIII, Section 1861(s)(7) of the Social Security Act. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| ANPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Margot Blige, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4642

RIN: 0938-AH13

1298. ● CHANGES IN COVERAGE AND PAYMENT POLICIES FOR PHYSICIAN ASSISTANT SERVICES (BPD-829-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k; 42 USC 1395u(b)(2); 42 USC 1395u(b)(12); 42 USC 1395x(s)

CFR Citation: 42 CFR 410.10; 42 CFR 410.74; 42 CFR 410.150; 42 CFR 414.1; 42 CFR 414.52; 42 CFR 491.2

Legal Deadline: None

Abstract: This proposed rule concerns the coverage and payment policies for services performed by physician assistants and services furnished as incident to these services. It would conform Medicare regulations to the provisions in section 6114 of the Omnibus Budget Reconciliation Act of 1989. It would provide consistent qualification requirements for physician assistants.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| ANPRM | 04/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Pat Moore, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-8090

RIN: 0938-AH26

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)
Proposed Rule Stage
1299. NEW MINIMUM STANDARDS FOR MEDICARE SUPPLEMENTAL (MEDIGAP) POLICIES (BPD-491-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing

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

Legal Authority: 42 USC 1395ss

CFR Citation: 42 CFR 403.200; 42 CFR 403.205; 42 CFR 403.206; 42 CFR 403.210; 42 CFR 403.215; 42 CFR 403.216; 42 CFR 403.220; 42 CFR 403.222; 42 CFR 403.232; 42 CFR 403.239; 42 CFR 403.250 to 403.258

HHS—HCFA

Proposed Rule Stage

Legal Deadline: None

Abstract: This rule would organize and codify in regulations the statutory changes to Medigap provisions made in 1987, 1988, 1989, 1990 and 1994. It will contain specific procedures for review of State regulatory plans (and individual policies) as required in OBRA '90. The new standards were enacted by OBRA '87, and '90, the Medicare Catastrophic Coverage Act of 1988, the Medicare Catastrophic Coverage Repeal Act of 1989, and the Social Security Act Amendments of 1994. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Julie Walton, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-08-18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4622

RIN: 0938-AD82

1300. "WITHOUT FAULT" AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (BPD-719-P)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1395gg

CFR Citation: 42 CFR 405; 42 CFR 401; 42 CFR 466.94; 42 CFR 411.23; 42 CFR 411.28; 42 CFR 466.86; 42 CFR 473.14; 42 CFR 413.20; 42 CFR 413.153

Legal Deadline: None

Abstract: This rule would amend the Medicare regulations to clarify our interpretation of "without fault" as it applies to physician, provider, supplier and beneficiary liability for overpayments. This definition would result in greater uniformity of

determinations by carriers and intermediaries. Additionally, this proposed 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. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Walczak, Health Insurance Specialist, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4475

RIN: 0938-AD95

1301. PROTECTION OF INCOME AND RESOURCES FOR COMMUNITY SPOUSES OF INSTITUTIONALIZED INDIVIDUALS (MB-023-P)

Priority: Other Significant

Legal Authority: 42 USC 1396r-5

CFR Citation: 42 CFR 435.630; 42 CFR 435.632; 42 CFR 435.634; 42 CFR 435.636; 42 CFR 435.638; 42 CFR 435.640; 42 CFR 435.642; 42 CFR 435.644; 42 CFR 435.646; 42 CFR 435.648

Legal Deadline: None

Abstract: These regulations would interpret section 303(a) of MCCA '88, as amended by section 608(d)(16) of the FSA (PL 100-485), section 6411(e)(3) of OBRA '89 and section 4714 of OBRA '90. Section 303(a) allocates income and resources between a spouse who is institutionalized and the spouse remaining in the community. It also provides special post-eligibility rules for institutionalized individuals who have spouses in the community. The revision would allow the community spouse to retain more income to meet living expenses.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 08/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: State, Local

Agency Contact: Jennifer Ryan, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-23-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4459

RIN: 0938-AE12

1302. COVERAGE OF PHYSICIAN ASSISTANT, NURSE PRACTITIONER, AND CLINICAL NURSE SPECIALIST SERVICES (BPD-708-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1395x(s)(2)(K); 42 USC 1396(d)(1)

CFR Citation: 42 CFR 410; 42 CFR 413; 42 CFR 414; 42 CFR 491

Legal Deadline: None

Abstract: This proposed rule concerns the coverage of payment for services performed by nurse practitioners and clinical nurse specialists and services furnished as an incident to those services. It would conform Medicare regulations to the provisions in section 6114 of OBRA '89, section 4155 of OBRA '90, and section 147(e) of SSA '94. In addition, under the authority of sections 1861(aa) and 1905(l) of the Social Security Act, it would revise our existing definition of "nurse practitioner" for purposes of the conditions rural health clinics must meet to qualify for payment under Medicare and Medicaid and that Federally qualified health clinics must meet to qualify for payment under Medicare.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Roberta Epps, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4503

RIN: 0938-AF00

HHS—HCFA

Proposed Rule Stage

1303. ALTERNATIVE SANCTIONS FOR PSYCHIATRIC HOSPITALS (HSQ-191-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395cc; 42 USC 1396a

CFR Citation: 42 CFR 488

Legal Deadline: None

Abstract: These regulations 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. These alternative sanctions could be imposed instead of terminating a psychiatric hospital's participation in the Medicare and Medicaid programs where deficiencies do not present immediate jeopardy to the health and safety of psychiatric hospital patients.

These amendments are necessary to conform HCFA regulations to changes made by section 6020 of OBRA '89 and section 4755 of OBRA '90.

The purpose of the legislation is to encourage correction of deficiencies that do not jeopardize patient health and safety before termination becomes necessary.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: State, Federal

Agency Contact: Pam Vocke, Director, Division of Program Operations, Department of Health and Human Services, Health Care Financing Administration, Room 2-D-2, ME, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7089

RIN: 0938-AF32

1304. MEDICAID PAYMENT FOR COVERED OUTPATIENT DRUGS UNDER REBATE AGREEMENTS (MB-046-F)

Priority: Other Significant

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

Legal Authority: 42 USC 1396a(a); 42 USC 1396b(i); 42 USC 1396r-8; 42 USC 1396b(a)

CFR Citation: 42 CFR 447; 42 CFR 441

Legal Deadline: None

Abstract: This rule will incorporate section 4401 of OBRA '90 to add specific requirements for Medicaid payment for covered outpatient drugs. The requirements concern: denial of Federal financial participation unless rebate agreements and drug use review are in effect; prohibiting some State plan drug access limitations for drugs covered under a rebate agreement; and the content of the rebate agreements. The drug rebate agreement was previously published in the Federal Register on February 21, 1991 (56 FR 7049). This rule will also reflect statutory revisions mandated by the Veteran's Health Care Act of 1992 and OBRA '93. The revision of the drug rebate dispute resolution process is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 09/19/95 | 60 FR 48442 |
| NPRM Comment Period End | 11/20/95 | 60 FR 48442 |
| Interim Final Rule | 03/01/96 | |
| Final Action | 00/00/00 | |

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Estelle Chisholm, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-15-26, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-3286

RIN: 0938-AF42

1305. FEDERALLY QUALIFIED HEALTH CENTER SERVICES (MEDICAID) (MB-043-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(13); 42 USC 1396b(m); 42 USC 1396d(l); 42 USC 1396n(b)

CFR Citation: 42 CFR 440; 42 CFR 447

Legal Deadline: None

Abstract: These regulations would establish a new category of facilities known as federally Qualified Health Centers (FQHCs) and a new category of Medicaid services known as FQHC

services. This new type of facility includes community health centers, migrant health centers and health care for the homeless programs, which are receiving or are eligible to receive certain grants from the Public Health Service, and health programs or facilities operated by an Indian tribe or tribal organization. These regulations would establish requirements for coverage and payment of FQHC services under the Medicaid program. These regulations would implement section 6404 of OBRA '89 and section 4704 of OBRA '90 and reflect statutory revisions mandated.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Worgo, Office of Medical Services, Department of Health and Human Services, Health Care Financing Administration, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5919

RIN: 0938-AF90

1306. REVISIONS TO RULES ON HEALTH CARE PREPAYMENT PLANS (OMC-016-P)

Priority: Other Significant

Legal Authority: 42 USC 1395i; 31 USC 9701

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This regulation would impose a range of requirements on Health Care Prepayment Plans corresponding to certain provisions for prepaid health plans under section 1876 of the Social Security Act. The expanded regulatory requirements would increase beneficiary protections and strengthen Federal oversight of the HCFA program.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Tim Love, Health Insurance Specialist, Office of Managed Care, Department of Health and Human

HHS—HCFA

Proposed Rule Stage

Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1094

RIN: 0938–AF97

1307. CONDITIONS OF PARTICIPATION FOR RURAL HEALTH CLINICS (BPD-764-P)

Priority: Other Significant

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

Legal Authority: 42 USC 13951(a); 42 USC 13951(b); 42 USC 13951(d); 42 USC 1395x(aa); 42 USC 1395oo(j); 42 USC 1395ww(a)(4); 42 USC 1396a(a)(13)(E)

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 486

Legal Deadline: None

Abstract: This rule would update our regulations to incorporate several health care coverage and payment provisions contained in Public Laws 100-203, 101-239, and 101-508 (the OBRA's '87, '89, and '90) and would propose administrative changes that clarify policy related to sharing space between rural health centers and other entities, such as physician offices, the replacement of the provider-based cost basis system with the all-inclusive rate payment system, and the allowance of separate payment under Part B for more complex laboratory services. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Helen Klein, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-06-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4641

RIN: 0938–AG05

1308. MEDICARE APPEALS OF INDIVIDUAL CLAIMS (BPD-453-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ff

CFR Citation: 42 CFR 405.732; 42 CFR 405.801; 42 CFR 405.837; 42 CFR 405.838; 42 CFR 405.839; 42 CFR 405.840

Legal Deadline: None

Abstract: This rule would conform the regulation to section 9341 of OBRA '86. Section 9341 extends to Medicare Part B claimants the right to a hearing before an Administrative Law Judge if the amount in controversy is at least \$500 and to judicial review, provided the amount in controversy is at least \$1000. Section 9341 also limits the review of national coverage determination and prohibits judicial review of any regulation or instruction, initially issued before January 1, 1981, relating to a method of determining the amount of payment under Part B.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Paul Olenick, Director, Division of Beneficiary and Insurance Issues, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4472

RIN: 0938–AG18

1309. APPOINTMENT OF REPRESENTATIVES FOR MEDICARE APPEALS (BPO-120-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ff; 42 USC 405(a); 42 USC 406; 42 USC 1395ii

CFR Citation: 42 CFR 405.870; 42 CFR 405.701(c); 42 CFR 405.801(c); 42 CFR 405.871; 42 CFR 405.872

Legal Deadline: None

Abstract: This rule would clarify current regulations concerning: who can be appointed as representatives at Medicare appeal proceedings; the appointment procedure for representatives; whether a representative may be paid for his or her services; and the representative's

specific responsibilities. These changes would improve the administration of the claims appeal process.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Betsy Horn, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-1-05-15, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-0973

RIN: 0938–AG30

1310. ENFORCEMENT REQUIREMENTS FOR RENAL DIALYSIS FACILITIES (HSQ-204-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 1395rr(h)

CFR Citation: 42 CFR 405; 42 CFR 405.2181; 42 CFR 405.2182; 42 CFR 405.2184

Legal Deadline: None

Abstract: This rule would implement section 12 of PL 100-93, which amended section 1881 of the Social Security Act by adding a new paragraph (h). Paragraph (h) (redesignated as (g) by OBRA '87) broadens the Secretary's authority to impose alternative sanctions on suppliers of end-stage renal disease services when the noncompliance of the supplier does not immediately jeopardize patient health and safety. Alternative sanctions provide HCFA with a more flexible response to facility deficiencies short of termination. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Debbie Schoenemann, Office of Survey & Certification,

HHS—HCFA

Proposed Rule Stage

Department of Health and Human Services, Health Care Financing Administration, S-2-19-26, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-6771
RIN: 0938-AG31

1311. DISCLOSURE OF CONFIDENTIAL PRO INFORMATION FOR RESEARCH PURPOSES (HSQ-208-P)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1320c-9
CFR Citation: 42 CFR 476.144
Legal Deadline: None
Abstract: This rule would allow Peer Review Organizations (PROs) to disclose confidential information to researchers without the consent of the individuals who would be identified. Currently, PROs can only disclose to the public nonconfidential aggregate data where no one is specifically identified. The statute, however, provides for limited disclosure in case there are circumstances the Secretary shall by regulations provide to assure adequate protection of the rights and interest of patients, health care practitioners, or providers. HCFA is now emphasizing the sharing of PRO data for educational and research purposes as evidenced by the implementation of the Uniform Clinical Data Set and the Health Care Quality Improvement Initiative. This regulatory revision will make confidential PRO information accessible to researchers while still protecting the identities of beneficiaries and practitioners from unwarranted disclosure. PRO flexibility to share information with researchers is comparable with the revised requirements in the PRO's Fourth Scope of Work contract.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None
Government Levels Affected: State, Federal

Agency Contact: Mike Rappaport, Director, Division of Systems Management, Health Standards Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S-1-09-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6759
RIN: 0938-AG33

1312. EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES, SANCTIONS, AND OVERPAYMENTS (HSQ-215-P)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1395hh
CFR Citation: 42 CFR 405.1803; 42 CFR 405.1811; 42 CFR 405.1835; 42 CFR 405.1843; 42 CFR 405.1805; 42 CFR 483.151; 42 CFR 484.36; 42 CFR 489.2; 42 CFR 489.18

Legal Deadline: None

Abstract: This rule would amend regulations on provider agreements to clarify the effect a change of ownership has on penalties and sanctions incurred by Medicare providers. It would state that all Medicare penalties and sanctions are automatically assigned to a new owner. It would also extend the same principle to suppliers; i.e., we would require the new owner of a supplier to be liable for any Medicare overpayments, penalties, and sanctions incurred by or imposed the previous owner.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: None
Government Levels Affected: Undetermined

Agency Contact: Irene Gibson, Deputy Director, Office of Survey & Certification, Department of Health and Human Services, Health Care Financing Administration, S-2-14-17, 7500 Security Boulevard, Baltimore, MD 21244
 Phone: 410 786-6768
RIN: 0938-AG59

1313. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF CATARACT SURGERY (BPD-797-PN)

Priority: Other Significant
Legal Authority: 42 USC 1395x(s)(1); 42 USC 1395y(a)(1)(A)
CFR Citation: None
Legal Deadline: None

Abstract: This notice announces the Medicare program's proposal to define

medical necessity with respect to Medicare coverage of preoperative testing for cataracts, cataract surgery, and Nd:YAG capsulotomy.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| Proposed Notice | 10/06/95 | 60 FR 52396 |
| NPRM Comment Period End | 12/05/95 | |
| Final Action | 00/00/00 | |

Small Entities Affected: Businesses
Government Levels Affected: Undetermined

Agency Contact: Karen McVeary, Technology & Special Analysis Staff, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Boulevard, Baltimore, MD 21297
 Phone: 410 786-4643
RIN: 0938-AG65

1314. NEW PAYMENT METHODOLOGY FOR ROUTINE EXTENDED CARE SERVICES PROVIDER IN A SWING BED HOSPITAL (BPD-805-P)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 1395tt
CFR Citation: 42 CFR 413.53; 42 CFR 413.114

Legal Deadline: None

Abstract: This proposed rule would revise the regulations governing the methodology for payment of routine extended care services provided in a swing bed hospital. Medicare payment for such services would be determined prospectively based on the average rate per patient day paid by Medicare for routine care services provided in a free standing skilled nursing facility (SNF) in the region where the hospital is located. This rule would also provide that payment for these services will be the higher of the payment cost rate in effect for the current calendar year or for the payment rate received by the swing-bed hospital for the prior calendar year. In addition, this rule would revise the regulations concerning the method used to allocate hospital general routine inpatient service costs for purposes of determining payment to swing-bed hospitals.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

HHS—HCFA

Proposed Rule Stage

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

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

RIN: 0938-AG68

1315. SALARY EQUIVALENCY GUIDELINES FOR PHYSICAL THERAPY, RESPIRATORY THERAPY, SPEECH PATHOLOGY, AND OCCUPATIONAL THERAPY (BPD-808-PN)

Priority: Other Significant

Legal Authority: 42 USC 1395x(v)(5)

CFR Citation: 42 CFR 413.106

Legal Deadline: None

Abstract: This notice proposes revisions to the salary equivalency guidelines for Medicare payment for the reasonable costs of physical and respiratory therapy services furnished by providers under arrangements with an outside contractor. The notice also proposes initial salary equivalency guidelines for speech language pathology and occupational therapy services furnished by providers under arrangements with an outside contractor. The guidelines would be used by Medicare fiscal intermediaries to determine the maximum allowable costs of those services.

