



# Federal Register

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**Monday,  
May 14, 2001**

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**Part VIII**

**Department of  
Health and Human  
Services**

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**Semiannual Regulatory Agenda**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**21 CFR Ch. I**

**42 CFR Chs. I-V**

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

**Unified Agenda of Federal Regulatory and Deregulatory Actions**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Semiannual regulatory agenda.

**SUMMARY:** The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the semiannual publication of an agenda outlining all current and projected rulemakings. The purpose of this exercise is to inform the public about regulatory actions under development within the Department, and to provide an opportunity for all concerned with the impact of these regulations to participate in their development at an early stage. The last such agenda was published on November 30, 2000.

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

**SUPPLEMENTARY INFORMATION:** The regulatory actions capsulized below do not necessarily reflect the new policy perspectives of the Bush administration and HHS Secretary Thompson. The statutorily dictated timing of the regulatory agenda caused the

Department to begin its efforts to put together information required for the agenda well before the new Administration came into place. The following agenda thus simply reflects ongoing efforts by HHS to comply with many longstanding statutory obligations, and/or to effect improvements at the program-implementation level based on the Department's experience in administering existing programs. The timing of the October 2001 agenda will, obviously, provide the Department with an opportunity to set out a regulatory agenda that does reflect the policy directions that Secretary Thompson desires to take.

Public commentary is invited. Comments should be sent to the addresses listed below, depending on the specific agenda entry that is of interest. Comments may be sent to the Office of the Secretary if the responsible component of the Department is not apparent, or if a comment covers subjects crossing agency lines.

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: Harry Posman, Executive Secretariat, Room 4753, 330 Independence Avenue SW., Washington, DC 20201; Phone 202-260-0669.

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

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

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

Health Care Financing Administration: Anthony Mazzarella, Deputy Director, Operation Support Group, 7500 Security Boulevard, C4-26-05, Baltimore, Maryland 21244; Phone 410-786-7501.

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

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

National Institutes of Health: Jerry Moore, 9000 Rockville Pike, Building 31, Room 1B25, Bethesda, Maryland 20205; Phone 301-496-4606.

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

Office of the Secretary: Ann C. Agnew, Executive Secretary to the Department, Room 603H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

**Dated:** March 14, 2001.

**Ann C. Agnew,**

*Executive Secretary to the Department.*

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

Sequence Number	Title	Regulation Identification Number
813	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants) .....	0991-AB12

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

Sequence Number	Title	Regulation Identification Number
814	Reproduction and Sale of Official Forms and Publications .....	0991-AA83
815	Shared Risk Exception to the Safe Harbor Provisions .....	0991-AA91
816	Civil Money Penalty Safe Harbor To Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries .....	0991-AB04
817	Safe Harbor for Ambulance Restocking .....	0991-AB05

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## Office of the Secretary—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
818	Revisions and Technical Corrections to 42 CFR Chapter V .....	0991-AB09
819	Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987 .....	0991-AB10

## Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
820	Civil Money Penalties for Medicare+Choice Organizations and Medicaid Managed Care Organizations .....	0991-AB03
821	Safe Harbor for Arrangements Involving Federally Qualified Health Centers .....	0991-AB06
822	Definition of Terms; Substantially in Excess and Usual Charges and Clarification of the Good Cause Exception .....	0991-AB13

## Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
823	Standards for Privacy of Individually Identifiable Health Information .....	0991-AB08

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

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

## Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
825	Final and Delegation of Authority To Implement SAMHSA's Accreditation Based System for Opioid Treatment Program Monitoring .....	0930-AA06

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

Sequence Number	Title	Regulation Identification Number
826	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices .....	0920-AA04
827	Methods for Estimating Radiation Dose and Guidelines for Assessing Probability of Cancer for Energy Employees Occupational Illness Compensation Program .....	0920-AA05

## Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
828	Packaging and Handling of Infectious Substances and Select Agents .....	0920-AA02
829	Control of Communicable Diseases .....	0920-AA03

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Departmental Management—Proposed Rule Stage

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

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
831	Natural Rubber-Containing Drugs; User Labeling .....	0910-AB56
832	Implementation of the Import Tolerance Provisions of the Animal Drug Availability Act of 1996 .....	0910-AB71
833	Part 600-Biological Products: General ( <b>Section 610 Review</b> ) .....	0910-AC06

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
834	Over-the-Counter (OTC) Drug Review .....	0910-AA01
835	Hearing Aids; Professional and Patient Labeling; Conditions for Sale .....	0910-AA39
836	Establishment Registration and Product Listing for Drugs and Biologics .....	0910-AA49
837	Investigational New Drugs: Export Requirements for Unapproved New Drug Products .....	0910-AA61
838	Safety Reporting and Recordkeeping Requirements for Marketed OTC Drugs .....	0910-AA86
839	Safety Reporting Requirements for Human Drug and Biological Products .....	0910-AA97
840	Radioactive Drugs for Basic Research .....	0910-AB00
841	Administrative Practices and Procedures; Advisory Opinions and Guidelines .....	0910-AB14
842	Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products .....	0910-AB28
843	Applications for FDA Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications .....	0910-AB34
844	Expanded Access to Investigational Therapies .....	0910-AB37
845	Electronic Submission of Adverse Drug Reaction Reports .....	0910-AB42
846	Distinguishing Marks for Drug Products Containing Insulin .....	0910-AB43
847	Pregnancy Labeling .....	0910-AB44
848	Positron Emission Tomography Drugs; Current Good Manufacturing Practices .....	0910-AB63
849	Current Good Manufacturing Practice for Medicated Feeds .....	0910-AB70
850	Fixed-Combination Prescription and Over-the-Counter Drugs for Human Use .....	0910-AB79
851	Repackaging Approval Requirements .....	0910-AB81
852	Stability Testing of Drugs .....	0910-AB82
853	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements .....	0910-AB88
854	Submission in Electronic Format of Certain Labeling Information .....	0910-AB91
855	Fees Relating to Drugs; Waiver and Reduction of Fees .....	0910-AB92
856	Periodic Testing for Certain Human Drug, Veterinary Drug, and Biological Product Final Specifications .....	0910-AB93
857	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection with Imported Food ..	0910-AB96
858	Medical Devices, Medical Device Establishment Registration and Listing Requirements; Amendment .....	0910-AB99
859	Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Gene Therapy or Xenotransplantation .....	0910-AC00
860	Reporting Information Regarding Potential Fabrication or Falsification of Data .....	0910-AC02
861	Status Reports for Quantity Marketed Information for Animal Drug Products Used in Food-Producing Animals .....	0910-AC04
862	Labeling Dietary Supplements for Women Who Are or May Become Pregnant .....	0910-AC09
863	Overwrap for Inhalation Products Packaged in Low Density Polyethylene (LDPE) Containers .....	0910-AC10
864	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of "No Residue" .....	0910-AC13
865	Control of Salmonella Enteritidis in Shell Eggs During Production and Retail .....	0910-AC14
866	Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition .....	0910-AC18
867	Use of Materials Derived from Ruminant Animals in FDA Regulated Products .....	0910-AC19
868	Postmarketing Reports of Substandard or Ineffective Bulk Ingredients and Bulk Ingredients from Unapproved Sources .....	0910-AC20

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## Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
869	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) .....	0910-AA02
870	Current Good Manufacturing Practice; Amendment of Certain Requirements for Finished Pharmaceuticals .....	0910-AA45
871	Bioavailability and Bioequivalence Requirements .....	0910-AA51
872	Labeling for Human Prescription Drugs; Revised Format .....	0910-AA94
873	Current Good Manufacturing Practice; Revision of Certain Labeling Controls .....	0910-AA98
874	Use of Ozone-Depleting Substances .....	0910-AA99
875	Exports; Notification and Recordkeeping Requirements .....	0910-AB16
876	Foreign Establishment Registration and Listing .....	0910-AB21
877	FDA Export Reform and Enhancement Act of 1996; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Later Export .....	0910-AB24
878	Blood Initiative .....	0910-AB26
879	Antibiotic Drug Approval and Exclusivity .....	0910-AB33
880	Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs .....	0910-AB39
881	Supplements and Other Changes to Approved New Animal Drug Applications .....	0910-AB49
882	Revisions to the General Safety Requirements for Biological Products; Direct Final Rule .....	0910-AB51
883	Discontinuation of a Lifesaving Product .....	0910-AB60
884	Supplements and Other Changes to an Approved Application .....	0910-AB61
885	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims .....	0910-AB66
886	Presubmission Conferences .....	0910-AB68
887	Surgeon's and Patient Examination Gloves; Reclassification .....	0910-AB74
888	CGMPs for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV (Lookback) .....	0910-AB76
889	Antibiotic Resistance Labeling .....	0910-AB78
890	180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications .....	0910-AB80
891	Food Additives: Food Contact Substances Notification System .....	0910-AB94
892	State Certification of Mammography Facilities .....	0910-AB98
893	Examination of Administrative Record and Other Advisory Committee Records .....	0910-AC03
894	Efficacy Evidence Needed for Products to be Used Against Toxic Substances When Human Studies Are Unethical .....	0910-AC05
895	Additional Safeguards for Children in Clinical Investigations of FDA Regulated Products .....	0910-AC07
896	Implementing Court Decisions, ANDA Approvals, and 180-Day Exclusivity .....	0910-AC11
897	Revocation of Conditions for Marketing Digoxin Products for Oral Use .....	0910-AC12

## Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
898	Infant Formula: Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports .....	0910-AA04
899	Food Labeling Review .....	0910-AA19
900	Medical Foods .....	0910-AA20
901	Classification of Computer Software Programs That Are Medical Devices .....	0910-AA41
902	Reinventing FDA Food Regulations .....	0910-AA58
903	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients .....	0910-AA89
904	Direct-to-Consumer Promotion Regulations .....	0910-AA90
905	Investigational Use New Animal Drug Regulations ( <b>Section 610 Review</b> ) .....	0910-AB02
906	Suitability Determination for Donors of Human Cellular and Tissue-Based Products .....	0910-AB27
907	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed .....	0910-AB50
908	Bulk Drug Substances for Use in Pharmacy Compounding .....	0910-AB57
909	Pharmacy and Physician Compounding of Drug Products .....	0910-AB58
910	Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness .....	0910-AB59
911	Mandatory HACCP Regulations for Manufacturers of Rendered Products .....	0910-AB72
912	Citizen Petitions; Actions That Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action .....	0910-AB73
913	Substances Prohibited From Use in Animal Food or Feed .....	0910-AB90

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

Sequence Number	Title	Regulation Identification Number
914	Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Rejected Admission into the United States .....	0910-AB95
915	Addition to the List of Drug Products That Have Been Withdrawn From the Market for Reasons of Safety or Effectiveness .....	0910-AC01
916	Addition to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness .....	0910-AC08
917	Premarket Notice Concerning Bioengineered Foods .....	0910-AC15
918	Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures .....	0910-AC16
919	Institutional Review Boards: Registration Requirements .....	0910-AC17
920	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived from Exposed Animal Populations .....	0910-AC21

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
921	Biological Products: Reporting of Biological Product Deviations in Manufacturing .....	0910-AA12
922	Fruit and Vegetable Juices: Development of HACCP and Label Warning Statements for Juices .....	0910-AA43
923	Drugs Used for Treatment of Narcotic Addicts .....	0910-AA52
924	Establishment Registration and Listing of Human Cells, Tissues, and Cellular and Tissue-Based Products .....	0910-AB05
925	Veterinary Feed Directives .....	0910-AB09
926	Shell Eggs: Warning, Notice and Safe Handling Labeling Statements and Refrigeration Requirements .....	0910-AB30
927	Postmarketing Studies for Human Drugs and Licensed Biological Products: Status Reports .....	0910-AB83
928	Current Good Manufacturing Practice for Blood and Blood Components; Blood Labeling Standards .....	0910-AB89

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
929	Designation of Medically Underserved Populations and Health Professional Shortage Areas .....	0906-AA44
930	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table .....	0906-AA55

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
931	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements .....	0906-AA41
932	Compliance Alternatives for Provision of Uncompensated Services .....	0906-AA52
933	Final Rule for the Health Professions, Nursing, Public Health, and Allied Health Training Grant Programs Under 42 CFR Parts 57 and 58 .....	0906-AA53

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
934	Ricky Ray Hemophilia Relief Fund Program .....	0906-AA56

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## Indian Health Service—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
935	Tribal Self-Governance Amendments .....	0917-AA05

## Indian Health Service—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
936	Indian Child Protection and Family Violence Prevention Act Minimum Standards of Character .....	0917-AA02

## Indian Health Service—Completed Actions

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

## National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
938	National Institutes of Health AIDS Research Loan Repayment Program .....	0925-AA02
939	Undergraduate Scholarship Program Regarding Professions Needed by the NIH .....	0925-AA10
940	National Cancer Institute Clinical Cancer Education Program .....	0925-AA17
941	National Institutes of Health Loan Repayment Program for Research .....	0925-AA18
942	NIH Center Grants .....	0925-AA24
943	National Institutes of Health Clinics Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds .....	0925-AA25
944	NIH Loan Repayment Program for Minority Health Disparities Research .....	0925-AA26
945	Pediatric Research Loan Repayment Program .....	0925-AA27
946	NIH Training Grants .....	0925-AA28

## National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
947	National Research Service Awards .....	0925-AA16
948	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program .....	0925-AA19
949	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects .....	0925-AA20

## National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identification Number
950	Traineeships .....	0925-AA11
951	Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization .....	0925-AA14
952	Federal Policy (Common Rule) for the Protection of Human Subjects .....	0925-AA21

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

Sequence Number	Title	Regulation Identification Number
953	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers .....	0940-AA01
954	Federal Policy (Common Rule) for the Protection of Human Subjects .....	0940-AA03

## Office of Public Health and Science—Completed Actions

Sequence Number	Title	Regulation Identification Number
955	Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human In Vitro Fertilization .....	0940-AA02

## Health Care Financing Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
956	End Stage Renal Disease (ESRD) Conditions for Coverage (HCFA-3818-P) ( <b>Section 610 Review</b> ) .....	0938-AG82
957	Recognition of the American Osteopathic Association for Critical Access Hospitals (HCFA-2099-PN) .....	0938-AK84

## Health Care Financing Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
958	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities-Update (HCFA-1163-P) .....	0938-AK47

## Health Care Financing Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
959	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (HCFA-6007-F) .....	0938-AD95
960	Medicaid Payment for Covered Outpatient Drugs Under Rebate Agreements (HCFA-2046-FC) .....	0938-AF42
961	Revision of Medicare/Medicaid Hospital Conditions of Participation (HCFA-3745-F) .....	0938-AG79
962	Home Health Agency (HHA) Conditions of Participation (HCFA-3819-F) .....	0938-AG81
963	Liability for Third Parties To Pay for Services (HCFA-2080-P) .....	0938-AH01
964	Criteria for Approval of Facilities to Perform Covered Heart, Liver, Lung, Pancreas and Intestinal Transplants (HCFA-3835-P) .....	0938-AH17
965	Hospice Care-Conditions of Participation (HCFA-3844-P) .....	0938-AH27
966	Requirements for Enrollment of Medicaid Recipients Under Cost Effective Employer-Based Group Health Plans (HCFA-2047-F) .....	0938-AH48
967	Terms, Definitions, and Addresses: Technical Amendments (HCFA-9877-FC) .....	0938-AH53
968	Requirements for Establishing and Maintaining Medicare Billing Privileges (HCFA-6002-P) .....	0938-AH73
969	Update of Ratesetting Methodology, Payment Rates and the List of Covered Surgical Procedures for Ambulatory Surgical Centers (HCFA-1885-FC) .....	0938-AH81
970	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (HCFA-3887-P) .....	0938-AH83
971	National Standard for Identifiers of Health Plans (HCFA-4145-P) .....	0938-AH87
972	Standard Unique Health Care Provider Identifier (HCFA-0045-F) .....	0938-AH99
973	Medicaid: Medical Child Support (HCFA-2081-P) .....	0938-AI21
974	Surety Bond Requirements for Comprehensive Outpatient Rehabilitation Facilities, Rehabilitation Agencies (HCFA-6005-P) .....	0938-AI48
975	Appeals of Carrier Determination That a Physician or Other Supplier Fails To Meet the Requirements for Medicare Billing Privileges (HCFA-6003-F) .....	0938-AI49
976	Security Standards (HCFA-0049-F) .....	0938-AI57