Timetable:

| Action | Date | FR Cite |
|-----------------|----------|---------|
| Proposed Notice | 04/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Jacqueline Gordon, Health Insurance Specialist, Division of Home Care and Therapy, Department of Health and Human Services, Health Care Financing Administration, C4-07-14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4517

RIN: 0938-AG70

1316. MEDICAID: OPTIONAL COVERAGE OF TB-RELATED SERVICES FOR INDIVIDUALS INFECTED WITH TUBERCULOSIS (MB-082-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(10)(A)(ii); PL 103-66, Sec 13603; 42 USC 1396a

CFR Citation: 42 CFR 435.219; 42 CFR 435.201; 42 CFR 440.250; 42 CFR 436.201; 42 CFR 436.219; 42 CFR 440.164

Legal Deadline: None

Abstract: This rule would amend the existing Medicaid regulations to provide for optional Medicaid coverage of low-income individuals infected with tuberculosis (TB). These individuals would be eligible only for specified TB-related services.

The rule would incorporate and interpret provisions of section 13603 of OBRA '93.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Jennifer Ryan, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-20-14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4459

RIN: 0938-AG72

1317. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—EXPANDED TO DESIGNATED HEALTH SERVICES (BPD-809-P)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395nn

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: This proposed rule would provide that a physician who has (or has a family member who has) a financial relationship with a health care entity may not make referrals to that entity for certain services (designated health services) under the Medicare

program, except under specified circumstances. This proposed rule would also deny payment to a State for expenditures for designated health services furnished on the basis of a physician referral that, all things being equal, would result in denial of payment under Medicare. The provisions of the proposed rule are based on sections 13562 and 13624 of the OBRA '93, as amended by SSA '94.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Betty Burrier, Office of Chronic Care Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0191

RIN: 0938-AG80

1318. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (BPD-819-P)

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

RIN: 0938-AG81

1319. END-STAGE RENAL DISEASE (ESRD) CONDITIONS OF COVERAGE (BPD-818-P)

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

RIN: 0938-AG82

1320. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION OF FINANCIAL SCREENING OF APPLICANTS FOR NURSING HOME ADMISSION (BPD-815-P)

Priority: Other Significant

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

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

HHS—HCFA

Proposed Rule Stage

CFR Citation: 42 CFR 409; 42 CFR 483; 42 CFR 413

Legal Deadline: None

Abstract: In this proposed rule we would define “distinct part” by specifying that a distinct part is a physically identifiable unit of an institution (that is, an entire ward wing, floor, or building) including all beds in the unit. In conjunction with this change we also propose an alternative approach for calculating medicare payments to a skilled nursing facility (SNF). This new “distinct costing” procedure would enable a participating SNF to establish a distinct costing area within the SNF for its relatively high intensity residents so that it can isolate and fully capture the routine cost of their care without resorting to the use of arbitrary certification boundaries to achieve this result. This proposed rule would also prohibit nursing homes from financially screening private pay applicants for admission. Instead, nursing homes would be permitted to charge up to a 2-month deposit before admission to ensure that sufficient funds are available to pay for care to which the individual may be entitled.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William Ullman, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-13-15, 7500 Security Blvd, Baltimore, MD 21244
Phone: 401 786-5667

RIN: 0938-AG84

1321. MEDICAID: NOMINAL COPAYMENTS FOR INSTITUTIONAL SERVICES FOR MEDICAID RECIPIENTS (MB-090-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(14); 42 USC 1396o

CFR Citation: 42 CFR 447.54; 42 CFR 447.55

Legal Deadline: None

Abstract: This final rule with comment period redefines the nominal maximum deductible, coinsurance, or copayment

charge that a State may impose on certain Medicaid recipients for each admission for inpatient hospital services. This revision of the copayment amount will help prevent undue hardships on Medicaid recipients who have low or no income by limiting the impact of rising health care costs.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Ingrid Osburne, Health Care Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-19-24, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786-4461

RIN: 0938-AG90

1322. WAGE INDEX USED TO ADJUST PAYMENT RATES FOR HOSPICE SERVICES UNDER THE MEDICARE PROGRAM (BPD-820-P)

Priority: Other Significant

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

Legal Authority: 42 USC 1395f(i); 5 USC 561 to 590

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: The Medicare hospice benefit has been in effect since 1983. This proposed rule would update the wage index used to adjust payment rates to reflect local differences in area wage levels. We are undertaking development of this proposed rule through a “negotiated rulemaking” proceeding under the Negotiated Rulemaking Act of 1990. This proposed rule is part of the Department’s regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|------------------|----------|-------------|
| Notice of Intent | 10/14/94 | 59 FR 52129 |
| NPRM | 05/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Janice Flaherty, Director, Division of Home Care & Therapy, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4637

RIN: 0938-AG93

1323. CATEGORIZATION AND CERTIFICATION REQUIREMENTS FOR A NEW SUBCATEGORY OF MODERATE COMPLEXITY TESTING (HSQ-222-P)

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

RIN: 0938-AG98

1324. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HSQ-225-P)

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

RIN: 0938-AG99

1325. MEDICAID COVERAGE OF PERSONAL CARE SERVICES (MB-071-P)

Priority: Other Significant

Legal Authority: 42 USC 1396d(a)(24)

CFR Citation: 42 CFR 440.70; 42 CFR 440.167; 42 CFR 440.170

Legal Deadline: None

Abstract: This rule would revise the Medicaid regulations to incorporate the provisions of OBRA '93 relating to coverage of personal care services. Personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded or an institution for mental disease is an optional Medicaid benefit, effective October 1, 1994. The services may be furnished both in the home and in other locations.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Mary Jean Duckett, Office of Long Term Care Services, Medicaid Bureau, Department of Health

HHS—HCFA

Proposed Rule Stage

and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-3294
RIN: 0938-AH00

1326. LIABILITY FOR THIRD PARTIES TO PAY FOR CARE AND SERVICES (MB-080-P)

Priority: Other Significant

Legal Authority: 42 USC 1396a(a)(25)(A); 42 USC 1396b(o)

CFR Citation: 42 CFR 433.135 to 152

Legal Deadline: None

Abstract: This rule would amend the regulations governing third party liability as required by OBRA '93. It would add ERISA plans, service benefit plans and health maintenance organizations to the definition of liable third parties. It would require States to prohibit any health insurer from taking into account when enrolling or making payments, that an individual is eligible for or receiving Medicaid. It would also require States to enact a law under which the State is deemed to have acquired a recipient's right to payment by a third party.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: State, Federal

Agency Contact: Robert Nakielny, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-21-01, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-4466

RIN: 0938-AH01

1327. MEDICARE PROGRAM: COVERAGE OF CERTIFIED NURSE-MIDWIFE SERVICES (BPD-496-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 13951; 42 USC 1395x(s); 42 USC 1395x(gg)

CFR Citation: 42 CFR 405; 42 CFR 410; 42 CFR 486

Legal Deadline: None

Abstract: This rule would specify that Medicare part B coverage includes the

services of a certified nurse-midwife furnished independent of the supervision of a physician (if that practice is allowed under the State law of the State in which the service is furnished). Section 4073 of the OBRA '87, as amended by section 411(h) of the MCCA '88, established separate Medicare Part B coverage of certified nurse-midwife services furnished after June 30, 1988. Section 13554 of OBRA '93 eliminates the limitation on coverage of certified-nurse midwife services. Services provided by a certified nurse-midwife outside the maternity cycle will now be covered under this provision.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Roberta Epps, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 419 786-4503

RIN: 0938-AH02

1328. • MEDICARE PROGRAM: UNIFORM ELECTRONIC COST REPORTING FOR SKILLED NURSING FACILITIES AND HOME HEALTH AGENCIES (BPD-788-P)

Priority: Other Significant

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

CFR Citation: 42 CFR 413.24

Legal Deadline: None

Abstract: This proposed rule would add the requirement that, for cost reporting periods beginning on or after October 1, 1995 all skilled nursing facilities and home health agencies must submit cost reports currently required under Medicare regulations in a uniform electronic format. This proposed rule would also allow a delay or waiver of this requirement where implementation would result in financial hardship for a provider.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas Talbott, Auditor, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4592

RIN: 0938-AH12

1329. • ADJUSTMENT IN PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES (BPD-831-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k(a)(2); 42 USC 1395l; 42 USC 1395z; 42 USC 1395aa; 42 USC 2630

CFR Citation: 42 CFR 416

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

Abstract: This rule would establish in regulations a process under which interested parties may request a review of the appropriateness of the current payment amount for IOLs furnished by Medicare participating ASCs. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Cathaleen Ahern, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-09-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4515

RIN: 0938-AH15

1330. • SCHEDULE OF LIMITS FOR SKILLED NURSING FACILITY INPATIENT ROUTINE SERVICE COSTS (BPD-837-NC)

Priority: Other Significant

Legal Authority: 42 USC 1395f(b); 42 USC 1395x(v)(1); 42 USC 1395yy

CFR Citation: 42 CFR 413

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

Abstract: This final notice with comment period sets forth an updated

HHS—HCFA

Proposed Rule Stage

schedule of limits on skilled nursing facility routine service costs for which payment may be made under the Medicare program. Section 1888(a) of the Social Security Act requires that for cost reporting periods, beginning on or after October 1, 1995 and every 2 years thereafter, the Secretary update the per diem cost limits for skilled nursing facility routine service costs.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 10/00/95 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Robert Kuhl, Technical Advisor, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4597

RIN: 0938-AH18

1331. • ADDITIONAL SUPPLIER STANDARDS (BPD-838-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 1395f; 42 USC 1395g(c); 42 USC 1395n; 42 USC 1495u(b)and(p); 42 USC 1395cc(d); 42 USC 1395gg(e)and(f)

CFR Citation: 42 CFR 424.57

Legal Deadline: NPRM, Statutory, January 1, 1996.

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Larry Bonander, Bureau of Policy Development, Department of Health and Human

Services, Health Care Financing Administration, C4-11-24, 7500 Security Boulevard, Baltimore, MD 21214

Phone: 410 786-4479

RIN: 0938-AH19

1332. • DELEGATION OF CIVIL MONEY PENALTIES (BPO-135-FC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 405(a); 42 USC 1302; 42 USC 1395x(aa); 42 USC 1395cc; 42 USC 1395ff(c); 42 USC 1395hh; 42 USC 1395ii

CFR Citation: None

Legal Deadline: None

Abstract: This rule would outline the processes and procedures to be undertaken in the imposition of civil money penalties and the appeals process.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 05/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joel Cohen, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-03-14-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3345

RIN: 0938-AH22

1333. • STATE PLAN AMENDMENT (SPA) RECONSIDERATION PROCESS (MB-096-P)

Priority: Other

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

Legal Authority: 42 USC 1396a(a)

CFR Citation: 42 CFR 430.18; 42 CFR 430.60

Legal Deadline: None

Abstract: This proposed rule would revise and streamline the State Plan Amendment (SPA) reconsideration process. Currently, when a State requests reconsideration of a denied

SPA, a hearing is held in all cases, even when the only dispute is over the interpretation of the statute. Under the proposed regulation, the State and HCFA could avoid the cost and delay of the hearing process by agreeing that the only issue is interpretation of the statute and permit the State to take the issue directly to court. The reconsidered decision would then be made without a hearing. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 03/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Robert Tomlinson, Office of Beneficiary Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-23-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4463

RIN: 0938-AH24

1334. • EVIDENCE OF LAWFUL PERMANENT RESIDENCE (MB-097-P)

Priority: Other

Legal Authority: 42 USC 1396b(v)

CFR Citation: 42 CFR 435.406; 42 CFR 435.408

Legal Deadline: None

Abstract: This proposed rule would revise HCFA regulations concerning documents which are required to determine proof of satisfactory immigration status for Medicaid eligibility. It would specify that lawful permanent residence be verified by whatever document is currently in use by the Immigration and Naturalization Services (INS) for that purpose. Currently, HCFA does not specify in regulations the current documents used by INS for determining proof of lawful permanent residence. HCFA needs to publish companion regulations to conform to final SSA regulations for the supplemental security income (SSI) program to ensure consistency among INS, HCFA, and SSA.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

HHS—HCFA

Proposed Rule Stage

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Robert Tomlinson, Office of Beneficiary Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-20-21, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4463

RIN: 0938-AH25

1335. • HOSPICE CARE - CONDITIONS OF PARTICIPATION (BPD-844-P)

Priority: Other Significant

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

Legal Authority: 42 USC 1395x(dd)

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: This proposed rule would revise the Medicare conditions of participation for hospices to held ensure the provision of quality care through an emphasis on patient-centered outcomes. Areas of change would include, among others, assessment of patient needs, clarification of physician roles, coordination of care for hospice patients residing in nursing homes, clarification of nursing roles, patient rights, and provision of services. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 09/30/96 | |

Small Entities Affected: Businesses

Government Levels Affected: State, Local

Agency Contact: Thomas Saltz, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4480

RIN: 0938-AH27

1336. • LIMITATIONS ON PAYMENT FOR HOME OXYGEN THERAPY BASED ON INHERENT REASONABLENESS CRITERIA (BPD-845-PN)

Priority: Economically Significant

Legal Authority: 42 USC 1395m(a); 42 USC 1395u(b)(8) and (9)

CFR Citation: 42 CFR 405.502(g); 42 CFR 414.210(d)

Legal Deadline: None

Abstract: This proposed notice sets forth our rationale for determining that Medicare's Part B payment allowances for home oxygen are grossly excessive and specifies the proposed change in our charge or methodology for determining home oxygen payment amounts.

Timetable:

| Action | Date | FR Cite |
|-----------------|----------|---------|
| NPRM | 10/00/95 | |
| Proposed Notice | 10/00/95 | |

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: William J. Long, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5655

RIN: 0938-AH28

1337. • MEDICAID: LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS; FEDERAL FISCAL YEAR 1997 (MB-098-N)

Priority: Other Significant

Legal Authority: 42 USC 1395r-4

CFR Citation: 42 CFR 447.297; 42 CFR 447.298

Legal Deadline: Other, Statutory, October 1995.

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

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Richard Strauss, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, Room C-4-18-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-2019
RIN: 0938-AH30

1338. • MEDICAID ELIGIBILITY QUALITY CONTROL, STAFFING AND TRAINING, AND UTILIZATION CONTROL: REMOVAL OF OBSOLETE AND RESTRICTIVE REQUIREMENTS (MB-099-P)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1302; 42 USC 1396a(a)(4); 42 USC 1396a(a)(26); 42 USC 1396b(g) and (i); 42 USC 1396b(u); 42 USC 1396d(a)(16); 42 USC 1396d(h)

CFR Citation: 42 CFR 431.861; 42 CFR 431.862; 42 CFR 431.863; 42 CFR 431.864; 42 CFR 432.10; 42 CFR 456

Legal Deadline: None

Abstract: This rule would remove several obsolete sections of the Medicaid regulations that specify rules and procedures for disallowing Federal financial participation for erroneous medical assistance payments due to eligibility and beneficiary liability errors as detected through the Medicaid eligibility quality control (MEQC) program for assessment periods from 1980 through June 1990. The rule also would eliminate certain regulations that specify Federal standards for personnel administration and training programs to allow States more flexibility and reduce burden. In addition, the rule would remove most of the regulations that prescribe requirements concerning control of the utilization of all Medicaid services, including specific requirements for control of utilization in institutions. The statutory requirements for utilization control remain in effect. This effort is part of our initiative to reinvent health care regulations.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 06/00/96 | |

HHS—HCFA

Proposed Rule Stage

Small Entities Affected: Businesses, Organizations

24-27A, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3235

1339. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1997 RATES (BPD-847-P)

Government Levels Affected: State, Local

RIN: 0938-AH31

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

Agency Contact: William Hickman, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, Room C-4-

RIN: 0938-AH34

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Final Rule Stage

Health Care Financing Administration (HCFA)

1340. DEDUCTION OF INCURRED MEDICAL EXPENSES (SPENDDOWN) (MB-020-F)

Phone: 410 786-3417

Phone: 410 786-4496

Priority: Substantive, Nonsignificant

RIN: 0938-AB07

RIN: 0938-AB50

Legal Authority: 42 USC 1302

1341. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (BPD-309-F)

1342. EFFECTIVE DATES FOR PROVIDER AGREEMENTS AND SUPPLIER APPROVALS (HSQ-139-F)

CFR Citation: 42 CFR 435.831; 42 CFR 436.831

Priority: Substantive, Nonsignificant

Priority: Substantive, Nonsignificant

Legal Deadline: None

Legal Authority: 42 USC 1395l(a)(1)(D); 42 USC 1395l(a)(2)(D); 42 USC 1395l(b)(3); 42 USC 1395l(h); 42 USC 1395cc(a)(2)(A); 42 USC 1396b(i)(7)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This final rule amends and responds to comments on a final rule with comment period published in the Federal Register on January 12, 1994. That final rule permits States flexibility to revise the process by which incurred medical expenses are considered to reduce an individual's or a family's income in order for the individual or family to become Medicaid eligible. Only States that cover the medically needy, and States that use more restrictive criteria to determine eligibility of the aged, blind, and disabled than the criteria used to determine eligibility for Supplemental Security Income (SSI) benefits, have a spenddown.

CFR Citation: 42 CFR 414.1; 42 CFR 414.2; 42 CFR 414.5; 42 CFR 405.556; 42 CFR 431.54; 42 CFR 447.342

CFR Citation: 42 CFR 431; 42 CFR 442; 42 CFR 488; 42 CFR 489; 42 CFR 498

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|-------------|
| NPRM | 09/02/83 | 48 FR 39959 |
| NPRM Comment Period End | 11/16/83 | 48 FR 39959 |
| Interim Final Rule | 01/12/94 | 59 FR 1659 |
| Final Rule With Comment Period | 01/12/94 | 59 FR 1659 |
| Comment Period End | 03/14/94 | |
| Effective Date | 03/14/94 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Roy Trudel, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244

Legal Deadline: None

Abstract: This rule will incorporate provisions of DEFRA, COBRA, OBRA '86, OBRA '87, the Technical and Miscellaneous Revenue Act of 1988, OBRA '89, and OBRA '90 regarding payment and "assignment" for diagnostic clinical laboratory tests establishing in regulations the methods for implementing fee schedules. This rule would set forth the methods by which the fee schedules would be updated and would allow certain adjustments for exceptions to the fee schedule. It will also reflect a statutory revision mandated by OBRA '93.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 08/18/93 | 58 FR 43156 |
| NPRM Comment Period End | 10/18/93 | 58 FR 43156 |
| Final Action | 06/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Charles Spalding, Director, Division of Ambulatory Care Services, Department of Health and Human Services, Health Care Financing Administration, C-4-05-24, 7500 Security Blvd., Baltimore, MD 21244

Legal Deadline: None

Abstract: This rule establishes uniform criteria for determining the effective dates of Medicare and Medicaid provider agreements and of the approval of Medicare suppliers when the provider or supplier is subject to survey as a basis for determining participation in those programs.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 10/08/92 | 57 FR 46362 |
| NPRM Comment Period End | 12/07/92 | |
| Final Action | 06/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Irene Givson, Deputy Director, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, S-02-14-17, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6768

RIN: 0938-AC88

HHS—HCFA

Final Rule Stage

1343. CHANGES CONCERNING SUSPENSION OF MEDICARE PAYMENTS AND DETERMINATIONS OF ALLOWABLE INTEREST EXPENSE (BPO-118-FC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1320b-4; 42 USC 1395g; 42 USC 1395x(v)(1)(A); 42 USC 1395l; 42 USC 1395gg

CFR Citation: 42 CFR 405.370 to 405.377; 42 CFR 413.5; 42 CFR 413.153

Legal Deadline: None

Abstract: This rule will change the Medicare regulations to provide for the following: (1) elimination of the requirement that in case of overpayments to health care providers, the contractor makes a determination that a suspension of payment is needed to protect the program against financial loss before the payment can be suspended; (2) clarification of procedures and roles of contractors, HCFA, and the Office of Inspector General relating to suspension of payment; (3) elimination of the requirement that investment income of providers from gifts, grants, and endowments be offset against allowable interest expenses if that investment income is commingled with other funds; and (4) extension of the list of exceptions to the interest expense investment income offset provision to include investment income from deferred compensation plans and self-insurance funds.

Timetable:

| Action | Date | FR Cite |
|-----------------------------------|----------|-------------|
| NPRM | 08/22/88 | 53 FR 31888 |
| NPRM Comment Period End | 10/21/88 | 53 FR 31888 |
| Final Rule With Comment Period | 06/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sam Guida, Director, Div. of Acct. Mgmt. & Collections, Division of Payment and Reporting Policy, Department of Health and Human Services, Health Care Financing Administration, S-2-08-28, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-7495

RIN: 0938-AC99

1344. PROHIBITION ON UNBUNDLING OF HOSPITAL OUTPATIENT SERVICES (BPD-426-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395y(a)(14); 42 USC 1395cc(a)(1)(H); 42 USC 1395cc(g); 42 USC 1395x(w)(1)

CFR Citation: 42 CFR 409; 42 CFR 410; 42 CFR 411; 42 CFR 412; 42 CFR 489; 42 CFR 1003

Legal Deadline: None

Abstract: This final rule, issued jointly by HCFA and the OIG, prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than the hospital, unless the services are furnished under an arrangement with the hospital. The hospital is obligated by its provider agreement to furnish the services directly or under an arrangement. These regulations also authorize the OIG to impose a civil money penalty, not to exceed \$2,000, against any individual who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for items or services furnished under Medicare, that is inconsistent with an arrangement under section 1866(a)(1)(H) of the Social Security Act or is in violation of the requirements for an arrangement. These regulations implement section 9343(c) of OBRA '86, section 4085(i)(17) of OBRA '87, and section 4157 of OBRA '90.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| NPRM | 08/05/88 | 53 FR 29486 |
| NPRM Comment Period End | 10/04/88 | 53 FR 29486 |
| Final Action | 04/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carolyn Mullen, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C-4-11-16, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4589

RIN: 0938-AD33

1345. CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS (HSQ-135-F)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1395y(a); 42 USC 1320c; 42 USC 1396a(a)(30); 42 USC 1395cc(a)

CFR Citation: 42 CFR 400.200; 42 CFR 411.15; 42 CFR 431.630; 42 CFR 433.15; 42 CFR 462.1; 42 CFR 462.101; 42 CFR 462.102; 42 CFR 462.106; 42 CFR 462.107; 42 CFR 466.1; 42 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83

Legal Deadline: None

Abstract: This rule will set forth several changes to regulations that govern Peer Review Organizations (PROs) and is based on statutory changes contained in COBRA '85 and OBRA '86. In addition, several technical changes will be included as a result of experience gained with the PRO program by HCFA. This rule also implements the new quality review requirements for certain Medicaid Health Maintenance Organization contracts.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|------------|
| NPRM | 03/16/88 | 53 FR 8654 |
| NPRM Comment Period End | 05/16/88 | 53 FR 8654 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Harvey Brook, Deputy Director, Office of Quality Improvement Programs, Department of Health and Human Services, Health Care Financing Administration, S-1-09-26, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6853

RIN: 0938-AD38

1346. REVISIONS TO THE FREEDOM OF INFORMATION REGULATIONS (OPA-001-P)

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing

HHS—HCFA

Final Rule Stage

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

Legal Authority: 5 USC 552(b)(4); EO 12600; PL 99-570, Sec 1801; PL 99-570, Sec 1802; PL 99-570, Sec 1803; PL 99-570, Sec 1804

CFR Citation: 42 CFR 401.101 to 401.102; 42 CFR 401.110; 42 CFR 401.120 to 401.123; 42 CFR 401.124 to 401.125; 42 CFR 401.105 to 401.108; 42 CFR 401.115 to 401.116

Legal Deadline: None

Abstract: This proposed rule would supplement the existing Department of Health and Human Services (HHS) Freedom of Information Act (FOIA) regulations by establishing rules specific to HCFA. The rule would also revise existing HCFA regulations to delete language that reiterates or conflicts with HHS-FOIA regulations or that pertains to SSA. This proposed rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Melody Hardy, Freedom of Information & Privacy Office, Department of Health and Human Services, Health Care Financing Administration, C2-01-11, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5358

RIN: 0938-AD60

1347. OMNIBUS NURSING HOME REFORM REQUIREMENTS (BPD-488-F)

Priority: Other Significant

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

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

CFR Citation: 42 CFR 418; 42 CFR 440; 42 CFR 441; 42 CFR 482; 42 CFR 483; 42 CFR 488; 42 CFR 431

Legal Deadline: None

Abstract: This final rule responds to public comments on the February 5, 1992, proposed rule that 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. This rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 02/05/92 | 57 FR 4516 |
| NPRM Comment Period End | 04/06/92 | 57 FR 4516 |
| Final Action | 04/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Bill Ullman, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5667

RIN: 0938-AD81

1348. HMO ORGANIZATIONAL STRUCTURE AND SERVICES (OMC-007-F)

Priority: Other Significant

Legal Authority: 42 USC 1395mm

CFR Citation: 42 CFR 417.100; 42 CFR 417.101; 42 CFR 417.103; 42 CFR 417.104; 42 CFR 417.107; 42 CFR 417.120; 42 CFR 417.122; 42 CFR 417.123; 42 CFR 417.124; 42 CFR 417.126; 42 CFR 417.143; 42 CFR 417.152

Legal Deadline: None

Abstract: This regulation will provide organizations which operate health maintenance organizations (HMOs) that are federally qualified under title XIII of the Public Health Service Act with greater flexibility in operating other health benefit plans. It will also authorize, with certain limitations, federally qualified HMOs to offer out-of-plan physician services and require

a reasonable deductible for those services. Further, this regulation would permit the HMO to use assets of the parent organization to meet fiscal soundness and insolvency protection requirements.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 07/15/93 | 58 FR 38170 |
| Correction Notice | 09/03/93 | 58 FR 46925 |
| NPRM Comment Period End | 09/13/93 | 58 FR 38170 |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Maureen Miller, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1097

RIN: 0938-AE25

1349. HOSPITAL STANDARD FOR HIV INFECTIOUS BLOOD AND BLOOD PRODUCTS (BPD-633-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(e)(9)

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule will require hospitals to notify the patient's attending physician whenever potentially HIV infectious blood has been administered, and to ask the physician to inform the patient of the need for HIV testing and counseling. If the physician is unavailable or declines to inform the patient, the hospital must notify the patient. This rule implements a recommendation of the President's Commission on AIDS.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 06/30/93 | 58 FR 34977 |
| NPRM Comment Period End | 08/30/93 | 58 FR 34977 |
| Final Action | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Janet Samen, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-13-07, 7500 Security Blvd., Baltimore, MD 21244

HHS—HCFA

Final Rule Stage

Phone: 410 786-5244

RIN: 0938-AE40

1350. MEDICARE, MEDICAID, AND CLIA PROGRAMS: REGULATIONS IMPLEMENTING THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA '88) (HSQ-226-F)

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

RIN: 0938-AE47

1351. CONDITIONS OF COVERAGE FOR ORGAN PROCUREMENT ORGANIZATIONS (BPD-646-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

CFR Citation: 42 CFR 485; 42 CFR 405; 42 CFR 482

Legal Deadline: Final, Statutory, November 16, 1991.

Abstract: This final rule will respond to comments on the final rule with comment period which set forth changes to the conditions of coverage for organ procurement organizations (OPOs). It deals with the definition of an OPO service area; qualifications of the board of directors; establishment of performance criteria for OPOs; clarify operational policy for certification and recertification of OPOs, competition for open areas, and, appeals of the Secretary's decisions. This rule contains provisions that are part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--|----------|-------------|
| NPRM | 06/21/91 | 56 FR 28513 |
| NPRM Comment Period End | 08/21/91 | 56 FR 28513 |
| Interim Final Rule With Comment Period | 09/08/94 | 59 FR 46500 |
| Effective Date | 10/11/94 | |
| Comment Period End | 11/07/94 | |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Claude Mone, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5666

RIN: 0938-AE48

1352. RESIDENT ASSESSMENT IN LONG-TERM CARE FACILITIES (HSQ-180-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395i-3; 42 USC 1396r; 42 USC 1302

CFR Citation: 42 CFR 483; 42 CFR 456.1; 42 CFR 456.600; 42 CFR 456.601; 42 CFR 456.602; 42 CFR 456.603; 42 CFR 456.608; 42 CFR 456.609; 42 CFR 456.610; 42 CFR 456.612; 42 CFR 456.651; 42 CFR 456.654; 42 CFR 483.20; 42 CFR 483.315

Legal Deadline: Final, Statutory, January 1, 1989.

Abstract: Sections 1819(b)(3) and 1919(b)(3) of the Social Security Act, as amended by PL 100-203, require skilled nursing facilities in the Medicare program and before October 1, 1990, as nursing facilities in the Medicaid program, to conduct a comprehensive, standardized assessment of each resident's capability to perform daily life functions. The assessment must also describe significant impairments in the resident's functional capacity and be based on a uniform minimum data set specified by the Secretary. Sections 1819(f)(6)(A) and 1919 (f)(6)(A) of the Act require the Secretary to specify a minimum data set of core elements and common definitions for use by nursing facilities in conducting the assessments. This rule would specify this minimum data set and establish guidelines for using it.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 12/28/92 | 57 FR 61614 |
| NPRM Comment Period End | 02/26/93 | 57 FR 61614 |
| Final Action | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sue Nonemaker, Health Standards Quality Bureau, Department of Health and Human Services, Health Care Financing

Administration, S-2-19-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6825

RIN: 0938-AE61

1353. POST-CONTRACT BENEFICIARY PROTECTIONS AND OTHER PROVISIONS (OMC-003-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395mm

CFR Citation: 42 CFR 417

Legal Deadline: None

Abstract: This rule will provide Medicare beneficiaries with certain coverage for pre-existing conditions under supplemental insurance after non-renewal or termination of a Medicare health maintenance organization (HMO) or competitive medical plan (CMP) contract; provide a 30-day open enrollment period for individuals who would otherwise lose prepaid Medicare coverage as a result of termination, non-renewal or reduction in service area of a risk contract; accelerate the deadline for risk contracting HMOs and CMPs to submit adjusted community rate proposals; require all HMOs and CMPs to furnish a copy of an executed enrollment application form to Medicare applicants, and require HCPPs to comply with HMO/CMP beneficiary application procedures.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 03/11/94 | 59 FR 11230 |
| NPRM Comment Period End | 05/09/94 | |
| Final Action | 01/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tracy Jensen, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1096

RIN: 0938-AE63

1354. EMPLOYER CONTRIBUTIONS TO HMOS (OMC-004-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 300e(c); 42 USC 300e-1(l); 42 USC 300e-9

CFR Citation: 42 CFR 417

HHS—HCFA

Final Rule Stage

Legal Deadline: None

Abstract: This rule would conform existing regulations to sections 5(b) and 7 of the Health Maintenance Organization (HMO) Amendments of 1988 (PL 100-517). It would prohibit employers from financially discriminating against HMO enrollees in setting the contributions the employers make to employees' health plans.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| NPRM | 07/05/91 | 56 FR 30723 |
| Comment Period End | 09/03/91 | 56 FR 30723 |
| Final Action | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Marty Abeln, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1096

RIN: 0938-AE64

1355. EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT) SERVICES (MB-28-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)(43); 42 USC 1396d(r)

CFR Citation: 42 CFR 441.50; 42 CFR 440.40

Legal Deadline: None

Abstract: Section 6403 of OBRA '89 defines in new section 1905(r) of the Social Security Act the following EPSDT services: screening services, vision services, dental services and hearing services. It also extends EPSDT services 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 and illnesses and conditions discovered by the screening services whether or not the services are covered under the State plan. Section 6403 also amended section 1902(a)(43) of the Act to require States to report to the Secretary certain information about EPSDT services provided under the plan during each fiscal year. This rule would set forth requirements to implement these statutory provisions.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 10/01/93 | 58 FR 51288 |
| NPRM Comment Period End | 11/30/93 | 58 FR 51288 |
| Final Action | 04/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: State, Local

Agency Contact: Robert Wardwell, Director, Office of Medical and Remedial Care Services, Department of Health and Human Services, Health Care Financing Administration, C4-14-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3254

RIN: 0938-AE72

1356. PAYMENT FOR NURSING AND ALLIED HEALTH SCIENCE EDUCATION (BPD-685-F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 101-239, Sec 6205; PL 101-508, Sec 4004; PL 101-508, Sec 4159; 42 USC 1395x note

CFR Citation: 42 CFR 413

Legal Deadline: NPRM, Statutory, July 1, 1990.