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

Sequence Number	Title	Regulation Identification Number
977	National Standard Employer Identifier (HCFA-0047-F) .....	0938-AI59
978	Medicare Program; Advance Refunding of Debt and Methodology for Repayment of Loan (HCFA-1777-P) .....	0938-AI75
979	Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements (HCFA-3004-F) .....	0938-AI89
980	Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests (HCFA-3250-F) .....	0938-AI92
981	Coverage of Religious Non-Medical Health Care Institutions (HCFA-1909-F) .....	0938-AI93
982	External Quality Review of Medicaid Managed Care Organizations (HCFA-2015-F) .....	0938-AJ06
983	Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA-3006-F) .....	0938-AJ10
984	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (HCFA-1910-F) .....	0938-AJ17
985	Hospital Conditions of Participation: Laboratory Services (HCFA-3014-F) .....	0938-AJ29
986	Medicare Hospice Care Amendments (HCFA-1022-P) .....	0938-AJ36
987	Emergency Medical Treatment and Labor Act (EMTALA) (HCFA-1063-P) .....	0938-AJ39
988	Protection for Women Who Elect Reconstruction After a Mastectomy (HCFA-2040-IFC) .....	0938-AJ44
989	Medicare Program: Prospective Payment System for Inpatient Rehabilitation Hospital Services (HCFA-1069-F) .....	0938-AJ55
990	DME Surety Bonds (HCFA-6006-P) .....	0938-AJ64
991	State Health Insurance Assistance Program (SHIP) (HCFA-4005-F) .....	0938-AJ67
992	HHA Surety Bond (HCFA-6001-P) .....	0938-AJ81
993	Application of Inherent Reasonableness to All Part B Services Other Than Physician Services (HCFA-1908-F) .....	0938-AJ97
994	Supplier Standards Related to Training Requirements for Oxygen, Therapeutic Shoes (HCFA-6010-NPRM) .....	0938-AJ98
995	Non-Federal Governmental Plans Exempt From HIPAA (HCFA-2033-IFC) .....	0938-AK00
996	End Stage Renal Disease Bad Debt Payment (HCFA-1126-P) .....	0938-AK02
997	Practice Expense Data Collection (HCFA-1111-IFC) .....	0938-AK14
998	Payment for Clinical Psychology Training Programs (HCFA-1089-F) .....	0938-AK15
999	Provisions of the Balanced Budget and Refinement Act of 1999; Hospital Inpatient Payments and Rates and Costs of Graduate Medical Education (HCFA-1131-IFC) .....	0938-AK20
1000	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (HCFA-3046-P) .....	0938-AK23
1001	Clinical Lab Requirements-Revisions to Regulations Implementing CLIA (HCFA-2226-F) .....	0938-AK24
1002	Prospective Fee Schedule for Ambulance Services (HCFA-1002-F) .....	0938-AK30
1003	Fire Safety Requirements for RNHCI, ASC, Hospices, PACE, Hospitals, and Long-Term Care Facilities (HCFA-3047-P) .....	0938-AK35
1004	Medicare Provider and Supplier Hearing Procedures (HCFA-2093-P) .....	0938-AK39
1005	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (HCFA-3050-F) .....	0938-AK40
1006	Requirements for the Recredentialing of Medicare+Choice Organizations Providers (HCFA-1160-F) .....	0938-AK41
1007	Supplementary Medical Insurance Premium Surcharge Agreements (HCFA-4007-P) .....	0938-AK42
1008	Medical Devices Coverage Decisions Related to Health Care Technology (HCFA-3059-P) .....	0938-AK43
1009	Medicaid Management Information System Revised Definition of "Mechanized Claims Processing and Information Retrieval System" (HCFA-2123-IFC) .....	0938-AK44
1010	Medicare Program; Reporting and Repayment of Overpayments (HCFA-6011-P) .....	0938-AK45
1011	Improvements to the Medicare+Choice Appeals and Grievance Procedures (HCFA-4024-F) .....	0938-AK48
1012	Civil Money Penalties, Assessments, and Revised Sanction Authorities (HCFA-6145-FC) .....	0938-AK49
1013	Payment for Upgraded Durable Medical Equipment (HCFA-1084-F) .....	0938-AK50
1014	Update to the Prospective Payment System for Home Health Agencies for FY 2002 (HCFA-1147-NC) .....	0938-AK51
1015	Recognition of the American Osteopathic Association for Ambulatory Surgical Center Programs (HCFA-2079-FN) .....	0938-AK53
1016	Prospective Payment System for Hospital Outpatient Services (HCFA-1159-P) .....	0938-AK54
1017	Medicare as Secondary Payer-Recovery of Conditional Payments (HCFA-6009-P) .....	0938-AK55
1018	Five Year Review of Work Relative Value Units Under the Physician Fee Schedule Proposed Notice (HCFA-1170-PN) .....	0938-AK56
1019	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2002 (HCFA-1169-P) .....	0938-AK57
1020	Changes to National Coverage Determinations and Local Coverage Determinations (HCFA-4019-FC) .....	0938-AK58
1021	Revisions to the Prospective Payment System for Hospital Outpatient Services Mandated by BIPA (HCFA-1179-IFC) .....	0938-AK59
1022	Challenges to National Coverage Determinations and Local Coverage Determinations (HCFA-3063-P) .....	0938-AK60
1023	Revised Process for Making Medicare Coverage Decisions (HCFA-3062-N) .....	0938-AK61
1024	Claims Attachment Standard (HCFA-0050-P) .....	0938-AK62
1025	Standards for Electronic Signatures (HCFA-0051-F) .....	0938-AK63
1026	Health Insurance Reform: Modifications to Standards for Electronic Transaction (HCFA-0003-IFC) .....	0938-AK64
1027	Replacement of Reasonable Charge Methodology by Fee Schedule (HCFA-1010-F) .....	0938-AK66

## HHS

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

Sequence Number	Title	Regulation Identification Number
1028	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships-Phase II (HCFA-1810-FC) .....	0938-AK67
1029	Increase in the Rate of Reimbursement of Photocopy Expenses for Prospective Payment System Providers (HCFA-3055-P) .....	0938-AK68
1030	Long Term Care Prospective Payment System for FY 2003 (HCFA-1177-P) .....	0938-AK69
1031	Modifications to Managed Care Rules Based on Provisions of BIPA and Technical Corrections (HCFA-1180-P) .....	0938-AK71
1032	Changes to the Hospital Inpatients Prospective Payment System for Fiscal Year 2002 Rates (HCFA-1158-P) .....	0938-AK73
1033	Changes to Inpatient BIPA for Fiscal Year 2001 (HCFA-1178-IFC) .....	0938-AK74
1034	Medicare+Choice ESRD Rates (HCFA-1182-PN) .....	0938-AK75
1035	Revisions to Transaction and Code Set Standards for Electronic Transactions (HCFA-0005-IFC) .....	0938-AK76
1036	Medicare Inpatient Disproportionate Share Hospital Adjustment Calculation (HCFA-1171-IFC) .....	0938-AK77
1037	Statement of Intent (HCFA-1185-P) .....	0938-AK79
1038	Procedures for Public Consultations for Coding and Payment Determinations for New Laboratory Tests (HCFA-1186-N) .....	0938-AK80
1039	Organ Procurement Organization Condition for Coverage (HCFA-3064-P) .....	0938-AK81
1040	Qualification Requirements for Directors of Laboratories Performing High Complexity Testing (HCFA-2094-NPRM)	0938-AK83
1041	Protection and Promotion of Resident Rights (HCFA-3065-P) .....	0938-AK85
1042	Standards for Electronic Transactions-Elimination of NDC Coding Standards (HCFA-0006-P) .....	0938-AK86
1043	Hospital Reference Laboratory and Medicare Secondary Payer (HCFA-1187-P) .....	0938-AK87
1044	Portability in the Group Health Insurance Market (HCFA-2048-F) .....	0938-AK88

## Health Care Financing Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1045	Changes to Peer Review Organization Regulations (HCFA-3135-F) .....	0938-AD38
1046	Protection of Income and Resources for Community Spouses of Institutionalized Individuals (HCFA-2023-P) .....	0938-AE12
1047	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Services (HCFA-2028-F) .....	0938-AE72
1048	Payment for Nursing and Allied Health Science Education (HCFA-1685-F) .....	0938-AE79
1049	Coverage of Screening Pap Smears (HCFA-3705-F) .....	0938-AE98
1050	Referral to Child Support Enforcement Agencies of Medicaid Families (HCFA-2051-F) .....	0938-AF68
1051	Disclosure of Confidential PRO and ESRD Network Organization Information for Research Purposes (HCFA-3208-P) .....	0938-AG33
1052	Effect of Change of Ownership on Provider and Supplier Penalties, Sanctions, Underpayments and Overpayments (HCFA-2215-P) .....	0938-AG59
1053	Optional Coverage of Certain Tuberculosis to TB-Related Services, TB-Infected Individuals (HCFA-2082-P) .....	0938-AG72
1054	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships-Expanded to Designated Health Services (HCFA-1809-FC) .....	0938-AG80
1055	Distinct Part Requirements for Nursing Homes and Prohibition on Financial Screening of Applicants for Nursing Home Admission (HCFA-3815-P) .....	0938-AG84
1056	CLIA Program: Categorization of Waived Tests (HCFA-2225-FC) .....	0938-AG99
1057	Additional Supplier Standards (HCFA-6004-FC) .....	0938-AH19
1058	State Plan Amendment (SPA) Reconsideration Process (HCFA-2096-P) .....	0938-AH24
1059	Medicare Coverage of Services of Speech-Language Pathologists and Audiologists (HCFA-1843-P) .....	0938-AH37
1060	Medicaid; Estate Recoveries (HCFA-2083-P) .....	0938-AH63
1061	Individual Market Health Insurance Reform: Portability From Group to Individual Coverage; Federal Rules for Access in the Individual Market; State Alternative Mechanisms to Federal Rules (HCFA-2882-F) .....	0938-AH75
1062	Disclosure of Peer Review Organization Information in Response to Beneficiary Complaints (HCFA-3241-P) .....	0938-AH85
1063	Medicaid Program; Amendment to the Preadmission Screening and Annual Resident Review Program (HCFA-2107-P) .....	0938-AH89
1064	Medically Needy Determinations Under Welfare Reform (HCFA-2109-IFC) .....	0938-AH92
1065	Medicaid Program; Coverage and Payment for Federally Qualified Health Center Services (HCFA-2043-P) .....	0938-AH95
1066	Nondiscrimination in Health Coverage in the Group Market (HCFA-2022-F) .....	0938-AI08
1067	Medicare Program; Improvements to the Appeals Process for Medicare Beneficiaries Enrolled in HMOs, CMPs, and HCPPs (HCFA-4024-P) .....	0938-AI11
1068	Medicare Program; Adjustments to Cost Limits for Skilled Nursing Facility Inpatient Routine Service Costs (HCFA-1896-FN) .....	0938-AI14