Abstract: This rule will set forth our policy for the payment of the costs of approved nursing and allied health science programs, an action 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 have been 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 clarify payment rules for certified registered nurse anesthetist programs. This rule will also implement section 4004 of OBRA '90 which provides that, effective with cost reporting periods beginning on or after October 1, 1990, under certain conditions, costs incurred by a hospital or educational institution related to the hospital for clinical training are treated as pass-through costs and paid on the basis of reasonable cost even though the hospital does not operate the education programs.

Timetable:

| Action | Date | FR Cite |
|--------|----------|-------------|
| NPRM | 09/22/92 | 57 FR 43659 |

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM Comment Period End | 11/23/92 | 57 FR 43659 |
| Final Action | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Hospital Services, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-1850
RIN: 0938-AE79

1357. COVERAGE OF SCREENING PAP SMEARS (BPD-705-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(s)(14); 42 USC 1395x(nn)

CFR Citation: 42 CFR 410.10; 42 CFR 410.15; 42 CFR 410.56

Legal Deadline: None

Abstract: This rule will establish regulations under section 6115 of OBRA '89 to govern Medicare Part B coverage of screening pap smears and related medically necessary services (including a physician's interpretation of the test results) provided to a woman for the early detection of cervical cancer.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 11/26/93 | 58 FR 62312 |
| NPRM Comment Period End | 01/24/94 | 58 FR 62312 |
| Final Action | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Joyce Eng, Office of Physician Ambulatory Care Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C-4-02-26, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-4619
RIN: 0938-AE98

HHS—HCFA

Final Rule Stage

1358. MEDICARE COVERAGE OF CLINICAL PSYCHOLOGIST, OTHER PSYCHOLOGIST, AND CLINICAL SOCIAL WORKER SERVICES—MEDICARE (BPD-706-F)

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 13951(c); 42 USC 1395x(hh)(2); 42 USC 1395x(ii)
CFR Citation: 42 CFR 410; 42 CFR 417; 42 CFR 424

Legal Deadline: None

Abstract: This rule will address provisions of section 6113 of OBRA '89 and section 4157 of OBRA '90. Section 6113 of OBRA '89 provides coverage for the services of clinical psychologists (CPs) and clinical social workers. It requires CPs to agree to consult with the patient's primary care or attending physician. Also, it eliminates the dollar limitation that previously applied to mental health services although the 62.5 percent limitation still applies. OBRA '89 also provides coverage for clinical social worker services, but places two limitations on separate payment, which apply to services provided to inpatients of hospitals and skilled nursing facilities that are Medicare participating. Section 4157 of OBRA '90 unbundled CP services from the definition of "inpatient hospital services."

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 12/29/93 | 58 FR 68829 |
| NPRM Comment Period End | 02/28/94 | 58 FR 68829 |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Regina Walker, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C-4-08-16, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-6735

RIN: 0938-AE99

1359. CASE MANAGEMENT (MB-27-F)

Priority: Other Significant

Legal Authority: 42 USC 1396d; 42 USC 1396n

CFR Citation: 42 CFR 431.51(c); 42 CFR 440.169; 42 CFR 440.250; 42 CFR 441.10; 42 CFR 441.18; 42 CFR 447.327; 42 CFR 431.54

Legal Deadline: None

Abstract: This rule will place into our regulations provisions of COBRA '85, OBRA '86, TEFRA '86, TMRA '88 and OBRA '87 dealing with case management services. These regulations will provide for optimal Medicaid coverage of case management services furnished to specific groups in specific geographic areas or political subdivisions within a State.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 10/15/93 | 58 FR 53481 |
| NPRM Comment Period End | 12/14/93 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Robert Wardwell, Director, Office of Medical and Remedial Care Services, Department of Health and Human Services, Health Care Financing Administration, C4-25-07, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-5659

RIN: 0938-AF07

1360. PAYMENT FOR FEDERALLY QUALIFIED HEALTH CENTER (FQHC) SERVICES (BPD-728-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(aa); 42 USC 13951

CFR Citation: 42 CFR 405.2401; 42 CFR 405.2430; 42 CFR 405.2446; 42 CFR 405.2448; 42 CFR 405.2450; 42 CFR 405.2463; 42 CFR 405.2466; 42 CFR 405.2468; 42 CFR 491.5; 42 CFR 491.8

Legal Deadline: None

Abstract: This final rule will respond to comments received as a result of our publication of a final rule with comment period (57 FR 24961) which established a new category of facility known as an FQHC, the services of which are covered under the Medicare program. Those regulations also established requirements for coverage and payment of FQHC services under Medicare. They implemented section 4161(a) of PL 101-508 and section 13556 of PL 103-66. This final rule will clarify or change policy, as appropriate, based on our evaluation of public comments.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|-------------|
| Effective Date | 06/12/92 | 57 FR 24961 |
| Final Rule with Comment Period | 06/12/92 | 57 FR 24961 |
| Comment Period End | 08/11/92 | |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Bernadette Schumaker, Acting Director, Office of Physician and Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-11-16, 7500 Security Blvd., Baltimore, MD 21244
 Phone: 410 786-0309

RIN: 0938-AF14

1361. PARTIAL HOSPITALIZATION SERVICES IN COMMUNITY MENTAL HEALTH CENTERS (BPD-736-IFC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k(a)(2)(J); 42 USC 1395x(ff); 42 USC 1395cc(e)(2)

CFR Citation: 42 CFR 400; 42 CFR 410; 42 CFR 413; 42 CFR 489; 42 CFR 498

Legal Deadline: None

Abstract: In accordance with section 4162 of OBRA '90, this rule sets forth the coverage criteria and payment methodology for partial hospitalization services furnished in community mental health centers. It also specified the requirements a community mental health center must meet in order to enter into a Medicare provider agreement to furnish partial hospitalization services. This interim final rule will respond to public comments.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|------------|
| Interim Final Rule | 02/11/94 | 59 FR 6570 |
| Effective Date | 03/13/94 | 59 FR 6570 |
| Comment Period End | 04/12/94 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Susan Levy, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

HHS—HCFA

Final Rule Stage

Phone: 410 786-9364

RIN: 0938-AF53

1362. MEDICAID: OUTSTATIONED INTAKE LOCATIONS FOR CERTAIN LOW-INCOME PREGNANT WOMEN, INFANTS AND CHILDREN UNDER AGE 19 (MB-052-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396a(a)(55)

CFR Citation: 42 CFR 435.901; 42 CFR 435.902; 42 CFR 435.903; 42 CFR 435.904; 42 CFR 435.907; 42 CFR 436.2; 42 CFR 435.3

Legal Deadline: None

Abstract: This rule implements a statutory requirement that State Medicaid agencies must provide for receipt and initial processing of Medicaid applications filed by certain low-income pregnant women, infants, and children under age 19, at locations which are other than those used for receipt and processing of Aid to Families with Dependent Children (AFDC) applications. The statutory requirement also provides that the application form for these individuals must not be the AFDC application form.

The rule is based on section 1902(a)(55) of the Social Security Act as added by section 4602 of OBRA '90, PL 101-508.

Timetable:

| Action | Date | FR Cite |
|--|----------|-------------|
| Interim Final Rule With Comment Period | 08/23/94 | 59 FR 48805 |
| Interim Final Rule | 09/23/94 | 59 FR 48805 |
| Comment Period End | 11/22/94 | 59 FR 48805 |
| Effective Date | 11/24/94 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Robert Tomlinson, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-07-22, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4531

RIN: 0938-AF69

1363. MEDICARE AND MEDICAID PROGRAMS: REQUIREMENTS FOR PHYSICIAN INCENTIVE PLANS IN PREPAID HEALTH CARE ORGANIZATIONS (OMC-010-FC)

Priority: Other Significant

Legal Authority: 42 USC 1395mm(i); 42 USC 1396b

CFR Citation: 42 CFR 417.01; 42 CFR 417.409; 42 CFR 417.495; 42 CFR 434.67; 42 CFR 1003.100 to 1003.103

Legal Deadline: None

Abstract: This rule would amend the regulations governing federally qualified health maintenance organizations (HMOs) and competitive medical plans (CMPs) contracting with the Medicare program, and certain HMOs and health insuring organizations (HIOs) contracting with States under the Medicaid program, by implementing changes made by sections 4204(a) and 4731(a) of OBRA '90 concerning physician incentive plans. The changes are intended to allow HMOs, CMPs, and HIOs the flexibility to provide reasonable financial incentives to their physicians and physician groups in order to eliminate unnecessary care while still protecting enrollees from reduced quality of care or reduced access to care.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| NPRM | 12/14/92 | 57 FR 59024 |
| Comment Period End | 04/13/93 | 58 FR 8568 |
| Final Action | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Tony Hausner, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-23-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1093

RIN: 0938-AF74

1364. PART B ADVANCE PAYMENTS TO PHYSICIANS/SUPPLIERS OR OTHER ENTITIES FURNISHING ITEMS OR SERVICES UNDER MEDICARE PART B (BPO-105-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395u

CFR Citation: 42 CFR 421.214

Legal Deadline: None

Abstract: This rule would amend Medicare regulations to provide advance payment to physicians, suppliers, or entities that furnish items or services under Medicare Part B. These payments could be made only when claims processing is so delayed that interest payments alone are insufficient to adequately compensate the provider, in light of cash flow needs. This change is intended to result in more efficient and economical administration of the Medicare program.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 07/18/94 | 59 FR 36415 |
| NPRM Comment Period End | 09/16/94 | 59 FR 36415 |
| Final Action | 12/00/95 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Bob Shaw, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-2-01-23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7671

RIN: 0938-AF85

1365. RETROACTIVE ENROLLMENT AND DISENROLLMENT IN RISK HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS (OMC-015-F)

Priority: Other Significant

Legal Authority: 42 USC 1395mm

CFR Citation: 42 CFR 417.448; 42 CFR 417.450; 42 CFR 417.456; 42 CFR 417.460; 42 CFR 417.461; 42 CFR 417.462; 42 CFR 417.464; 42 CFR 417.584

Legal Deadline: None

Abstract: This rule will allow retroactive enrollment of up to 90 days for individuals enrolling with an eligible organization (which has a risk-sharing contract under section 1876 of the Social Security Act) under a health benefit plan operated, sponsored, or contributed to, by the individual's employer or former employer (or the employer or former employer of the individual's spouse). The regulation implements section 4204(e) of OBRA '90. In addition, the rule will permit

HHS—HCFA

Final Rule Stage

the Secretary to authorize retroactive disenrollment in specific cases.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| NPRM | 12/27/93 | 58 FR 68366 |
| Comment Period End | 02/25/94 | 58 FR 68366 |
| Final Action | 05/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Anne Manley, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1096

RIN: 0938-AF98

1366. PAYMENT FOR PREADMISSION SERVICES (BPD-731-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ww(a)(4)

CFR Citation: 42 CFR 412.2(c); 42 CFR 413.40

Legal Deadline: None

Abstract: This rule confirms the provisions published in an interim final rule with comment period on January 12, 1994. In addition, this final rule responds to comments received on the interim final rule with comment period. The interim final rule implemented section 4003 of OBRA '90, entitled "Expansion of DRG Payment Window," which amended the statutory definition of "inpatient operating cost" to include certain preadmission services.

Timetable:

| Action | Date | FR Cite |
|--|----------|------------|
| Effective Date | 01/12/94 | 59 FR 1654 |
| Interim Final Rule With Comment Period | 01/12/94 | 59 FR 1654 |
| Comment Period End | 03/14/94 | |
| Final Action | 03/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Nancy Edwards, Director, Division of Prospective Payment System, Department of Health and Human Services, Health Care Financing Administration, C5-06-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4531

RIN: 0938-AG00

1367. CHANGE IN PROVIDER AGREEMENT REGULATIONS RELATED TO FEDERAL EMPLOYEE HEALTH BENEFITS (BPD-748-F)

Priority: Substantive, Nonsignificant

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

Legal Authority: 5 USC 8904(b)

CFR Citation: 42 CFR 489

Legal Deadline: None

Abstract: This rule will amend current Medicare regulations to require that payment for inpatient hospital services furnished to retired Federal workers age 65 and older who are enrolled in a Federal Employee Health Benefits (FEHB) plan but who are not covered under Medicare Part A (Hospital Insurance) must accept as payment in full an amount that approximates as closely as possible the inpatient hospital Medicare prospective payment rate. The rule will also amend current Medicare regulations to authorize HCFA to consider termination or nonrenewal of a hospital's Medicare provider agreement for knowingly and willfully failing to accept, on a repeated basis, the Medicare rate as payment in full from an FEHB plan. This rule will implement section 7002(f) of OBRA '90, enacted November 5, 1990. This rule is part of the Department's regulatory initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 02/10/94 | 59 FR 6228 |
| NPRM Comment Period End | 04/11/94 | 59 FR 6228 |
| Final Action | 02/00/96 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Paul Olenick, Director, Division of Beneficiary and Insurance Issues, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4472

RIN: 0938-AG03

1368. INTERMEDIARY AND CARRIER FUNCTIONS (BPO-111-F)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1395h; 42 USC 1395u

CFR Citation: 42 CFR 421.100; 42 CFR 421.200

Legal Deadline: None

Abstract: Current regulations list functions that intermediaries and carriers must perform. All intermediaries and all carriers must perform all the enumerated functions. This rule changes the regulations to bring them into greater conformance with the Medicare statute, which gives the Health Care Financing Administration flexibility to move some functions from one contractor to another to reduce inefficiency, lower cost or achieve better program administration. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|---------------------------------|----------|-------------|
| NPRM | 02/22/94 | 59 FR 8446 |
| NPRM Comment Period End | 04/25/94 | 59 FR 8446 |
| Notice to Reopen Comment Period | 07/17/94 | 59 FR 35664 |
| Comment Period End | 10/11/94 | |
| Final Action | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Alan Bromberg, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-2-01-23, 2300 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7441

RIN: 0938-AG06

1369. REVISED MEDICAID MANAGEMENT INFORMATION SYSTEMS (MB-38-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396b(r)

CFR Citation: 42 CFR 433.1; 42 CFR 431.17; 42 CFR 447.10; 42 CFR 447.45; 42 CFR 74.20; 42 CFR 74.21

HHS—HCFA

Final Rule Stage

Legal Deadline: None

Abstract: This notice sets forth revised general functional requirements for the Medicaid Management Information System (MMIS). The MMIS consists of software and hardware used to process Medicaid claims and to retrieve and produce utilization and management information about services that are required by the Medicaid agency or Federal Government for administrative or audit purposes. The revised requirements allow States more flexibility to exercise variations in the implementation.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| Proposed Notice | 11/22/93 | 58 FR 61692 |
| Comment Period End | 01/21/94 | |
| Final Action | 12/00/95 | |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Richard Friedman, Director, Div. of Systems Data and Analysis, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-17-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3292
RIN: 0938-AG10

1370. END-STAGE RENAL DISEASE (ESRD) PAYMENT EXCEPTION REQUESTS AND ORGAN PROCUREMENT COSTS (BPD-763-F)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1395rr

CFR Citation: 42 CFR 413.170; 42 CFR 413.172; 42 CFR 413.174; 42 CFR 413.176; 42 CFR 413.178; 42 CFR 413.179; 42 CFR 413.180; 42 CFR 413.182; 42 CFR 413.184; 42 CFR 413.186; 42 CFR 413.188; 42 CFR 413.190; 42 CFR 413.192; 42 CFR 413.194; 42 CFR 413.196; ...

Legal Deadline: None

Abstract: These regulations specify the criteria HCFA will use to determine if a facility furnishing dialysis services to patients with end-stage renal disease

qualifies for a higher payment under an exception to the prospectively determined payment rate; and the procedures used to evaluate ESRD payment exceptions requests. The rule also revised the way HCFA computes acquisition costs for organs that are transplanted into Medicare beneficiaries. The rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 08/26/94 | 59 FR 44097 |
| NPRM Comment Period End | 10/25/94 | 59 FR 44097 |
| Final Action | 12/00/95 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Michael Powell, Health Insurance Specialist, Division of End-Stage Renal Disease, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4557

RIN: 0938-AG20

1371. MEDICARE PROGRAM: LIMITATIONS ON MEDICARE COVERAGE OF INTERMITTENT POSITIVE PRESSURE BREATHING MACHINE THERAPY (BPD-781-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(n); 42 USC 1395y(a)(1)(A)

CFR Citation: None

Legal Deadline: None

Abstract: Intermittent positive pressure breathing (IPPB) machine therapy is currently covered under Medicare as durable medical equipment for patients whose ability to breathe is severally impaired. Based on a Public Health Service recommendation, we propose to place limitations on Medicare coverage of IPPB machine therapy.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| Proposed Notice | 06/29/94 | 59 FR 33520 |
| Comment Period End | 08/29/94 | |
| Final Action | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Francine Spencer, Office of Chronic Care & Insurance

Policy, Department of Health and Human Services, Health Care Financing Administration, C4-04-05, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4614

RIN: 0938-AG44

1372. TELEPHONE AND ELECTRONIC REQUESTS FOR REVIEW OF PART B INITIAL CLAIM DETERMINATIONS (BPO-121-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 1395hh; 42 USC 1395ff

CFR Citation: 42 CFR 405.807

Legal Deadline: None

Abstract: Current Medicare regulations allow a Medicare beneficiary to appeal, in writing, decisions to deny payment for a claim under supplementary medical insurance. This rule would allow a beneficiary to appeal an initial payment determination either in writing or by telephone. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 07/10/95 | 60 FR 35544 |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Rosalind Little, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-01-05-18, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6972

RIN: 0938-AG48

1373. SCHEDULE OF LIMITS ON HOME HEALTH AGENCY COSTS PER VISIT (BPD-793-N)

Priority: Other Significant

Legal Authority: 42 USC 1395f(b); 42 USC 1395x(v)(1)(A); 42 USC 1395x(v)(1)(L); 42 USC 1395hh; PL 103-66, Sec 13564(a); 42 USC 1395cc(a)

HHS—HCFA

Final Rule Stage

CFR Citation: None

Legal Deadline: None

Abstract: This notice responds to public comments on the February 14, 1995 notice with comment period (60 FR 8389) that set forth a revised schedule of limits on home health agency costs that may be paid under the Medicare program for cost reporting periods beginning on or after July 1, 1993. The revised limits replaced the per-visit limits that were set forth in our July 8, 1993 notice with comment period (58 FR 36748). The February 14 notice also provided, in accordance with the provisions of OBRA '93, that there will be no changes in the home health agency cost limits for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|------------|
| Other Provisions Effective | 07/01/93 | 60 FR 8389 |
| Notice With Comment Period | 02/14/95 | 60 FR 8389 |
| Comment Period End | 04/17/95 | |
| Final Action | 03/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Michael Bussacca, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21207

Phone: 410 786-4602

RIN: 0938-AG54

1374. MEDICAID PROGRAM: NURSE-MIDWIFE SERVICES (MB-085-F)

Priority: Other Significant

Legal Authority: PL 103-66, Sec 13605

CFR Citation: 42 CFR 440

Legal Deadline: None

Abstract: This rule would expand coverage of nurse-midwife services under the Medicaid program by including coverage for those services the nurse-midwives perform outside the maternity cycle as allowed by State law and regulation. The provisions of this rule conform the regulations to the legislative provisions of OBRA '93.

Timetable:

| Action | Date | FR Cite |
|--------|----------|-------------|
| NPRM | 07/18/94 | 59 FR 36419 |

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM Comment Period End | 09/16/94 | 59 FR 36419 |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Linda Sizelove, Office of Medical Services, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-24-02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3255

RIN: 0938-AG73

1375. MEDICAID PROGRAM: FEES FOR VACCINE ADMINISTRATION UNDER PEDIATRIC IMMUNIZATION PROGRAM (MB-084-FN)

Priority: Other Significant

Legal Authority: PL 103-66, sec 13631; 42 USC 1396a(a)(62); 42 USC 1396s

CFR Citation: None

Legal Deadline: None

Abstract: This notice establishes a regional maximum fee that a Medicaid provider may charge for the administration of qualified pediatric vaccines under the Medicaid Pediatric Immunization Program. It also specifies the methodology used to develop this maximum fee and allows a State to pay a rate lower than the maximum fee if the State can ensure federally vaccine-eligible children adequate access to the vaccines at the lower rate. This notice implements section 1928(c)(2)(C)(ii) of the Social Security Act, as added by section 13631 of OBRA '93.

Timetable:

| Action | Date | FR Cite |
|----------------------------|----------|-------------|
| Effective Date | 10/01/94 | 59 FR 50235 |
| Notice With Comment Period | 10/03/94 | 59 FR 50235 |
| Comment Period End | 12/12/94 | |
| Final Action | 04/00/96 | |

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Marge Sciulli, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-21-26, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-0691

RIN: 0938-AG77

1376. REVISION OF MEDICARE HOSPITAL CONDITIONS OF PARTICIPATION (BPD-745-P)

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

RIN: 0938-AG79

1377. MEDICARE PROGRAM: CHANGES TO THE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 1996 RATES (BPD-825-FC)

Priority: Other Significant

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

Legal Authority: 42 USC 1395ww

CFR Citation: 42 CFR 412; 42 CFR 413

Legal Deadline: NPRM, Statutory, May 1995. Final, Statutory, September 1995.

Abstract: This rule would make revisions to the inpatient hospital prospective payment systems for operating costs and capital-related costs. It also would include changes in the methods amounts and factors used to determine the prospective payment rates applicable to discharges occurring during FY 1996. In addition, the rule would set forth the rate of increase limits for hospitals and hospital units excluded from the prospective payment systems. Finally, this rule would eliminate the requirement for physicians to sign an "attestation form" for each Medicare patient discharged from a hospital. This rule includes provisions that are part of HCFA's regulatory reform initiative and the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|-------------|
| NPRM | 06/02/95 | 60 FR 29202 |
| NPRM Comment Period End | 08/01/95 | 60 FR 29202 |
| Final Rule With Comment Period | 09/01/95 | 60 FR 45778 |
| Effective Date | 10/01/95 | |
| Comment Period End | 11/01/95 | |
| Final Action | 00/00/00 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: State, Federal

Agency Contact: Nancy Edwards, Director, Division of Prospective Payment Systems, Department of Health and Human Services, Health Care Financing Administration, C5-07-22, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4531

RIN: 0938-AG95

1378. MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES AND ADJUSTMENTS TO THE RELATIVE VALUE UNITS (RVUS) UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996 (BPD-827-FC)

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

RIN: 0938-AG96

1379. MEDICARE PROGRAM: PHYSICIAN FEE SCHEDULE UPDATE FOR CALENDAR YEAR 1996 & PHYSICIAN VOLUME PERFORMANCE STANDARD RATES OF INCREASE FOR FEDERAL FISCAL YEAR 1996 (BPD-828-FN)

Priority: Other Significant

Legal Authority: 42 USC 1395w-4

CFR Citation: None

Legal Deadline: Other, Statutory, October 31, 1995.
Annual update required.

Abstract: This notice announces the calendar year 1996 updates to the Medicare physician fee schedule and the federal fiscal year 1996 performance standard rates of increase for expenditures and volume of physicians' services under the Medicare Supplementary Medical Insurance (Part B) program as required by sections 1848(d) and (f) of the Social Security Act.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 10/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Terrence Kay, Director, Division of Physician Services, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-10-

26, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-4497

RIN: 0938-AH03

1380. PART A PREMIUM FOR 1996 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (OACT-051-N)

Priority: Substantive, Nonsignificant

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

CFR Citation: None

Legal Deadline: Other, Statutory, September 30, 1995.

Other deadline is for publication of Notice.

Abstract: This notice announces the hospital insurance premium for calendar year 1996 under the Medicare's hospital insurance program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. The uninsured aged are those individuals who are not insured under the Social Security or Railroad Retirement Acts and do not otherwise meet the requirements for entitlement to Medicare Part A. The disabled beneficiaries are those who lose monthly Social Security cash payments because they returned to work even though their disability continues. Section 1818(d) of the Social Security Act specifies the method to be used to determine this amount.

Timetable:

| Action | Date | FR Cite |
|--------|----------|-------------|
| Notice | 10/16/95 | 60 FR 53631 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin, Director, Division of Hospital Insurance, Department of Health and Human Services, Health Care Financing Administration, N-3-26-00, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6389

RIN: 0938-AH06

1381. MEDICARE PROGRAM: MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATES BEGINNING JANUARY 1, 1996 (OACT-050-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395r

CFR Citation: None

Legal Deadline: Other, Statutory, September 1995.
Other deadline is for publication of Notice.

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees, in the Medicare Supplementary Insurance (SMI) program for the 12 months beginning January 1, 1996. It also announces the monthly SMI premium rate to be paid by all enrollees during the 12 months beginning January 1, 1996.

Timetable:

| Action | Date | FR Cite |
|--------|----------|-------------|
| Notice | 10/16/95 | 60 FR 53626 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Carter Warfield, Director, Division of Supplementary Medical Insurance, Department of Health and Human Services, Health Care Financing Administration, N-3-26-00, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-6396

RIN: 0938-AH07

1382. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR 1996 (OACT-049-N)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395e

CFR Citation: None

Legal Deadline: Other, Statutory, September 15, 1995.
Other deadline is for publication of Notice.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1996 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute

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Final Rule Stage

specifies the formulae to be used to determine these amounts.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| Notice | 10/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Wandishin, Director, Division of Hospital Insurance, Department of Health and Human Services, Health Care Financing Administration, N-3-36-24, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-6389

RIN: 0938-AH08

1383. • LIMITATIONS ON AGGREGATE PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS: FEDERAL FISCAL YEAR 1995 (MEDICAID PROGRAM) (MB-094-N)

Priority: Substantive, Nonsignificant

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

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

Legal Deadline: None

Abstract: This notice announces the final Federal fiscal year (FFY) 1995 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: State, Federal

Agency Contact: Richard Strauss, Health Insurance Specialist, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-18-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-2019

RIN: 0938-AH09

1384. • REPORTING OF INTEREST FROM ZERO COUPON BONDS (BPD-647-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395x(v)

CFR Citation: 42 CFR 413.153

Legal Deadline: None

Abstract: This final rule requires Medicare providers to report all interest expense and income from zero coupon bonds in the cost reporting period in which the interest was accrued.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 12/13/93 | 58 FR 65150 |
| Final Action | 01/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Ann Pash, Health Insurance Specialist, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-03-17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4615

RIN: 0938-AH11

1385. • UPDATE OF THE REASONABLE COMPENSATION EQUIVALENT LIMITS FOR SERVICES FURNISHED BY PHYSICIANS (BPD-816-N)

Priority: Other Significant

Legal Authority: 42 USC 1395xx

CFR Citation: 42 CFR 405.482(f)

Legal Deadline: None

Abstract: This notice sets forth updated payment limits on the amount of allowable compensation for services furnished by physicians to providers that are not covered by the prospective payment system or per resident payments for graduate medical education. These services are paid for by Medicare on a reasonable cost basis. The revised reasonable compensation equivalent limits are based on updated economic index data and replace the limits that were published in the Federal Register on February 20, 1985.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|---------|
| Final Action | 01/00/96 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ward Pleines, Health Insurance Specialist, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-03-03, 7500

Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4528

RIN: 0938-AH14

1386. • CRITERIA AND PROCEDURES FOR EXTENDING COVERAGE TO CERTAIN DEVICES AND RELATED SERVICES (BPD-841-FC)

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

RIN: 0938-AH21

1387. • CLIA PROGRAM; GRANTING AND WITHDRAWAL OF AUTHORITY TO PRIVATE NONPROFIT ACCREDITATION ORGANIZATIONS AND OF CLIA EXEMPTION UNDER STATE LABORATORY PROGRAMS; TECHNICAL CORRECTIONS

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 263a

CFR Citation: 42 CFR 493.501; 42 CFR 493.506; 42 CFR 493.513; 42 CFR 493.515; 42 CFR 493.521

Legal Deadline: None

Abstract: This rule clarifies that a state may obtain approval from HCFA for exemption of its licensed laboratories from CLIA requirements given if it does not license all laboratories in the state. We are also making technical revisions and corrections to the final rule published July 31, 1992, that include data format requirements, laboratory performance information to be sent to us by accreditation organizations and CLIA-exempt states and the right of a state to appeal termination of its exemption for failure to pay required law.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|---------|
| Final Rule With Comment Period | 11/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Josephine Simmons, Chief, Laboratory Performance Branch, HSQB, HCFA, HHS, Department of Health and Human Services, Health

HHS—HCFA

Final Rule Stage

Care Financing Administration, 7500 Security Blvd, Room 52-19-26, Baltimore, MD 21244
Phone: 410 786-3409

RIN: 0938-AH32

1388. • MEDICARE PROGRAM; SPECIAL ENROLLMENT PERIODS AND WAITING PERIODS (BPD-752-FC)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1302; 42 USC 1395

CFR Citation: 42 CFR 406; 42 CFR 407; 42 CFR 408; 42 CFR 416

Legal Deadline: None

Abstract: This rule will reflect statutory changes made by OBRA's 1987, 1989, 1990 and 1993. It will provide an additional way for certain disabled individuals to qualify for special enrollment periods (SEPs); extend through 1998 the period during which disabled individuals under age 65 may take advantage of SEPs if they are covered under large group health plans; and provide that a second 24-month waiting period is not required for disability-based reentitlement if the current impairment is the same as or directly related to the impairment on

which the previous period of entitlement was based.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|---------|
| Final Rule with Comment Period | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Margaret Jefferson, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., C4-07-22, Baltimore, MD 21244
Phone: 410 786-4482

RIN: 0938-AH33

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

Long-Term Actions

1389. PARTICIPATION IN CHAMPUS AND CHAMPVA, HOSPITAL ADMISSIONS FOR VETERANS, DISCHARGE RIGHTS NOTICE, AND HOSPITAL RESPONSIBILITY FOR EMERGENCY CARE (BPD-393-F)

Priority: Other Significant

Legal Authority: 42 USC 1395x; 42 USC 1395cc; 42 USC 1395dd

CFR Citation: 42 CFR 488.18; 42 CFR 489.20; 42 CFR 489.24; 42 CFR 489.25; 42 CFR 489.26; 42 CFR 489.27; 42 CFR 489.53; 42 CFR 1003

Legal Deadline: None

Abstract: This final rule requires Medicare participating hospitals with emergency departments to provide upon request medical examinations and treatments for individuals with emergency medical conditions and women in labor. A participating hospital that has specialized capabilities or facilities (such as burn, shock trauma, or neonatal intensive care units) must accept an appropriate transfer if they have the capacity to treat the individual. Hospitals failing to meet those requirements may have their Medicare provider agreements terminated, and hospitals and responsible physicians may be subject to civil money penalties. Under section 9122 of COBRA '85, Medicare participating hospitals are required to accept CHAMPUS and CHAMPVA payment as payment in full for services provided to CHAMPUS and CHAMPVA

beneficiaries. These regulations also implement section 9305(b) of OBRA '86, which requires Medicare hospitals to give patients a notice of their discharge rights.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|----------|-------------|
| NPRM | 06/16/88 | 53 FR 22513 |
| NPRM Comment Period End | 08/15/88 | 53 FR 22513 |
| Final Rule With Comment Period | 06/22/94 | 59 FR 32086 |
| Effective Date | 07/22/94 | |
| Comment Period End | 08/22/94 | |
| Final Action | 00/00/00 | |

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter, Director, Division of Hospital Service, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-1304

RIN: 0938-AC58

1390. CRITERIA AND PROCEDURES FOR MAKING MEDICAL SERVICES COVERAGE DECISIONS THAT RELATE TO HEALTH CARE TECHNOLOGY (BPD-432-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395y

CFR Citation: 42 CFR 400.200; 42 CFR 405.201; 42 CFR 405.203; 42 CFR

405.205; 42 CFR 405.207; 42 CFR 405.209

Legal Deadline: None

Abstract: The final rule establishes in regulations generally applicable criteria and procedures for determining whether a service is "reasonable and necessary" under the Medicare program; it sets forth the coverage decisionmaking process; and it summarizes and provides an analysis of the public comments that we received in response to the January 30, 1989 proposed rule (54 FR 4302). The objective of the criteria and procedures set forth in this rule is to ensure that Federal funds are expended only for medical services that are appropriate to meet an individual's medical needs.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 01/30/89 | 54 FR 4302 |
| NPRM Comment Period End | 03/31/89 | 54 FR 4302 |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David Higbee, Technology & Special Analysis Staff, Department of Health and Human Services, Health Care Financing Administration, C4-10-07, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4643