## HHS

## Health Care Financing Administration—Completed Actions (Continued)

Sequence Number	Title	Regulation Identification Number
1069	Medicare/Medicaid Program; User Fees for Information, Products, and Services (HCFA-6021-P) .....	0938-AI46
1070	Prospective Payment System for Hospital Outpatient Services (HCFA-1005-F) .....	0938-AI56
1071	State Plan Requirements for Durable Medical Equipment Providers (HCFA-2007-P) .....	0938-AI63
1072	Medicaid Program; Home and Community-Based Services (HCFA-2010-FC) .....	0938-AI67
1073	Medicaid Managed Care; Regulatory Program To Implement Certain Medicaid Provisions of the Balanced Budget Act of 1997 (HCFA-2001-F) .....	0938-AI70
1074	Prospective Fee Schedule for Ambulance Services (HCFA-1002-P) .....	0938-AI72
1075	Revision of Procedures for Requesting Exceptions to Cost Limits for SNFs and Elimination of Reclassifications (HCFA-1883-F) .....	0938-AI80
1076	Expanded Coverage for Diabetes Outpatient Self-Management Training Services (HCFA-3002-F) .....	0938-AI96
1077	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance: Millennium Compliance (HCFA-4002-GNC) .....	0938-AJ15
1078	Medicare/Medicaid and CLIA Programs: Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of California (HCFA-2245-N) .....	0938-AJ47
1079	Medicare Program: Criteria for Making National Coverage Decision (HCFA-3432-P) .....	0938-AJ54
1080	Medicare Program; Sustainable Growth Rate for Fiscal Year 2000 (HCFA-1110-N) .....	0938-AJ60
1081	Medicare and Medicaid Programs; Programs for All-Inclusive Care for the Elderly (PACE) (HCFA-1903-P) .....	0938-AJ63
1082	Clinical Social Worker Services (HCFA-1088-F) .....	0938-AJ71
1083	Medicaid Disproportionate Share Hospital Payments-Institutions for Mental Disease (HCFA-2062-N) .....	0938-AJ74
1084	The Children's Health Insurance Program: Implementing the Balanced Budget Act of 1997 (HCFA-2006-F) .....	0938-AJ75
1085	Medicare Program Update of Ambulatory Surgical Center Payment Rates Effective for Services On or After October 1, 1999 (HCFA-1085-N) .....	0938-AJ86
1086	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities-Update (HCFA-1112-F) .....	0938-AJ93
1087	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (HCFA-2065-F) .....	0938-AJ96
1088	Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded .....	0938-AJ99
1089	Flexibility in Payment Methods for Services of Hospitals, Nursing Facilities, and Intermediate Care Facilities for the Mentally Retarded (HCFA-2004-F) .....	0938-AK04
1090	Hospital Conditions of Participation; Anesthesia Services (HCFA-3049-F) .....	0938-AK08
1091	Changes to the Appeals Process for Beneficiaries Receiving Home Health Services in the Fee For Service Program (HCFA-4006-P) .....	0938-AK10
1092	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2001 (HCFA-1120-F) .....	0938-AK11
1093	Revisions to Medicaid Upper Payment Limit Requirements for Hospital, Nursing Facility, Intermediate Care Facility Services for the Mentally Retarded and Clinic Services (HCFA-2071-F) .....	0938-AK12
1094	Hospice Wage Index (HCFA-1135-N) .....	0938-AK13
1095	HIPAA Program; Bona Fide Wellness Programs (HCFA-2078-F) .....	0938-AK19
1096	Application of Federal Financial Participation Limits (HCFA-2086-F) .....	0938-AK22
1097	Prospective Payment System for Hospital Outpatient Services: Exception to the Provider-Based Location Criteria for PPS-Exempt Facilities (HCFA-1143-F) .....	0938-AK25
1098	Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 2001 (HCFA-4010-GNC) ...	0938-AK26
1099	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2001 (HCFA-8007-N) .....	0938-AK27
1100	Mandatory Transmission of OASIS for Non-Medicare/Medicaid Patients in Home Health Agencies and Continued Delay of Requirements for Patients Receiving Personal Care Services (HCFA-2070-N) .....	0938-AK28
1101	Removal of the Requirements for the Cardiac Pacemaker Registry (HCFA-3045-F) .....	0938-AK29
1102	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships-Phase II (HCFA-1810-FC) .....	0938-AK31
1103	Elimination of Application of Federal Financial Participation Limits (HCFA-2086-P) .....	0938-AK32
1104	Conforming Regulations Changes and Statutory Revisions for Approval and Oversight of Accreditation Organizations (HCFA-2088-P) .....	0938-AK36

## Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1105	Program Performance Standards for the Operation of Head Start Programs .....	0970-AB99
1106	Safeguarding Child Support and Expanded FPLS Information .....	0970-AC01

HHS

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

Sequence Number	Title	Regulation Identification Number
1107	Developmental Disabilities and Bill of Rights Act .....	0970-AC07

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1108	Construction and Major Renovation of Head Start and Early Head Start Facilities .....	0970-AB54
1109	Child Support Enforcement for Indian Tribes .....	0970-AB73
1110	Child Support Enforcement Program Omnibus Conforming Regulation .....	0970-AB81
1111	Family Child Care Program Option for Head Start Programs .....	0970-AB90
1112	Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions .....	0970-AC00
1113	High Performance Bonus Awards Under the TANF Program .....	0970-AC06
1114	Individual Development Accounts .....	0970-AC08

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
1115	Standards for Safe Transportation .....	0970-AB24
1116	Incentive Payments and Audit Penalties to States and Political Subdivisions .....	0970-AB85
1117	State Self-Assessments To Determine Compliance With Federal Regulations .....	0970-AB96
1118	National Medical Support Notice .....	0970-AB97

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1119	Grants for State and Community Programs on Aging, Intrastate Funding Formulas; Training, Research and Discretionary Programs; Vulnerable Elder Rights; and Grants to Indians and Native Hawaiians .....	0985-AA00
1120	Grants for State and Community Programs on Aging, Family Caregivers, American Indians, and Native Hawaiians (Section 610 Review) .....	0985-AA01

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

Proposed Rule Stage

**813. • GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) AND GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (GRANTS)**

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

**Legal Authority:** 5 USC 301; 41 USC 701 et seq, sec 2455; PL 103-355; 31 USC 6101 note; EO 12859

**CFR Citation:** 45 CFR 76; 45 CFR 82

**Legal Deadline:** None

**Abstract:** This proposed common rule is revised to simplify and streamline nonprocurement debarment and suspension requirements, as well as correspond to procurement regulations where possible. The revision will separate the debarment and suspension and Drug-Free Workplace regulations, and will be written in the plain language format.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Diane Osterhus, Federal Assistance Policy Specialist, Department of Health and Human Services, Office of the Secretary, Room 517D, Office of Grants and Acquisition Management, 200 Independence Avenue SW., Washington, DC 20201  
Phone: 202 690-6901  
Fax: 202 690-5729

HHS—OS

Proposed Rule Stage

Email: diane.osterhus@hhs.gov

RIN: 0991-AB12

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

Final Rule Stage

**814. REPRODUCTION AND SALE OF OFFICIAL FORMS AND PUBLICATIONS**
**Priority:** Info./Admin./Other**Legal Authority:** 42 USC 1320b-10**CFR Citation:** 45 CFR 101**Legal Deadline:** None

**Abstract:** This interim final rule with comment period will establish procedures for implementation of section 312 of the Social Security Independence Act. It amends existing prohibitions against “misuse of symbols, emblems, or names in reference to Social Security or Medicare.” Section 312 also prohibits the “unauthorized reproduction, reprinting, or distribution for fee” of a “form, application, or other publication of the Social Security Administration or of the Department of Health and Human Services.” It requires prior written authorization for any such activity in accordance with the Secretary’s regulations. The Department plans to distinguish between forms and publications that potentially involve misuse in contrast to benign or desirable reproductions and distributions, and to provide pre-authorization for the latter. The rule will be developed in consultation with the Social Security Administration.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	11/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Michael Herrell, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW., Washington, DC 20201  
Phone: 202 690-5739

RIN: 0991-AA83

**815. SHARED RISK EXCEPTION TO THE SAFE HARBOR PROVISIONS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1320a-7b; 42 USC 1395hh; PL 104-191, sec 216(b)**CFR Citation:** 42 CFR 1001**Legal Deadline:** Final, Statutory, January 1, 1997.

**Abstract:** This final rule establishes a new statutory exception for risk-sharing arrangements under the Federal health care programs’ anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at “substantial financial risk” for the cost or utilization of the items or services that the individual or entity is obligated to provide.