RIN: 0938-AD07

HHS—HCFA

Long-Term Actions

1391. MEDICARE COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES (BPD-425-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395k; 42 USC 1395l; 42 USC 1395w-4; 42 USC 1395x(s); 42 USC 1395x(p); 42 USC 1395cc(e)

CFR Citation: 42 CFR 410; 42 CFR 485; 42 CFR 486

Legal Deadline: None

Abstract: This rule would implement section 9337 of OBRA '86 which provides Medicare coverage for outpatient occupational therapy services furnished by providers and independent practitioners, identical to the coverage for outpatient physical therapy. It also would implement section 6133(a) of OBRA '89 which increased the payment limit for outpatient occupational therapy services provided by independent practitioners.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Sheridan Gladhill, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C-4-05-27, 7500 Security Blvd., Baltimore, MD 21244 Phone: 410 786-1782

RIN: 0938-AD32

1392. MEDICARE SECONDARY PAYER FOR DISABLED INDIVIDUALS (BPD-482-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 1395y(b)

CFR Citation: 42 CFR 411

Legal Deadline: None

Abstract: This rule implements the Medicare secondary payer (MSP) provision for disabled individuals who are covered under large group health plans (LGHPs). Under this provision LGHPs may not take into account that

such individuals are entitled to Medicare. The rule contains procedures under which a plan can appeal a determination of nonconformance which could lead to a tax penalty. It reflects statutory revisions mandated by OBRA '86, OBRA '89, and OBRA '93, some of which also affect the MSP provisions for persons who are entitled on the basis of age or end-stage renal disease. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 03/08/90 | 55 FR 8491 |
| NPRM Comment Period End | 05/08/90 | 55 FR 8491 |
| Final Rule With Comment | 08/31/95 | 60 FR 45344 |
| Effective Date | 09/29/95 | |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Herbert Pollock, Office of Chronic Care & Insurance Policy, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C-4-08-14, 7500 Security Blvd., Baltimore, MD 21244 Phone: 410 786-4474

RIN: 0938-AD73

1393. FEE SCHEDULE FOR PAYMENT OF CLINICAL PSYCHOLOGIST SERVICES (BPD-495-P)

Priority: Other Significant

Legal Authority: 42 USC 1395k(a)(2)(B)(iii); 42 USC 1395x(hh); 42 USC 1395w-4; 42 USC 1395x(b); 42 USC 1395l(a)(1)(L); 42 USC 1395x(s)

CFR Citation: 42 CFR 414

Legal Deadline: None

Abstract: This proposed rule would establish fee schedules for payment of clinical psychologist services furnished under Medicare Part B. It implements a portion of section 4077(b) of OBRA '87 as amended. It further implements section 6113(a) of OBRA '89 and section 4157 of OBRA '90.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Elisa Tunanidas, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-26, 7500 Security Blvd., Baltimore, MD 21244 Phone: 410 786-4505

RIN: 0938-AD84

1394. SURVEY REQUIREMENTS AND ALTERNATIVE SANCTIONS FOR HOME HEALTH AGENCIES (HSQ-169-F)

Priority: Other Significant

Legal Authority: 42 USC 1395w-2; 42 USC 1395bbb

CFR Citation: 42 CFR 488; 42 CFR 489; 42 CFR 498

Legal Deadline: None

Abstract: These rules will establish periodic, unannounced surveys of home health agencies (HHAs) and other survey requirements and also will specify a number of sanctions that could be used, when an HHA is out of compliance with Federal requirements, as an alternative or in addition to terminating an HHA's participation in the Medicare program.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 08/02/91 | 56 FR 37054 |
| NPRM Comment Period End | 10/01/91 | 56 FR 37054 |
| Final Action | 00/00/00 | |

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Local, Federal

Agency Contact: Pam Vocke, Director, Division of Program Operations, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, S-2-19-26, 6300 Security Blvd., Baltimore, MD 21244 Phone: 410 786-3487

RIN: 0938-AE39

1395. FIRE SAFETY STANDARDS FOR HOSPITALS, LONG-TERM CARE FACILITIES, AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED (BPD-650-FC)

Priority: Substantive, Nonsignificant

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

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

Legal Authority: 42 USC 1395x; 42 USC 1396d

CFR Citation: 42 CFR 482.41(b)(1); 42 CFR 483.70(a); 42 CFR 483.470(j)(2)(i)(C); 42 CFR 416.44(a); 42 CFR 418.100(d)

Legal Deadline: None

Abstract: This final rule with comment period revises the fire safety standards for hospitals, long term care facilities participating in Medicare and Medicaid, intermediate care facilities for the mentally retarded, ambulatory surgical centers (ASCs) and hospices. It deletes references to the 1967 and 1973, 1981, and 1985 editions of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA) and requires compliance with only the 1994 edition of the LSC. This is a part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|-------------|
| NPRM | 08/01/90 | 55 FR 31196 |
| NPRM Comment Period End | 10/01/90 | 55 FR 31196 |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: James Kenton, Division of Skilled Nursing Care, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C4-11-06, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-5629

RIN: 0938-AE97

1396. CHANGES TO THE LONG-TERM CARE FACILITY SURVEY PROCESS (HSQ-175-FC)

Priority: Substantive, Nonsignificant

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

Legal Authority: PL 101-239, Sec 6901(a); 42 USC 1395i-3; 42 USC 1395aa(d); 42 USC 1396r

CFR Citation: 42 CFR 442; 42 CFR 488

Legal Deadline: None

Abstract: This final rule with comment period amends 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 could cause confusion in connection with directions State survey agencies must follow in determining facility compliance.

Timetable:

| Action | Date | FR Cite |
|---------------------------------------|----------|---------|
| Interim Final Rule Effective Date | 10/19/94 | |
| Interim Final Rule Comment Period End | 11/18/94 | |
| Final Rule With Comment Period | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Additional Information:

TIMETABLE: Pending court ruling.

Agency Contact: Pam Vocke, Director, Division of Program Operations, Office of Survey and Certification, Department of Health and Human Services, Health Care Financing Administration, S-2-19-26, 6300 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-3487

RIN: 0938-AF02

1397. OBRA '90 AND MISCELLANEOUS MANAGED CARE TECHNICAL AMENDMENTS (OMC-018-FC)

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 434.20 to 44; 42 CFR 435.212; 42 CFR 435.362

Legal Deadline: None

Abstract: This rule will require certain health insuring organizations to be subject to the regulations governing prepaid health plans. This rule will also allow State-only funds to be paid to Medicaid contracting entities. These funds will not be considered when

computing the rate at which Federal financial participation is made. Further, this rule will incorporate several technical amendments from section 4732 of OBRA '90.

Timetable:

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

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Jane McClard, Health Insurance Specialist, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-03-02-01, 7500 Security Blvd., Baltimore, MD 21244
Phone: 410 786-4460

RIN: 0938-AF15

1398. PRESUMPTIVE LIMITS ON PAYMENTS TO HMOS, CMPS, AND HCPPS (OMC-006-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 1395mm(h); 42 USC 1395x(v)(1)(A)

CFR Citation: 42 CFR 417.532(a)(3); 42 CFR 417.802; 42 CFR 417.800(c)

Legal Deadline: None

Abstract: This rule will establish presumptive limits for Medicare payments to Health Maintenance Organizations and Competitive Medical Plans, and to Health Care Prepayment Plans (HCPPs) that furnishes inpatient hospital care. It will also revise the criteria that HCFA uses to determine reasonable costs for HCPPs that do not furnish inpatient hospital care. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|-------------------------|----------|------------|
| NPRM | 02/22/94 | 59 FR 8435 |
| NPRM Comment Period End | 04/25/94 | 59 FR 8435 |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

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Agency Contact: A. G. D'Alberto, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S-3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-7610
RIN: 0938-AF16

1399. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS REVISIONS (BPD-727-P)

Priority: Other

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

Legal Authority: 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g(a); 42 USC 1395l; 42 USC 1395x(u); 42 USC 1395hh; 42 USC 1395jj; 42 USC 1395oo; 42 USC 1395ww

CFR Citation: 42 CFR 405.1801; 42 CFR 405.1889

Legal Deadline: None

Abstract: Under section 1878 of the Social Security Act, the Provider Reimbursement Review Board (PRRB) has the authority to adjudicate substantial reimbursement disputes between providers and intermediaries. This proposed rule would revise, update, and clarify various provisions of the regulations pertaining to provider appeals before intermediaries and the PRRB. This rule is part of HCFA's regulatory reform initiative.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Morty Marcus, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4477

RIN: 0938-AF28

1400. REFERRAL TO CHILD SUPPORT ENFORCEMENT AGENCIES OF MEDICAID FAMILIES (MB-051-F)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1396k

CFR Citation: 42 CFR 433.160; 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.151

Legal Deadline: None

Abstract: This rule will require State Medicaid agencies to refer Medicaid families with an absent parent to child support enforcement (CSE) agencies. Section 9142 of OBRA '87 required CSE agencies to provide all CSE services to such Medicaid families who have assigned to the State their rights to medical support. The purpose of these rules is to require States to make this referral to State CSE agencies to ensure that those recipients requiring CSE services receive them.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 09/22/93 | 58 FR 49272 |
| NPRM Comment | 11/22/93 | 58 FR 49272 |
| Period End | | |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Randy Graydon, Director, Division of Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, C4-22-27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4451

RIN: 0938-AF68

1401. ASSESSING INTEREST AGAINST MEDICARE SECONDARY PAYER (MSP) DEBTS (BPO-108-P)

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3711; 31 USC 3717; 42 USC 1395y(b)(2)(B)

CFR Citation: 42 CFR 411.40; 42 CFR 405.376

Legal Deadline: None

Abstract: This proposal would establish in HCFA rules provisions concerning interest charges on amounts owed to the Federal government when an overpayment occurs because Medicare was billed and made payment as the primary payer, rather than as the secondary payer. We also propose to clarify the date of determination that an overpayment has occurred so that all parties would have a clear understanding of the period subject to payment of interest charges.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: None

Additional Information:

TIMETABLE: Pending revisions resulting from PL 103-432.

Agency Contact: John Albert, Health Insurance Specialist, Bureau of Program Operations, Department of Health and Human Services, Health Care Financing Administration, S-03-02-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7457

RIN: 0938-AF87

1402. GENERAL CRITERIA AND STANDARDS FOR EVALUATING PERFORMANCE OF CONTRACT OBLIGATIONS (HSQ-207-NC)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302; 42 USC 1320c; 42 USC 1320-2

CFR Citation: 42 CFR 462

Legal Deadline: None

Abstract: This notice provides general criteria and standards that will be used to evaluate the effective and efficient performance of Utilization and Quality Control Peer Review Organizations (PROs) for new contracts entered into on or after April 1, 1993, by the 53 PROs.

Timetable:

| Action | Date | FR Cite |
|---------------------|----------|---------|
| Notice With Comment | 00/00/00 | |
| Period | | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Kathleen Kelso, Health Standards & Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S-1-09-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7214

RIN: 0938-AG32

1403. WITHDRAWAL OF COVERAGE OF DIAGNOSTIC NOCTURNAL PENILE TUMESCENCE TESTING (IMPOTENCE TESTING) (BPD-780-FN)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395y(a)(i)(A)

CFR Citation: None

Legal Deadline: None

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Abstract: This notice announces the Medicare program's intent to withdraw coverage for diagnostic nocturnal penile tumescence (NPT) testing in the sleep disorder clinic and to exclude coverage for nocturnal penile tumescence testing by plethysmography and other monitoring devices in all settings. Public Health Service studies show that NPT testing is not a reliable index for evaluating impotence. Therefore, it does not meet HCFA's criteria for effectiveness.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-----------|
| Proposed Notice | 01/04/94 | 59 FR 308 |
| Comment Period End | 03/07/94 | 59 FR 309 |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Bob Ulikowski, Office of Physician & Ambulatory Care Policy, Department of Health and Human Services, Health Care Financing Administration, C4-10-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5721

RIN: 0938-AG43

1404. NONCOVERAGE OF ELECTROSTIMULATION OF SALIVARY GLANDS FOR THE TREATMENT OF XEROSTOMIA (DRY MOUTH) (BPD-782-FN)

Priority: Substantive, Nonsignificant

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

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces the Medicare program's intent to exclude from coverage electrostimulation of the salivary glands in the treatment of xerostomia secondary to Sjogren's Syndrome. Public Health Service (PHS) studies show that there is insufficient data to establish the clinical utility of electrostimulation to evaluate its long-term effectiveness, or to identify those xerostomia patients who would benefit from this procedure. Also, PHS reports that electrostimulation is not widely accepted as a treatment for xerostomia secondary to Sjogren's Syndrome.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|-------------|
| Proposed Notice | 05/23/94 | 59 FR 26653 |
| Comment Period End | 07/22/94 | |
| Final Action | 00/00/00 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Francina Spencer, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-040-05, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4614

RIN: 0938-AG45

1405. CLINICAL LABORATORY IMPROVEMENT AMENDMENT (CLIA) FEE SCHEDULES (HSQ-219-FC)

Priority: Other Significant

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

Legal Authority: 42 USC 263a(m)

CFR Citation: 42 CFR 493.638; 42 CFR 493.649

Legal Deadline: None

Abstract: The preamble to this final rule with comment period announces updated fees that laboratories must pay as required by CLIA '88. Fee increases are necessary to meet the costs of program administration, which are to be borne by the laboratories. In addition, technical conforming changes are made to the regulations to ensure consistent and complete references. This rule is part of HCFA's regulatory reform initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Ed Mortimore, Survey & Certification, Department of Health and Human Services, Health Care Financing Administration, S-2-18-14, 7500 Security Blvd, Baltimore, MD 21244

Phone: 410 786-3509

RIN: 0938-AG87

1406. MANDATORY MEDIGAP CROSSOVER CLAIMS TRANSMITTAL REQUIREMENTS (BPD-811-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395ss

CFR Citation: 42 CFR 403.206; 42 CFR 403.212; 42 CFR 403.222; 42 CFR 403.232; 42 CFR 403.204; 42 CFR 424.68

Legal Deadline: None

Abstract: This regulation proposes to require Medicare supplemental issuers to accept from Medicare carriers direct transmittal of claims submitted for services furnished to Part B Medicare beneficiaries by participating physicians and suppliers; pay user fees associated with this claims transmittal requirement; and meet certain other requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 00/00/00 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: Thomas Hoyer, Director, Office of Chronic Care & Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Bldg., Baltimore, MD 21244

Phone: 410 786-5661

RIN: 0938-AG94

1407. • DEFINITION OF SKILLED NURSING FACILITY (SNF) AND HOME HEALTH AGENCY (HHA) FOR COVERAGE OF DURABLE MEDICAL EQUIPMENT (DME) (BPD-834-P)

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 1495x(n)

CFR Citation: 42 CFR 409; 42 CFR 410

Legal Deadline: None

Abstract: This proposed rule would define skilled nursing facilities (SNF) (under Medicare and Medicaid) for purposes of Medicare coverage of DME and home health. A Medicare SNF (as defined under section 1819 of the Act) can not be considered a home under

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Medicare Part B for DME and home health coverage. This proposed rule would presume that all Medicaid NFs are section 1819(a) facilities and this would not be considered a home for DME and home health coverage. This rule would identify non-Medicare nursing homes as skilled facilities based upon the receipt of skilled care by a proportion of their resident population that is at least comparable to the proportion typically found in participating Medicare SNFs. This proposed rule is part of the Department's regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 09/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: Undetermined

Agency Contact: Thomas Hoyer, Director, Office of Chronic Care and Insurance Policy, Department of Health and Human Services, Health Care Financing Administration, C4-02-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4605

RIN: 0938-AH16

1408. • MEDICARE COVERAGE OF LIVER TRANSPLANTATION (BPD-835-PN)

Priority: Other Significant

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

CFR Citation: None

Legal Deadline: None

Abstract: This notice announces proposed changes in Medicare's national coverage policy for liver transplantations. Currently, Medicare coverage for liver transplantation in adults is limited to seven diagnosis. This notice proposes to expand the diagnoses for which Medicare would

cover a liver transplant to include all end stage liver disease except malignancies, hepatitis B, and hemochromatosis. We are also proposing a change in the criteria for approval of a facility to perform liver transplants.

Timetable: Next Action Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Lana Price, Director, Division of End Stage Renal Disease, Bureau of Policy Development, Department of Health and Human Services, Health Care Financing Administration, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4533

RIN: 0938-AH17

1409. • PROVISIONS THAT ALLOW RURAL PRIMARY CARE HOSPITALS (RPHS) TO ENTER INTO SWING-BED AGREEMENTS (BPD-839-P)

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1395i-4

CFR Citation: 42 CFR 485.645

Legal Deadline: None

Abstract: This proposed rule would revise the provisions under which Rural Primary Care Hospitals (RPHs) are allowed to enter into swing-bed agreements. These changes are being made to conform the regulations to changes made by section 102(c) of Public Law 103-432. Changes are also being made to ensure consistent treatment of similar facilities, and to protect the health and safety of patients in RPH swing beds.

Timetable:

| Action | Date | FR Cite |
|--------------------------|----------|---------|
| NPRM | 04/00/96 | |
| Next Action Undetermined | | |

Small Entities Affected: Undetermined

Government Levels Affected: None

Agency Contact: George Morey, Office of Hospital Policy, Department of Health and Human Services, Health Care Financing Administration, C5-08-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4653

RIN: 0938-AH20

1410. • TRANSFER OF ASSETS FOR LESS THAN FAIR MARKET VALUE: MEDICAID PROGRAM (MB-095-P)

Priority: Other Significant

Legal Authority: 42 USC 1396p(c)

CFR Citation: 42 CFR 435; 42 CFR 436

Legal Deadline: None

Abstract: These regulations would conform the Medicaid regulations to section 1917(c) and (d) of the Social Security Act, as amended by section 13611 of OBRA 1993. Section 1917(c) of the Act addresses the treatment of transfers of assets for less than fair market value. These regulations would specify the conditions that would result in the denial of coverage for certain medical services to otherwise eligible individuals who transfer assets for less than fair market value. These regulations would also set forth the rules under which a trust must be considered in determining eligibility for Medicaid. The provisions would apply to any individual who established a trust and who is a Medicaid applicant or recipient.

Timetable: Next Action Undetermined

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Roy Trudel, Division of Eligibility Policy, Medicaid Bureau, Department of Health and Human Services, Health Care Financing Administration, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3417

RIN: 0938-AH23

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Health Care Financing Administration (HCFA)
Completed Actions
1411. CLARIFICATIONS OF MEDICARE'S ACCRUAL BASIS OF ACCOUNTING POLICY (BPD-366-F)
Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 413.24; 42 CFR 413.100
Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 06/27/95 | 60 FR 33126 |
| Final Action Effective | 07/27/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: John Eppinger
 Phone: 410 786-4518

RIN: 0938-AD01

1412. OPTIONAL PAYMENT SYSTEM FOR LOW MEDICARE VOLUME SKILLED NURSING FACILITIES (BPD-409-F)
Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 413.300; 42 CFR 413.302; 42 CFR 413.304; 42 CFR 413.308; 42 CFR 413.310; 42 CFR 413.312; 42 CFR 413.314; 42 CFR 413.316; 42 CFR 413.320; 42 CFR 413.321; 42 CFR 413.1; 42 CFR 413.24
Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 07/21/95 | 60 FR 37590 |
| Final Action Effective | 08/21/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Bob Kuhl
 Phone: 410 786-4597

RIN: 0938-AD02

1413. TRANSFER OF RESOURCES FOR LESS THAN FAIR MARKET VALUE (MB-10-P)
Priority: Other Significant

CFR Citation: 42 CFR 435; 42 CFR 436
Completed:

| Reason | Date | FR Cite |
|--|----------|---------|
| Withdrawn New regulation (MB-095-P) under development. | 01/12/95 | |

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Roy Trudel
 Phone: 410 786-3417

RIN: 0938-AD18

1414. PAYMENT FOR DURABLE MEDICAL EQUIPMENT AND ORTHOTIC AND PROSTHETIC DEVICES (BPD-494-F)
Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 414.220; 42 CFR 414.222; 42 CFR 414.226; 42 CFR 414.228; 42 CFR 414.229; 42 CFR 414.232
Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 07/10/95 | 60 FR 35402 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: William Long
 Phone: 410 786-5655

RIN: 0938-AD65

1415. UNIFORM ELECTRONIC COST REPORTING SYSTEM FOR HOSPITALS (BPD-689-F)
Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 413.24
Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 06/27/95 | 60 FR 33123 |
| Final Action Effective | 07/27/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Thomas Talbott
 Phone: 410 786-4592

RIN: 0938-AE80

1416. ALLOWING CERTIFICATIONS AND RECERTIFICATIONS BY NURSE PRACTITIONERS AND CLINICAL NURSE SPECIALISTS FOR CERTAIN SERVICES (BPD-709-FC)
Priority: Other Significant

CFR Citation: 42 CFR 424
Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 07/26/95 | 60 FR 38266 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Roberta Epps
 Phone: 410 786-4503

RIN: 0938-AF01

1417. MEDICAID THIRD PARTY LIABILITY: COST EFFECTIVENESS WAIVERS (MB-39-F)
Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 433.138; 42 CFR 433.139; 42 CFR 433.137
Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 07/10/95 | 60 FR 35498 |
| Final Action Effective | 09/08/95 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Richard Friedman
 Phone: 410 786-3292

RIN: 0938-AF11

1418. REQUIRED COVERAGE OF NURSE PRACTITIONER SERVICES—MEDICAID (MB-41-F)
Priority: Other Significant

CFR Citation: 42 CFR 440
Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 04/21/95 | 60 FR 19856 |
| Final Action Effective | 05/22/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Robert Wardwell
 Phone: 410 786-5659

RIN: 0938-AF12

1419. PHYSICIAN OWNERSHIP OF AND REFERRALS TO HEALTH CARE FACILITIES THAT FURNISH CLINICAL LABORATORY SERVICES AND FINANCIAL RELATIONSHIP REPORTING REQUIREMENTS (BPD-674-FC)
Priority: Other Significant

CFR Citation: 42 CFR 411
Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 08/14/95 | 60 FR 41914 |

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Betty Burrier
 Phone: 410 786-0191

RIN: 0938-AF40

HHS—HCFA

Completed Actions

1420. MEDICARE AND MEDICAID PROGRAMS; ADVANCE DIRECTIVES (BPD-718-F)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 417.436; 42 CFR 417.801; 42 CFR 431.20; 42 CFR 431.107; 42 CFR 434.28; 42 CFR 483.10; 42 CFR 484.10; 42 CFR 489.10; 42 CFR 489.100; 42 CFR 489.104; 42 CFR 498.3; 42 CFR 417.472; 42 CFR 489.102

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 06/27/95 | 60 FR 33262 |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Thomas Hoyer
 Phone: 410 786-5661
RIN: 0938-AF50

1421. CLARIFICATION OF RESUMPTION OF ENTITLEMENT RULES FOR MEDICARE PATIENTS WITH END-STAGE RENAL DISEASE (BPD-738-F)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 406.13

Completed:

| Reason | Date | FR Cite |
|------------------------|----------|-------------|
| Final Action | 05/08/95 | 60 FR 22533 |
| Final Action Effective | 06/07/95 | |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Paul Olenick
 Phone: 410 786-4472
RIN: 0938-AG19

1422. STANDARDS FOR QUALITY OF WATER USED IN DIALYSIS AND REVISED GUIDELINES ON REUSE OF HEMODIALYZER FILTERS FOR END-STAGE RENAL DISEASE PATIENTS (BPD-766-F)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 405.2140; 42 CFR 405.2150

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 09/18/95 | 60 FR 48039 |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Jackie Sheridan
 Phone: 410 786-4635
RIN: 0938-AG21

1423. COMMUNITY SUPPORTED LIVING ARRANGEMENTS SERVICES (MB-070-P)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 435.3; 42 CFR 435.260; 42 CFR 440.1; 42 CFR 440.190; 42 CFR 441.400; 42 CFR 441.402; 42 CFR 441.404; 42 CFR 441.406; 42 CFR 441.408; 42 CFR 441.410; 42 CFR 441.412; 42 CFR 441.414

Completed:

| Reason | Date | FR Cite |
|---|----------|---------|
| Withdrawn - Funding ceased to exist after 9/30/95 | 03/20/95 | |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Mary Jean Duckett
 Phone: 410 786-3294
RIN: 0938-AG35

1424. CONDITIONS FOR PAYMENT FOR PHYSICIANS' SERVICES IN TEACHING SETTINGS (BPD-792-P)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 405; 42 CFR 415; 42 CFR 400

Completed:

| Reason | Date | FR Cite |
|-----------------------------|----------|---------|
| Combined With RIN 0938-AG96 | 08/15/95 | |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: William Morse
 Phone: 410 786-4520
RIN: 0938-AG53

1425. DATE FOR FILING MEDICARE COST REPORTS (BPD-794-F)

Priority: Other
CFR Citation: 42 CFR 405.376; 42 CFR 413.24

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 06/27/95 | 60 FR 33137 |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Katie Walker
 Phone: 410 786-7278
RIN: 0938-AG55

1426. EXPANSION OF THE DEFINITION OF EYE AND EAR SPECIALTY HOSPITALS (BPD-804-P)

Priority: Substantive, Nonsignificant
CFR Citation: 42 CFR 413

Completed:

| Reason | Date | FR Cite |
|--|----------|---------|
| Withdrawn - Sunset date of legislation has been reached. | 08/16/95 | |

Small Entities Affected: None
Government Levels Affected: None
Agency Contact: Carolyn Mullen
 Phone: 410 786-4589
RIN: 0938-AG67

1427. CATEGORIZATION OF CLIA TESTS AND PERSONNEL MODIFICATIONS (HSQ-216-FC)

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

CFR Citation: 42 CFR 493.2; 42 CFR 493.3; 42 CFR 493.5; 42 CFR 493.45; 42 CFR 493.9; 42 CFR 493.47; 42 CFR 493.18; 42 CFR 493.19; 42 CFR 493.20; 42 CFR 493.49; 42 CFR 493.25; 42 CFR 493.35; 42 CFR 493.37; 42 CFR 493.39; 42 CFR 493.43; ...

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 04/24/95 | 60 FR 20035 |

Small Entities Affected: None
Government Levels Affected: State
Agency Contact: Judith Yost
 Phone: 410 786-3531
RIN: 0938-AG71

1428. CRITERIA FOR MEDICARE COVERAGE OF LUNG TRANSPLANTS (BPD-812-FN)

Priority: Other Significant
CFR Citation: None

Completed:

| Reason | Date | FR Cite |
|---|----------|---------|
| Withdrawn - Public comments received did not require revisions. | 08/10/95 | |

Small Entities Affected: Businesses

HHS—HCFA

Completed Actions

Government Levels Affected: None Phone: 410 786-5666
Agency Contact: Claude Mone RIN: 0938-AG83

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
 Administration for Children and Families (ACF)**

Proposed Rule Stage

1429. FOSTER CARE, ADOPTION ASSISTANCE, AND CHILD WELFARE SERVICES

Priority: Other Significant
Legal Authority: 42 USC 627; 42 USC 671; 42 USC 1320
CFR Citation: 45 CFR 1355; 45 CFR 1356; 45 CFR 1357
Legal Deadline: NPRM, Statutory, July 1, 1995.

Abstract: This NPRM will propose requirements that implement the statutory provisions of the Social Security Act Amendments of 1994 on review of State programs under Parts B and E of the Social Security Act for conformity with State Plan requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None
Government Levels Affected: State
Additional Information: This action was previously reported under RIN 0980-AA08.

Agency Contact: Daniel H. Lewis, Deputy Associate Commissioner, Children's, Bureau, Adm on Children, Youth & Families, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
 Phone: 202 205-8594
RIN: 0970-AA97

1430. BLOCK GRANT PROGRAMS (LOW INCOME HOME ENERGY ASSISTANCE PROGRAM—LIHEAP)—FY 1995 AND FY 1996 PROVISIONS

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 8621
CFR Citation: 45 CFR 96
Legal Deadline: None

Abstract: This Notice of Proposed Rulemaking will amend the DHHS block grant regulations to implement changes to the Low Income Home

Energy Assistance Program (LIHEAP) statute which were made by the Human Services Amendments of 1994 (Pub. L. 103-252). Several of the provisions in the new law are self-implementing, but a few require implementing regulations. The major provisions requiring implementing regulations are: (1) Inclusion of new Assurance 16, to require grantees to submit as a part of their annual application a description of their "self-sufficiency" activities and to submit a report to DHHS on the effect of these activities; (2) Inclusion of allowable uses of DOE rules for weatherization services provided with LIHEAP funds; (3) Inclusion for requirements for submission of data on households served. In addition, other related amendments to the regulations will be included, concerning the following issues: (1) Consideration of different weighting of factors under the allocation formula for the leveraging incentive program; (2) Hearing requirements for audit disallowances; and (3) Allotments for territories requirements.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: None
Government Levels Affected: State, Tribal
Agency Contact: Janet M. Fox, Director, Division of Energy Assistance, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
 Phone: 202 401-9351
RIN: 0970-AB47

1431. ADMINISTRATIVE FLEXIBILITY RULE

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 205.31

Legal Deadline: None

Abstract: This proposed rule adds a new section 205.31 which will provide a simple administrative process for requesting waivers of certain AFDC regulatory provisions. Such waivers will give States more flexibility to devise procedures for the effective and efficient administration of their AFDC programs. The major provisions for which waivers will be granted are: (1) the requirements for prospective budgeting of income; (2) the time period for calculating the total amount of overpayment and the determination of when the initial overpayment begins; and (3) other provisions on various disregards and self-employment business expenses.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None
Government Levels Affected: State

Agency Contact: Mack Storrs, Director, Division of AFDC Program, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
 Phone: 202 401-9289

RIN: 0970-AB49

1432. DESIGNATION OF ALTERNATIVE AGENCY TO SERVE INDIAN TRIBAL CHILDREN

Priority: Substantive, Nonsignificant
Legal Authority: 42 USC 9801
CFR Citation: 45 CFR 1302
Legal Deadline: None

Abstract: This NPRM will specify a process by which an Indian tribe may identify and establish an alternative agency to provide Head Start Services if the agency previously serving the tribe is terminated.

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Proposed Rule Stage

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 02/00/96 | |

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB52

1433. CONSTRUCTION OF HEAD START FACILITIES

Priority: Other Significant

Legal Authority: 42 USC 9801

CFR Citation: 45 CFR 1309

Legal Deadline: None

Abstract: This NPRM will establish procedures to be used by Head Start agencies in requesting to use Head Start grant funds to construct or renovate a Head Start facility.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 01/00/96 | |

Small Entities Affected: Governmental Jurisdictions, Organizations

Government Levels Affected: Local, Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start, Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB54

1434. QUALITY STANDARDS FOR HEAD START PROGRAMS

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

RIN: 0970-AB55

1435. HEAD START FELLOWSHIPS PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 9801

CFR Citation: 45 CFR 1311

Legal Deadline: None

Abstract: This NPRM will establish the policies and procedures to be used in selecting individuals to be part of the Head Start Fellowship Program.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/95 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB56

1436. REPORTING OVERDUE SUPPORT INFORMATION TO CONSUMER REPORTING AGENCIES

Priority: Substantive, Nonsignificant

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

Legal Authority: PL 103-432

CFR Citation: 45 CFR 302; 45 CFR 303

Legal Deadline: None

Abstract: This rule contains provisions regarding required State laws for reporting information concerning unpaid child support obligations to consumer reporting agencies. These provisions implement the requirements of section 212 of the Social Security Act Amendments of 1994, which amend title IV-D of the Social Security Act. These provisions require States to adopt procedures for periodic reporting of information to consumer reporting agencies. This regulatory package will also include technical changes to other child support regulations to support the

President's Regulatory reinvention initiative.

Timetable:

| Action | Date | FR Cite |
|--------------------|----------|---------|
| NPRM | 12/00/95 | |
| Interim Final Rule | 10/00/96 | |

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Local

Agency Contact: Marianne Upton, Branch Chief, Policy Division, Office of Child Support Enforcement, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-5373

RIN: 0970-AB57

1437. • ON-SITE FOSTER CARE ELIGIBILITY REVIEWS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 1356

Legal Deadline: None

Abstract: This NPRM will propose requirements that govern on-site eligibility reviews that the Administration for Children and Families conducts to assure State agencies' compliance with the statutory requirements under Title IV-E of the Social Security Act for eligibility of foster care providers and eligibility of the children in foster care.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 04/00/96 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Daniel H. Lewis, Deputy Associate, Commissioner, Children's Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8594

RIN: 0970-AB60

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Final Rule Stage

1438. AMENDMENTS TO DEVELOPMENTAL DISABILITIES RULES**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 6000 et seq**CFR Citation:** 45 CFR 1385; 45 CFR 1386; 45 CFR 1387; 45 CFR 1388**Legal Deadline:** Final, Statutory, April 29, 1991.