**Timetable:**

Action	Date	FR Cite
ANPRM	05/23/97	62 FR 28410
ANPRM Comment Period End	06/09/97	
Interim Final Rule	11/19/99	64 FR 63504
Final Rule	08/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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

RIN: 0991-AA91

**816. CIVIL MONEY PENALTY SAFE HARBOR TO PROTECT PAYMENT OF MEDICARE AND MEDIGAP PREMIUMS FOR ESRD BENEFICIARIES**
**Priority:** Substantive, Nonsignificant**Legal Authority:** Social Security Act, sec 1128A(a)(5)**CFR Citation:** 42 CFR 1003**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	05/02/00	65 FR 25460
NPRM Comment Period End	07/03/00	
Final Action	10/00/01	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

RIN: 0991-AB04

**817. SAFE HARBOR FOR AMBULANCE RESTOCKING**
**Priority:** Substantive, Nonsignificant**Legal Authority:** PL 100-93, sec 14(a)

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	05/22/00	65 FR 32060
NPRM Comment Period End	07/21/00	
Final Action	10/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0991-AB05

**818. REVISIONS AND TECHNICAL CORRECTIONS TO 42 CFR CHAPTER V**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1320a-7; 42 USC 1320a-7a; 42 USC 1320a-7b; 42 USC 1320a-7d(b); 42 USC 1395u

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

**Legal Deadline:** None

**Abstract:** This final rule sets forth several miscellaneous revisions and technical corrections to the OIG

regulations codified in 42 CFR chapter V. Among other revisions, this rule makes revisions or clarifications to the term “item or service” contained in part 1003 of this chapter, to the reinstatement procedures relating to exclusions resulting from the default on health education or scholarship obligations set forth in part 1001, and to the statute of limitations for the OIG to impose an exclusion under part 1001.

**Timetable:**

Action	Date	FR Cite
NPRM	10/20/00	65 FR 63035
NPRM Comment Period End	12/20/00	
Final Action	09/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:**

Undetermined

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

**RIN:** 0991-AB09

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

**Priority:** Other Significant

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	10/26/00	65 FR 64194
NPRM Comment Period End	11/27/00	
Final Action	11/00/01	
Final Action Effective	01/00/02	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Federal

**Agency Contact:** Roinsue Frohboese, Department of Health and Human Services, Office of the Secretary  
Phone: 202 619-0403

**RIN:** 0991-AB10

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

**Long-Term Actions**

**Office of the Secretary (OS)**

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 1003

**Legal Deadline:** None

**Abstract:** This proposed rule would reflect OIG’s authority to impose civil

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

**Timetable:**

Action	Date	FR Cite
NPRM	To Be Determined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

## HHS—OS

## Long-Term Actions

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

RIN: 0991-AB03

### 821. SAFE HARBOR FOR ARRANGEMENTS INVOLVING FEDERALLY QUALIFIED HEALTH CENTERS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 100-93, sec 14(a)

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

RIN: 0991-AB06

### 822. DEFINITION OF TERMS; SUBSTANTIALLY IN EXCESS AND USUAL CHARGES AND CLARIFICATION OF THE GOOD CAUSE EXCEPTION

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec. 1128(b)(A) of the Social Security Act

**CFR Citation:** 42 CFR 1001

**Legal Deadline:** None

**Abstract:** This proposed rule would amend the OIG exclusion regulations at 42 CFR 1001.701, addressing excessive claims, by including definitions for the terms "substantially in excess" and "usual charges", and by clarifying the "good cause" exception set forth in this section.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**  
**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

RIN: 0991-AB13

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Completed Actions

## Office of the Secretary (OS)

### 823. STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

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

**CFR Citation:** 45 CFR 160; 45 CFR 164

#### Completed:

Reason	Date	FR Cite
Final Rule	12/28/00	65 FR 82462
Delay of Effective Date To 04/14/2001	02/26/01	66 FR 12434
Comment Period Extended	03/30/01	66 FR 12738

**Regulatory Flexibility Analysis**  
**Required:** Yes

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

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

**Agency Contact:** Roxanne Gibson  
Phone: 202 260-5083

RIN: 0991-AB08

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Long-Term Actions

## Substance Abuse and Mental Health Services Administration (SAMHSA)

### 824. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT APPLICATIONS DUE DATE CHANGE FROM MARCH 31 TO OCTOBER 1 FOR FY 2001 AND BEYOND

**Priority:** Routine and Frequent

**Legal Authority:** Not Yet Determined

**CFR Citation:** 45 CFR 96; 45 CFR 96.122(d); 45 CFR 96.130(e); 45 CFR 96.134(d)

**Legal Deadline:** None

**Abstract:** The Substance Abuse and Mental Health Services Administration (SAMHSA) (formerly, the Alcohol, Drug Abuse and Mental Health

Administration (ADAMHA)) has permitted applicants for its Substance Abuse Prevention and Treatment (SAPT) Block Grant program to submit an application for a grant as late as March 31 of the fiscal year for which it is applying. Starting with the fiscal year 2001 applications, SAMHSA is proposing a new date for receipt of the applications for SAPT Block Grants of October 1 of the fiscal year for which Block Grant funding is being requested. However, the deadline for two application components required to be submitted by that due date may be extended for a limited period, not to extend beyond December 31 of the

same fiscal year when good cause is demonstrated.

#### Timetable:

Action	Date	FR Cite
NPRM	02/04/00	65 FR 5474
NPRM Comment Period End	03/20/00	
Next Action Undetermined		

**Regulatory Flexibility Analysis**  
**Required:** No

**Government Levels Affected:** State

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

**HHS—SAMHSA**

**Long-Term Actions**

**Agency Contact:** Thomas Reynolds,  
Department of Health and Human  
Services, Substance Abuse and Mental

Health Services Administration, 5600  
Fishers Lane, Room 13C-20, Parklawn,  
Rockville, MD 20857

Phone: 301 443-0179

**RIN:** 0930-AA04

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

**Completed Actions**

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

**Priority:** Other Significant

**CFR Citation:** 42 CFR 8

**Completed:**

Reason	Date	FR Cite
Final Rule	01/17/01	66 FR 4075
60-Day Delay of Effective Date To 05/18/2001	03/19/01	66 FR 15347

**Regulatory Flexibility Analysis  
Required:** Yes

**Government Levels Affected:** None

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

**RIN:** 0930-AA06

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)  
Centers for Disease Control and Prevention (CDC)**

**Proposed Rule Stage**

**826. • AMENDMENTS TO QUALITY  
ASSURANCE AND ADMINISTRATIVE  
PROVISION FOR APPROVAL OF  
RESPIRATORY PROTECTIVE DEVICES**

**Priority:** Other Significant

**Legal Authority:** 29 USC 651 et seq;  
30 USC 3; 30 USC 5; 30 USC 7; 30  
USC 811; 30 USC 842(h); 30 USC 844

**CFR Citation:** 42 CFR 84

**Legal Deadline:** None

**Abstract:** NIOSH plans to propose the  
Administrative/Quality Assurance  
sections of 42 CFR part 84, Approval  
of Respiratory Protective Devices. Areas  
for potential modification in this  
module are: 1) upgrade of Quality  
Assurance requirements; 2) ability to  
use private sector quality auditors and  
private sector testing laboratories in the  
approval program; 3) revised approval  
label requirements; 4) updated and  
restructured fee schedule; and 5) fee  
retention in the Respirator program.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

**Regulatory Flexibility Analysis  
Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Larry Elliott, Acting  
Director, Office of Compensation  
Analysis and Support, Department of  
Health and Human Services, Centers for  
Disease Control and Prevention,  
NIOSH, R44, 5555 Ridge Avenue,  
Cincinnati, OH 45213  
Phone: 513 841-4400

**RIN:** 0920-AA04

**827. • METHODS FOR ESTIMATING  
RADIATION DOSE AND GUIDELINES  
FOR ASSESSING PROBABILITY OF  
CANCER FOR ENERGY EMPLOYEES  
OCCUPATIONAL ILLNESS  
COMPENSATION PROGRAM**

**Priority:** Other Significant

**Legal Authority:** PL 106-398, sec 3623

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** Pursant to Executive Order  
13179, which implements section 3623  
of the Energy Employees Occupational  
Illness Compensation Program Act,  
Public Law 106-398, NIOSH plans to  
propose and finalize regulations, to  
establish:

1) Guidelines to assess the likelihood  
that an individual with cancer

sustained that cancer in the  
performance of duty at a Department  
of Energy facility or an atomic weapons  
employer facility, as defined in that  
Act; and

2) Methods for arriving at and  
providing reasonable estimates of the  
radiation doses received by individuals  
applying for assistance under this  
program for whom there are inadequate  
records of radiation exposure.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/01	

**Regulatory Flexibility Analysis  
Required:** No

**Small Entities Affected:** No

**Government Levels Affected:**  
Undetermined

**Agency Contact:** Roland Berry Ann,  
Team Leader, Policy Development,  
Respirator Branch, Department of  
Health and Human Services, Centers for  
Disease Control and Prevention,  
NIOSH, P04, 1095 Willowdale Road,  
Morgantown, WV 26505  
Phone: 304 285-5907

**RIN:** 0920-AA05

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Centers for Disease Control and Prevention (CDC)**
**Long-Term Actions**
**828. PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS**
**Priority:** Other Significant**Legal Authority:** 42 USC 264; 42 USC 271; 42 USC 262 note; 31 USC 9701; 18 USC 3559; 18 USC 3571**CFR Citation:** 42 CFR 72.6 (Renumbered); 42 CFR 72.7 (Renumbered); 42 CFR 72.1-5 (Revision)**Legal Deadline:** None

**Abstract:** The purpose of this NPRM is to update regulations governing the packaging, labeling, and shipment of infectious agents. Materials must be packaged in such a way as to prevent damage and leakage during transport in order to protect workers and the public from exposure.