Final, Statutory, October 3, 1994.

Abstract: This rule updates current rules with clarifications and new requirements to implement recent changes in the Developmental Disabilities Assistance and Bill of Rights Act Amendments of 1990 (Pub. L. 101-496) and 1994 (Pub. L. 103-230).**Timetable:**

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 05/18/95 | 60 FR 26774 |
| Final Action | 05/00/96 | |

Small Entities Affected: None**Government Levels Affected:** State**Additional Information:** This action was previously reported under RIN 0980-AA48.**Agency Contact:** John Doyle, Director, Administration and Planning Staff, Administration on Developmental Disabilities, Department of Health and Human Services, Administration for Children and Families, 200 Independence Avenue SW., Room 315D, Washington, DC 20201
Phone: 202 690-5504**RIN:** 0970-AB11**1439. FAMILY VIOLENCE PREVENTION AND SERVICES****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 10407**CFR Citation:** 45 CFR 1370**Legal Deadline:** NPRM, Statutory, August 26, 1992. Final, Statutory, September 25, 1992.**Abstract:** Would implement the requirements under the Family Violence Prevention and Services Act which provides various grants related to domestic violence.**Timetable:**

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 12/10/93 | 58 FR 64920 |
| Final Action | 12/00/95 | |

Small Entities Affected: Governmental Jurisdictions, Organizations**Government Levels Affected:** State, Local**Agency Contact:** Margaret Washnitzer, Director, Division of State Assistance, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-2333**RIN:** 0970-AB18**1440. CHILD ABUSE AND NEGLECT STATE GRANT PROGRAM****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 5101**CFR Citation:** 45 CFR 1340**Legal Deadline:** None**Abstract:** The primary purpose of this rule is to revise existing regulations at 45 CFR 1340 in order to implement recent amendments to the Child Abuse Prevention and Treatment Act with respect to confidentiality requirements.**Timetable:**

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 05/18/94 | 59 FR 26046 |
| Final Action | 02/00/96 | |

Small Entities Affected: None**Government Levels Affected:** State**Agency Contact:** Emily Cooke, Acting Director, National Center on Child Abuse and Neglect, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8586**RIN:** 0970-AB23**1441. STANDARDS FOR SAFE TRANSPORTATION****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1310**Legal Deadline:** None**Abstract:** This rule establishes Head Start Performance Standards for the safe transportation of Head Start children, including vehicle requirements, driver qualifications and training and safety rules for children and staff while enroute and loading and unloading of vehicles.**Timetable:**

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 06/15/95 | 60 FR 31612 |
| Final Action | 06/00/96 | |

Small Entities Affected: Organizations**Government Levels Affected:** None**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569**RIN:** 0970-AB24**1442. STANDARDS FOR PURCHASE OF FACILITIES****Priority:** Other Significant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1309**Legal Deadline:** None**Abstract:** This regulation established standards for the purchase of facilities as required by the Head Start Improvement Act of 1992.**Timetable:**

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 12/01/94 | 59 FR 61575 |
| Final Action | 01/00/96 | |

Small Entities Affected: Organizations**Government Levels Affected:** None**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569**RIN:** 0970-AB31**1443. NATIONAL VOTER REGISTRATION ACT OF 1993 PROVISIONS AFFECTING PUBLIC ASSISTANCE AGENCIES****Priority:** Other Significant**Legal Authority:** PL 103-31**CFR Citation:** 45 CFR 205.50 (a)(4); 45 CFR 206.10; 42 CFR 431.307 (a); 42 CFR 431.307 (b)**Legal Deadline:** None**Abstract:** Incorporates general guidance for public assistance agencies regarding registration procedures to be carried out by State Public Assistance offices. It

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Final Rule Stage

removes former prohibitions from distributing such materials in these offices.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 11/22/94 | 59 FR 60109 |
| Final Action | 12/00/95 | |

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Local

Agency Contact: Mack Storrs, Director, Division of AFDC Program, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9289

RIN: 0970-AB32

1444. CHILD CARE—REVISED REGULATIONS

Priority: Other Significant

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 98.255; 45 CFR 98.256; 45 CFR 98.257

Legal Deadline: None

Abstract: The Administration for Children and Families will amend existing regulations which govern the administration of child care programs under Title IV-A of the Social Security Act (AFDC Child Care, Transitional Child Care, At-Risk Child Care) and the Child Care and Development Block Grant. Based on recent legislative changes, as well as comments from state and tribal program administrators, child care advocates and other interested parties, we are examining a number of specific regulatory provisions. The purpose of this regulatory package will be to implement legislative changes, reduce program differences, and promote better program coordination. We do not expect these changes to result in significant program costs; administrative savings may result.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 05/11/94 | 59 FR 24510 |
| Final Action | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: Undetermined

Agency Contact: Olivia M. Golden, Commissioner, Administration on Children, Youth and Families, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8572

RIN: 0970-AB33

1445. FAMILY PRESERVATION AND SUPPORT

Priority: Other Significant

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

Legal Authority: 42 USC 430 to 435

CFR Citation: 45 CFR 1355; 45 CFR 1356; 45 CFR 1357

Legal Deadline: None

Abstract: This rule will amend the requirements under title IV-B subpart 1 for the Child and Family Services State plan and set forth the requirements the State must adhere to in the development and submission of its comprehensive five year plan under title IV-B, subpart 2, family preservation and support services. The submission of this jointly developed plan is required in order to receive both child and family services funds under subpart 1 and family preservation and support services funds under subpart 2 for fiscal years 1995 and following.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 10/04/94 | 59 FR 50646 |
| Final Action | 01/00/96 | |

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Daniel H. Lewis, Deputy Associate Commissioner, Children's Bureau, ACYF, Department of Health and Human Services,

Administration for Children and Families, P.O. Box 1182, Washington, DC 20013

Phone: 202 205-8618

RIN: 0970-AB34

1446. ADMINISTRATION OF NATIVE AMERICANS 45 CFR PART 1336

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 2991

CFR Citation: 45 CFR 1336

Legal Deadline: None

Abstract: This regulation amends 45 CFR part 1336 to implement legislative requirements. It will incorporate an appeals procedure affording applicants the opportunity to appeal based on organizational ineligibility or activities deemed ineligible, when determined by the ANA Commissioner. Native American organizations are expected to welcome these changes which provide for an appeal of appeals decisions and comport with amendments to the statute.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 04/21/95 | 60 FR 19994 |
| Final Action | 11/00/95 | |

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: Sharon McCully, Director, Planning and Support, Department of Health and Human Services, Administration for Children and Families, 200 Independence Ave SW., Washington, DC 20201
Phone: 020 690-5780

RIN: 0970-AB37

1447. REDUCTION OF REPORTING REQUIREMENTS FOR THE STATE SYSTEMS ADVANCE PLANNING DOCUMENT (APD) PROCESS

Priority: Other Significant

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 95.600

Legal Deadline: None

Abstract: These rules decrease the reporting burden on States and increase

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their flexibility within the State systems APD process by increasing the threshold under which APDs and related procurement documents need not be submitted for Federal approval. Additionally, States will no longer be required to submit biennial security plans for Federal review and approval.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|------------|
| NPRM | 07/21/95 | 60 FR 7858 |
| Final Action | 07/00/96 | |

Small Entities Affected: Undetermined

Government Levels Affected: None

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

Agency Contact: Bill Davis, Management Analyst, Department of Health and Human Services,

Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-6404

RIN: 0970-AB46

1448. INCOME AND RESOURCE DISREGARDS RELATED TO INTERESTS OF INDIVIDUAL INDIANS IN TRUST OR RESTRICTED LANDS

Priority: Substantive, Nonsignificant

Legal Authority: PL 103-66

CFR Citation: 45 CFR 233

Legal Deadline: None

Abstract: These rules incorporate statutory disregards in the AFDC program and the Adult Assistance programs in Guam, Puerto Rico and the Virgin Islands. The first provides that up to \$2,000 per year of income derived from interests of individual Indians in trust or restricted lands shall

not be considered in determining assistance. The second is a provision requiring that interests of individual Indians in trust or restricted lands shall not be considered a resource in determining eligibility for assistance.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| NPRM | 10/25/94 | 59 FR 51536 |
| Final Action | 02/00/96 | |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Mack A. Storrs, Director, Division of AFDC Program, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401-9289

RIN: 0970-AB59

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Long-Term Actions

Administration for Children and Families (ACF)

1449. INCOME ELIGIBILITY CRITERIA FOR INDIAN TRIBES

Priority: Substantive, Nonsignificant

Legal Authority: 45 USC 9801

CFR Citation: 45 CFR 1305

Legal Deadline: None

Abstract: This NPRM will revise the income eligibility criteria used in enrolling Head Start children and

families to allow Indian tribes, in certain situations, to enroll more children whose families do not meet Head Start's income criteria than would otherwise be possible.

Timetable:

| Action | Date | FR Cite |
|--------|----------|---------|
| NPRM | 12/00/96 | |

Small Entities Affected: Organizations

Government Levels Affected: Tribal

Agency Contact: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Department of Health and Human Services, Administration for Children and Families, P.O. Box 1182, Washington, DC 20013
Phone: 202 205-8569

RIN: 0970-AB53

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Completed Actions

Administration for Children and Families (ACF)

1450. BLOCK GRANT PROGRAMS (LOW-INCOME HOME ENERGY ASSISTANCE PROGRAM—LIHEAP) FY 91 AND FY 92 PROVISIONS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 96

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/01/95 | 60 FR 21322 |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Janet M. Fox
Phone: 202 401-9351

RIN: 0970-AB15

1451. BLOCK GRANT PROGRAMS (LOW-INCOME HOME ENERGY ASSISTANCE PROGRAM—LIHEAP)—FY 93 AND FY 94 PROVISIONS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 96

Completed:

| Reason | Date | FR Cite |
|--|----------|---------|
| Withdrawn - Responsibility is transferred to ASPE. | 10/01/95 | |

Small Entities Affected: None

Government Levels Affected: State

Agency Contact: Janet M. Fox

Phone: 202 401-9351

RIN: 0970-AB16

1452. STATEWIDE AUTOMATED CHILD WELFARE INFORMATION SYSTEM

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1355; 45 CFR 1356

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/19/95 | 60 FR 26829 |

Small Entities Affected: None

Government Levels Affected: None

HHS—ACF

Completed Actions

Agency Contact: Naomi B. Marr
 Phone: 202 401-6960
RIN: 0970-AB38

1453. REFUGEE RESETTLEMENT PROGRAM: MISCELLANEOUS, COMPREHENSIVE CHANGES

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

CFR Citation: 45 CFR 400

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 06/28/95 | 60 FR 33617 |

Small Entities Affected: None

Government Levels Affected: State, Local

Agency Contact: Toyo A. Biddle
 Phone: 202 401-9250

RIN: 0970-AB42

1454. DIRECT PAYMENTS TO INDIAN TRIBES AND TRIBAL ORGANIZATIONS UNDER TITLE IV-B, SUBPART 1

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1357.40

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 06/22/95 | 60 FR 28735 |

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Michael Ambrose
 Phone: 202 205-8618

RIN: 0970-AB44

1455. REPATRIATION - ADVANCE APPROVAL OF COSTS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 212

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 04/21/95 | 60 FR 19862 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: David B. Smith

Phone: 202 401-9255
RIN: 0970-AB45

1456. AFCARS DATA ELEMENT ON FOSTER CARE PAYMENTS

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1355

Completed:

| Reason | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 08/09/95 | 60 FR 40505 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Daniel H. Lewis
 Phone: 202 205-8619

RIN: 0970-AB58

1457. • REMOVAL OF KEYS AMENDMENT REGULATIONS

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: 42 USC 1302

CFR Citation: 45 CFR 1397

Legal Deadline: None

Abstract: Effective March 31, 1995, the Social Security Administration has responsibility for the Key Amendments as part of the independent agency legislations. We are eliminating these Departmental rules so that Social Security can proceed with their own regulations and guidance.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/16/95 | 60 FR 26000 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Madeline Mocko, Director, Office of Legislation and Budget, Department of Health and Human Services, Administration for Children and Families, 370 L'enfant Promenade SW., WWashington, DC 20447

Phone: 202 401-9223

RIN: 0970-AB61

1458. • REMOVAL OF OBSOLETE FAMILY ASSISTANCE REGULATION

Priority: Substantive, Nonsignificant

Reinventing Government: This rulemaking is part of the Reinventing

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 205; 45 CFR 224; 45 CFR 233; 45 CFR 238; 45 CFR 239; 45 CFR 240; 45 CFR 282

Legal Deadline: None

Abstract: This notice removes several obsolete provisions from the Code of Federal Regulations. Most involve work program activities which were superseded when State welfare agencies began their JOBS programs in 1989 and 1990.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/17/95 | 60 FR 26373 |

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Maneline Mocko, Director, Office of Legislation and Budget, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447
 Phone: 202 401-9223

RIN: 0970-AB62

1459. • ELIMINATION OF OBSOLETE BLOCK GRANT RULES

Priority: Substantive, Nonsignificant

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

Legal Authority: 42 USC 9912

CFR Citation: 45 CFR 1010; 45 CFR 1050; 45 CFR 1060; 45 CFR 1061; 45 CFR 1064; 45 CFR 1067; 45 CFR 1068; 45 CFR 1069; 45 CFR 1070; 45 CFR 1076

Legal Deadline: None

Abstract: This final rule removes a number of obsolete provisions from the Code of Federal Regulations. These provisions concern program activities under the former Community Services Administration (CSA) which were superseded by Community Services Block Grant Act, enacted as part of the Omnibus Budget Reconciliation Act of 1981.

Timetable:

| Action | Date | FR Cite |
|--------------|----------|-------------|
| Final Action | 05/17/95 | 60 FR 26374 |

Small Entities Affected: None

HHS—ACF

Completed Actions

Government Levels Affected: None

Budget, Department of Health and Human Services, Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447

Phone: 202 401-9223

Agency Contact: Madeline Mocko, Director, Office of Legislation and

RIN: 0970-AB63

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Administration on Aging (AOA)**

Long-Term Actions

1460. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, INTRASTATE FUNDING FORMULAS; TRAINING, RESEARCH AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; AND GRANTS TO INDIANS & NATIVE HAWAIIANS

Priority: Substantive, Nonsignificant

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

Legal Authority: PL 102-375, sec 202(a)(10); PL 102-375, sec 202(a)(14); PL 102-375, sec 305(a); PL 102-375, sec 305(a)(1); PL 102-375, sec 305(a)(2)(c); PL 102-375, sec 305(a)(2); PL 102-375, sec 305(a)(2)(D); PL 102-375, sec 305(a)(1)(E); PL 102-375, sec 305(a)(2)(E); PL 102-375, secs 305(d)(1) to 305(d)(4); PL 102-375, sec 305(a)(A)(i); PL 102-375, sec

306(a)(6)(O)(i); PL 102-375, sec 306(a)(13); PL 102-375, sec 307(a)(1); PL 102-375, sec 307(a)(C)(i)

CFR Citation: 45 CFR 1321; 45 CFR 1324; 45 CFR 1326; 45 CFR 1327; 45 CFR 1328

Legal Deadline: None
Unknown until law is reauthorized.

Abstract: The Administration on Aging (AoA) anticipates revising current rules to reflect the changes resulting from the pending reauthorization of the Older Americans Act which incorporates greater flexibility for the States.
PURPOSE: The purpose of these revisions are to implement the newly enacted law. in the development and provision of community-based services.

Timetable:

| Action | Date | FR Cite |
|--------------------------------|--|---------|
| Elder Rights Protection | | |
| | NPRM 11/15/94 (59 FR 59056) | |
| | NPRM Comment Period End 01/17/95 (59 FR 59056) | |

Intrastate Funding Formulas

NPRM 10/17/94 (59 FR 12728)
Final Action 08/01/95

OAA Amendments in FY '96

NPRM 08/01/96
Next Action Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Agency Contact: Edwin Walker, Director, Office of Program Development and Operations, Department of Health and Human Services, Administration on Aging, 330 Independence Avenue SW., Room 4733, Cohen Bldg., Washington, DC 20201

Phone: 202 619-0011

RIN: 0985-AA00

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