**Timetable:**

Action	Date	FR Cite
NPRM	10/28/99	64 FR 58022
Next Action Undetermined		

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

**Agency Contact:** Dr. Jonathan Y. Richmond, Director, Office on Health and Safety, Department of Health and Human Services, Centers for Disease Control and Prevention, MS F05, 1600 Clifton Road NE, Atlanta, GA 30333  
Phone: 404 639-2453

**RIN:** 0920-AA02

**Abstract:** CDC proposes to modify certain regulatory responsibilities of 42 CFR 70 and 42 CFR 71 that relate to quarantine in order to bring the regulations up to date regarding modern communicable disease concerns.

**Timetable:**

Action	Date	FR Cite
Final Rule	To Be	Determined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** State**Federalism:** Undetermined

**Agency Contact:** Chuck Gollmar, Deputy Director, Department of Health and Human Services, Centers for Disease Control and Prevention, MS D23, 1600 Clifton Road NE., Atlanta, GA 30333  
Phone: 404 639-7070

Email: cgollar@cdc.gov

**RIN:** 0920-AA03
**829. CONTROL OF COMMUNICABLE DISEASES**

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

**Legal Authority:** 42 USC 216; 42 USC 243; 42 USC 264; 42 USC 271**CFR Citation:** 42 CFR 70; 42 CFR 71**Legal Deadline:** None
**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Departmental Management (HHSDM)**
**Proposed Rule Stage**
**830. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 5 USC 504(c)(1)**CFR Citation:** 45 CFR 13**Legal Deadline:** None

**Abstract:** The Equal Access to Justice Act requires agencies to pay fees to parties prevailing against the Government in certain administrative proceedings. The Act has been amended several times since its 1980

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment	08/17/87	
Period End		
Second NPRM	08/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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

**RIN:** 0990-AA02
**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Food and Drug Administration (FDA)**
**Prerule Stage**
**831. NATURAL RUBBER-CONTAINING DRUGS; USER LABELING**
**Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321; 21 USC 374; 21 USC 379; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371**CFR Citation:** 21 CFR 201**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
ANPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

## HHS—FDA

## Prerule Stage

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

**RIN:** 0910—AB56

### 832. IMPLEMENTATION OF THE IMPORT TOLERANCE PROVISIONS OF THE ANIMAL DRUG AVAILABILITY ACT OF 1996

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 360b

**CFR Citation:** 21 CFR 556

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
ANPRM	07/00/01	
NPRM	02/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** George A. (“Bert”) Mitchell, Associate Director for Policy and Regulations, Office of the Director, Department of Health and Human Services, Food and Drug Administration, HFV-1, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855  
Phone: 301 827-2957

**RIN:** 0910—AB71

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** 21 CFR parts 600 through 680 describe regulations applicable to biological products. Part 600 describes regulations for general establishment standards, establishment inspections, and the reporting of adverse experiences applicable to manufacturers of licensed biological products. FDA is initiating a review

under section 610 of the Regulatory Flexibility Act for the regulations in part 600. The purpose of this review is to determine if any of the regulations in part 600 should be continued without change, or should be amended or rescinded, to minimize adverse economic impacts on small entities. FDA will consider, and solicit comments on the following: (1) the continued need for a regulation in part 600; (2) the nature of complaints or comments received concerning a regulation in part 600; (3) the complexity of a regulation in part 600; (4) the extent to which a regulation in part 600 overlaps, duplicates, or conflicts with other Federal, State, or government rules; and (5) the degree to which technology, economic conditions or other factors have changed in the area affected by a regulation in part 600.

#### Timetable:

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

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910—AC06

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Proposed Rule Stage

### Food and Drug Administration (FDA)

#### 834. OVER-THE-COUNTER (OTC) DRUG REVIEW

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 321p; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

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

**Legal Deadline:** None

**Abstract:** The OTC drug review establishes conditions under which

OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for “Antidotes, Toxic Ingestion Products” was combined with NPRM for “Emetic

## HHS—FDA

## Proposed Rule Stage

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

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

**Timetable:****Acne (Topical) Products**

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

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

NPRM 10/21/93 (58 FR 54466)  
Final Action 03/13/95 (60 FR 13590)  
NPRM (Amendment) 05/10/96 (61 FR 21392)  
Final Action (Amendment) 11/18/96 (61 FR 58629)

**Anorectal Products**

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

**Antacid Drug Products**

ANPRM 04/05/73 (38 FR 8714)  
NPRM 11/12/73 (38 FR 31260)  
Final Action 06/04/74 (39 FR 9862)  
NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)  
Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)  
NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)  
NPRM (Amendment)(Sodium Bicarb.) 02/02/94 (59 FR 5060)  
Final Action (Technical Amendment) 11/25/94 (59 FR 60555)  
Final Action (Amendment) (Testing) 02/08/96 (61 FR 4822)  
Final Action (Amendment) (Overindulgence) 12/00/01  
Final Action (Amendment)(Sodium B.) 06/00/02

**Anthelmintic Products**

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

**Antibiotic First Aid Products**

ANPRM 04/01/77 (42 FR 17642)  
NPRM 07/09/82 (47 FR 29986)  
Final Action 12/11/87 (52 FR 47312)  
NPRM (Amendment) 08/18/89 (54 FR 34188)  
Final Action 03/15/90 (55 FR 9721)  
NPRM (Amendment) 05/11/90 (55 FR 19868)  
NPRM (Amendment) 06/08/90 (55 FR 23450)  
Final Action (Amendment) 10/03/90 (55 FR 40379)  
Final Action (Amendment) 12/05/90 (55 FR 50171)  
NPRM (Amendment) (Warning) 02/14/96 (61 FR 5918)  
Final Action (Amendment)(Warning) 11/15/96 (61 FR 58471)

**Anticaries Products**

ANPRM 03/28/80 (45 FR 20666)  
NPRM 09/30/85 (50 FR 39854)  
NPRM 06/15/88 (53 FR 22430)  
Final Action 10/06/95 (60 FR 52474)  
Final Action (Technical Amendment) 10/07/96 (61 FR 52285)

**Antidiarrheal Products**

ANPRM 03/21/75 (40 FR 12924)  
NPRM 04/30/86 (51 FR 16138)  
NPRM (Amendment)(Trav. Diar.) 12/00/01  
Final Action 12/00/01

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

ANPRM 01/05/82 (47 FR 444)

**Antiemetic Products**

ANPRM 03/21/75 (40 FR 12934)  
NPRM 07/13/79 (44 FR 41064)  
Final Action 04/30/87 (52 FR 15886)  
NPRM (Amendment) 08/26/93 (58 FR 45216)  
Final Action 04/11/94 (59 FR 16981)  
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)  
Final Action (Amendment) (Warning) 12/00/01

**Antiflatulent Drug Products**

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

**Antifungal (Topical) Products**

ANPRM 03/23/82 (47 FR 12480)  
NPRM 12/12/89 (54 FR 51136)  
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25240)  
Final Action (Amdt.)(Diaper Rash) 12/18/92 (57 FR 60430)  
Final Action (Partial) 09/02/93 (58 FR 46744)  
Final Action 09/23/93 (58 FR 49890)  
NPRM (Amendment) (Indications) 07/22/99 (64 FR 39452)  
Final Action 08/29/00 (65 FR 52302)  
NPRM (Amendment) Clotrimazole 05/00/01

**Antimicrobial Products**

ANPRM 09/13/74 (39 FR 33103)  
NPRM 01/06/78 (43 FR 1210)  
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25246)  
Final Action (Diaper Rash) 03/00/04

**Antiperspirant Products**

ANPRM 10/10/78 (43 FR 46694)  
NPRM 08/20/82 (47 FR 36492)  
Final Action 04/00/02

**Aphrodisiac Products**

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

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

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)

## HHS—FDA

## Proposed Rule Stage

**Cough/Cold (Antihistamine) Products**

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 01/15/85 (50 FR 2200)  
 NPRM (Amendment) 08/24/87 (52 FR 31892)  
 Final Action 12/09/92 (57 FR 58356)  
 Final Action (Amendment)(Warning) 01/28/94 (59 FR 4216)  
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)  
 Reopen Record (Common Cold) 08/25/00 (65 FR 51780)  
 Final Action (Amendment)(Warning) 12/00/01  
 Final Action 12/00/02

**Cough/Cold (Antitussive) Products**

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 10/19/83 (48 FR 48576)  
 Final Action 08/12/87 (52 FR 30042)  
 NPRM (Amendment) (Warning) 07/06/89 (54 FR 28442)  
 NPRM (Amendment) 10/02/89 (54 FR 40412)  
 Final Action (Amendment) (Warning) 07/06/90 (55 FR 27806)  
 Final Action (Amendment) 10/03/90 (55 FR 40381)  
 NPRM (Amendment)(Warning) 06/19/92 (57 FR 27666)  
 NPRM (Amendment)(Ingredients) 12/09/92 (57 FR 58378)  
 Final Action (Amendment)(Warning) 10/20/93 (58 FR 54232)  
 Final Action (Amdt.)(Ingredients) 06/03/94 (59 FR 29172)  
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)  
 NPRM (Amendment)(Flammability) 07/20/98 (63 FR 38762)  
 Final Action (Amendment)(Flammability) 08/01/00 (65 FR 46864)  
 Final Action (Amendment)(Warning) 12/00/01

**Cough/Cold (Bronchodilator) Products**

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 10/26/82 (47 FR 47520)  
 Final Action 10/02/86 (51 FR 35326)  
 NPRM (Amendment)(Warning) 06/19/92 (57 FR 27662)  
 Final Action (Amendment)(Warning) 10/20/93 (58 FR 54238)  
 NPRM (Amendment)(MDI) 03/09/95 (60 FR 13014)  
 NPRM (Amendment)(Ephedrine) 07/27/95 (60 FR 38643)  
 Final Action (Amendment) (MDI) 05/20/96 (61 FR 25142)  
 Final Action (Amendment) (Ephedrine) 12/00/01

**Cough/Cold (Combination) Products**

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 08/12/88 (53 FR 30522)  
 NPRM (Amendment)(DPH Combinations) 02/23/95 (60 FR 10286)  
 Final Action (Theophylline) 07/27/95 (60 FR 38636)  
 NPRM (Amendment) (Ephedrine Combo) 12/00/01  
 Final Action 12/00/01

**Cough/Cold (Diphenhydramine) Products**

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

**Cough/Cold (Expectorant) Products**

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

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

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 07/09/82 (47 FR 30002)  
 Final Action 09/14/92 (57 FR 41857)

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

ANPRM 09/09/76 (41 FR 38312)  
 NPRM 01/15/85 (50 FR 2220)  
 NPRM (Amendment) 06/19/92 (57 FR 27658)  
 Final Action 08/23/94 (59 FR 43386)  
 Final Action; Partial Stay 03/08/96 (61 FR 9570)  
 Final Action (Amendment)(Levmetamfetamine) 07/30/98 (63 FR 40647)  
 NPRM (Phenylpropanolamine) 06/00/01

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

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

**Daytime Sedatives**

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

**Diaper Rash Products (Merged w/other 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)

**Eligibility Criteria for Additional Conditions**

ANPRM 10/03/96 (61 FR 51625)  
 NPRM 12/20/99 (64 FR 71062)  
 Final Action 06/00/01

**Emetic Products**

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

**Exocrine Pancreatic Insufficiency Products**

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

**External Analgesic Products**

ANPRM 12/04/79 (44 FR 69768)  
 NPRM 02/08/83 (48 FR 5852)  
 NPRM (Amendment) (Dandruff) 07/30/86 (51 FR 27360)  
 NPRM (Amendment) (Anorectal) 08/25/88 (53 FR 32592)  
 NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40818)  
 NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3370)  
 NPRM (Amendment) (1%Hydrocortisone) 02/27/90 (55 FR 6932)  
 NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25234)  
 Final Action (Diaper Rash) 12/18/92 (57 FR 60426)  
 NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)  
 Final Action (Amendment)(Warning) 12/00/01

**Fever Blister Products (Internal)**

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

**First Aid Antiseptic**

ANPRM 09/13/74 (39 FR 33103)  
 NPRM 01/06/78 (43 FR 1210)  
 NPRM (Revised) 07/22/91 (56 FR 33644)  
 Final Action 12/00/02

**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)

**Healthcare Antiseptic Products**

ANPRM 09/13/74 (39 FR 33103)  
 NPRM 01/06/78 (43 FR 1210)  
 NPRM (Revised) 06/17/94 (59 FR 31402)  
 Final Action 12/00/01

**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)  
 NPRM 12/00/01

**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)

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**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 10/20/93 (58 FR 54224)  
 NPRM (Amendment)(Sodium Bicarbonate)  
 02/02/94 (59 FR 5068)  
 NPRM (Prof. Labeling)(Acute MI) 06/13/96  
 (61 FR 30002)  
 NPRM (Amendment)(Alcohol Warning)  
 11/14/97 (62 FR 61041)  
 Final Action (Alcohol Warning) 10/23/98  
 (63 FR 56789)  
 Final Action (Aspirin Prof. Label) 10/23/98  
 (63 FR 56802)  
 NPRM (Amendment)(Ibuprofen) 10/00/01  
 Final Action 12/00/01  
 Final Action  
 (Amendment)(Overindulgence) 12/00/01  
 Final Action (Sodium Bicarbonate)  
 06/00/02

**Internal Deodorant Products**

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

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

NPRM (Sodium Labeling) 04/25/91 (56 FR  
 19222)  
 NPRM 04/05/93 (58 FR 17553)  
 Final Action 01/28/94 (59 FR 3998)  
 NPRM (Do not mix drugs) 08/03/94 (59 FR  
 39499)  
 NPRM (Amendment) (Do not mix drugs)  
 10/04/95 (60 FR 52058)  
 NPRM (Unless a doctor tells you) 03/04/96  
 (61 FR 8450)  
 Final Action (Sodium Labeling) 04/22/96  
 (61 FR 17798)  
 NPRM (Calcium/Magnesium/Potassium)  
 04/22/96 (61 FR 17807)  
 Withdrawal (Unless a doctor tells you)  
 02/27/97 (62 FR 9024)  
 Final Action (Format/Examples) 03/17/99  
 (64 FR 13254)  
 Final Action (Technical Amendment)  
 01/03/00 (65 FR 7)  
 Final Action (Ca/Mg/K/Na) 07/00/01

**Laxative Products**

ANPRM 03/21/75 (40 FR 12902)  
 NPRM 01/15/85 (50 FR 2124)  
 NPRM (Amendment) (Directions/Bulk)  
 10/01/86 (51 FR 35136)  
 NPRM (Amendment) (Docusate Salts)  
 09/02/93 (58 FR 46589)  
 NPRM (Amendment)(Sodium Phosphates)  
 03/31/94 (59 FR 15139)  
 NPRM (Phenolphthalein) 09/02/97 (62 FR  
 46223)  
 Final Action (Sodium Phosphates)  
 05/21/98 (63 FR 27836)  
 NPRM (Amendment)(Phosphates Label)  
 05/21/98 (63 FR 27886)  
 NPRM (Amendment)(Stim. Laxative)  
 06/19/98 (63 FR 33592)  
 Final Action; stay (Na Phos. Enema)  
 12/07/98 (63 FR 67399)  
 Part. With. (Na Phos. Prof. Lab.) 12/09/98  
 (63 FR 67817)  
 Final Action (Phenolphthalein) 01/29/99  
 (64 FR 4535)  
 Final Action 01/00/02  
 Final Action (Stim. Laxative) 12/00/03

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

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

**Male Genital Desensitizer Products**

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

**Menstrual Products**

ANPRM 12/07/82 (47 FR 55075)  
 NPRM 11/16/88 (53 FR 46194)  
 Final Action 12/00/01

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

ANPRM 01/05/82 (47 FR 436)

**NDA Labeling Exclusivity (Merged with other rulemaking)**

NPRM 11/09/93 (58 FR 59622)

**Nailbiting/Thumbsucking Deterrent Products**

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

**Nighttime Sleep Aid Products**

ANPRM 12/08/75 (40 FR 57292)  
 NPRM 06/13/78 (43 FR 25544)  
 Final Action 02/14/89 (54 FR 6814)  
 NPRM (Amendment) 08/26/93 (58 FR  
 45217)  
 Final Action (Amendment) 04/11/94 (59  
 FR 16982)  
 NPRM (Amendment)(Warning) 08/29/97  
 (62 FR 45767)  
 Final Action (Amendment)(Warning)  
 12/00/01

**Ophthalmic Products**

ANPRM 05/06/80 (45 FR 30002)  
 NPRM 06/28/83 (48 FR 29788)  
 Final Action 03/04/88 (53 FR 7076)  
 Final Action (Anti-infective) 12/18/92 (57  
 FR 60416)  
 NPRM (Amendment) (Warning) 02/23/98  
 (63 FR 8888)  
 Final Action 06/21/00 (65 FR 38426)

**Oral Discomfort (Relief) Products**

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

**Oral Health Care Products**

ANPRM 05/25/82 (47 FR 22760)  
 NPRM 01/27/88 (53 FR 2436)  
 NPRM (Amendment) (Antimicrobials)  
 02/09/94 (59 FR 6084)  
 NPRM 04/00/01  
 ANPRM (Plaque/Gingivitis) 12/00/01

**Oral Wound Healing Products**

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

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

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

**Otic Products (Earwax)**

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

**Otic Products (Swimmers Ear)**

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

**Overindulgence Remedies**

ANPRM 10/01/82 (47 FR 43540)  
 NPRM 12/24/91 (56 FR 66742)  
 Final Action 12/00/01

**Overindulgence Remedies/Prevention of Inebriation**

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

**Pediculicide Products**

ANPRM 06/29/82 (47 FR 28312)  
 NPRM 04/03/89 (54 FR 13480)  
 Final Action 12/14/93 (58 FR 65452)  
 NPRM (Labeling Amendment) 12/00/01

**Phenylpropanolamine Products (Labeling)**

NPRM 02/14/96 (61 FR 3912)

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

ANPRM 09/07/82 (47 FR 39412)

**Poison Treatment Products**

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

**Quinine for Malaria**

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

**Salicylate (Reye Syndrome)**

NPRM (Amendment)(Warning) 05/05/93  
 (58 FR 26886)  
 ANPRM 10/20/93 (58 FR 54228)  
 Final Action (Warning) 12/00/01

**Skin Bleaching Products**

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

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**Skin Protectant Products**

ANPRM 08/04/78 (43 FR 34628)  
 NPRM 02/15/83 (48 FR 6820)  
 NPRM (Amendment) (Astringent) 04/03/89  
 (54 FR 13490)  
 NPRM (Amendment) (Poison Ivy) 10/03/89  
 (54 FR 40808)  
 NPRM (Amendment) (Fvr Blister/Ext)  
 01/31/90 (55 FR 3362)  
 NPRM (Amendment) (Diaper Rash)  
 06/20/90 (55 FR 25204)  
 Final Action (Astringent) 10/21/93 (58 FR  
 54466)  
 Final Action (Witch Hazel) 06/03/94 (59 FR  
 28767)  
 Final Action (Astringent) 07/00/01  
 Final Action (Poison Ivy) 07/00/01  
 Final Action 07/00/01

**Smoking Deterrent Products**

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

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

NPRM 05/16/90 (55 FR 20434)  
 Final Action 11/07/90 (55 FR 46914)  
 NPRM 08/25/92 (57 FR 38568)  
 Final Action 05/10/93 (58 FR 27636)  
 Final Action 04/22/98 (63 FR 19799)  
 Final Action 08/24/98 (63 FR 44996)  
 Final Action 12/00/01

**Stimulant (Overindulgence) Products**

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

**Stimulant Products**

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

**Stomach Acidifier Products**

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

**Sunscreen Products**

ANPRM 08/25/78 (43 FR 38206)  
 NPRM 05/12/93 (58 FR 28194)  
 NPRM (Amendment) 06/08/94 (59 FR  
 29706)  
 NPRM (Amendment)(Avobenzon)  
 09/16/96 (61 FR 48645)  
 Final Action (Avobenzon Enf. Pol.)  
 04/30/97 (62 FR 23350)  
 Final Action 05/21/99 (64 FR 27666)  
 ANPRM (and Insect Repellant) 08/00/01  
 NPRM (UVA/UVB) 09/00/01

**Sweet Spirits of Nitre**

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

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

NPRM 02/17/95 (60 FR 9554)  
 Final Action 07/00/02

**Vaginal Contraceptive Products**

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

**Vaginal Drug Products**

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

**Vitamin/Mineral Products**

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

**Wart Remover Products**

ANPRM 10/03/80 (45 FR 65609)  
 NPRM 09/03/82 (47 FR 39102)  
 NPRM (Amendment) 03/27/87 (52 FR  
 9992)  
 Final Action 08/14/90 (55 FR 33246)  
 NPRM (Amendment)(Directions) 01/28/94  
 (59 FR 4015)  
 Final Action (Amnd.)(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)  
 NPRM 01/00/02

**Weight Control Products**

ANPRM 02/26/82 (47 FR 8466)  
 NPRM 10/30/90 (55 FR 45788)  
 Final Action 08/08/91 (56 FR 37792)  
 NPRM (Phenylpropanolamine) 06/00/01

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

**Agency Contact:** Gerald M. Rachanow,  
 Regulatory Counsel, Division of Over-  
 the-Counter Drug Products, Department  
 of Health and Human Services, Food  
 and Drug Administration, HFD-560,  
 Center for Drug Evaluation and  
 Research, 5600 Fishers Lane, Rockville,  
 MD 20857

Phone: 301 827-2222

RIN: 0910-AA01

**835. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** This action may affect State, local or tribal governments and the private sector.**Legal Authority:** 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.

**Timetable:**

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

**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.

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

Phone: 301 827-2974

RIN: 0910-AA39

**836. ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR DRUGS AND BIOLOGICS****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262**CFR Citation:** 21 CFR 207**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/01	

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

**Agency Contact:** Howard P. Muller,  
 Regulatory Policy Staff, Department of  
 Health and Human Services, Food and  
 Drug Administration, Suite 3037 (HFD-

HHS—FDA

Proposed Rule Stage

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

RIN: 0910-AA49

### 837. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

**Priority:** Routine and Frequent

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

**CFR Citation:** 21 CFR 312.110

**Legal Deadline:** None

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

requirements. These provisions would implement recent changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996.

#### Timetable:

Action	Date	FR Cite
NPRM	07/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov

RIN: 0910-AA61

### 838. SAFETY REPORTING AND RECORDKEEPING REQUIREMENTS FOR MARKETED OTC DRUGS

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Audrey Thomas, Regulatory Policy Analyst, Regulatory

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

RIN: 0910-AA86

### 839. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a-n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b-j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

**CFR Citation:** 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 600; 21 CFR 320; 21 CFR 601; 21 CFR 606

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

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

HHS—FDA

Proposed Rule Stage

Fax: 301 827-5562

RIN: 0910-AA97

**840. RADIOACTIVE DRUGS FOR BASIC RESEARCH**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 361

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

RIN: 0910-AB00

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

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

RIN: 0910-AB14

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

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 1271

**Legal Deadline:** None

**Abstract:** As part of implementing the proposed regulatory approach to human cellular and tissue-based products, the Food and Drug Administration (FDA) is proposing to require manufacturers of human cells and tissue to follow current good tissue practice (GTP), which includes proper handling, processing, and storage of human cells and tissue, recordkeeping, and the maintenance of a quality program. FDA is also proposing to amend the current good manufacturing practice regulations that apply to medical device products and biological products containing human cells or tissues in order to incorporate the new GTP requirements into existing good manufacturing practice regulations.

**Timetable:**

Action	Date	FR Cite
NPRM	01/08/01	66 FR 1508

Action	Date	FR Cite
NPRM Comment Period End	05/08/01	
Final Action	01/00/03	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

RIN: 0910-AB28

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 312; 21 CFR 314

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Regulatory Policy

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Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910—AB34

#### 844. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 360bbb

**CFR Citation:** 21 CFR 312

**Legal Deadline:** None

**Abstract:** The proposed rule would revise the investigational new drug regulations to clarify the conditions under which individual patients may receive investigational drugs for treatment use; to clarify the conditions under which a small group of patients may receive investigational drugs for treatment use under an expanded access protocol; and to clarify the criteria under which sponsors can recover costs for providing investigational drugs to patients for certain treatment uses.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910—AB37

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

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

**Abstract:** The proposed rule would set forth requirements on the electronic submission of adverse drug reaction reports using international medical terminology, electronic data format, and electronic transmission standards.

**Timetable:**

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

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910—AB42

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 201

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910—AB43

#### 847. PREGNANCY LABELING

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 201

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Virginia G. Beakes, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and

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## Proposed Rule Stage

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RIN: 0910—AB44

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 220

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

**Abstract:** Positron emission tomography (PET) is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug. PET drugs are usually injected intravenously into patients for diagnostic purposes. Most PET drugs are produced using cyclotrons at locations that are in close proximity to the patients to whom the drugs are administered (e.g., in hospitals or academic institutions). Each PET drug is compounded under a physician's prescription and, due to the short half-lives of PET drugs, is administered to the patient within a few minutes or hours.

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP) to assure that the drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess. FDA's CGMP requirements for drug products are set forth in 21 CFR parts 210 and 211.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act (Modernization Act) (Pub. L. 105-115). Section 121 of the Modernization Act contains several provisions affecting the regulation of PET drugs. Section 121(c)(1)(A) of the Modernization Act directs FDA to establish, within two

years after enactment, appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) requires FDA to consult with patient advocacy groups, professional associations, manufacturers, and other interested persons as the agency develops PET drug CGMP requirements and approval procedures. FDA's proposed rule on PET drug CGMP's will be designed to reflect the unique nature of PET drug products.

#### Timetable:

Action	Date	FR Cite
NPRM	09/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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RIN: 0910—AB63

#### 849. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 225

**Legal Deadline:** None

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

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

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

RIN: 0910—AB70

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

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 300.50; 21 CFR 330.10

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	07/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

## HHS—FDA

## Proposed Rule Stage

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910—AB79

### 851. REPACKAGING APPROVAL REQUIREMENTS

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

**Abstract:** The proposed rule would set forth requirements for FDA prior approval of certain types of repackaging of approved drug products by persons who are not holders of approved applications for the products. The proposed rule would ensure that FDA approves changes to drug product containers and closure systems by both application holders and repackagers.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910—AB81

### 852. STABILITY TESTING OF DRUGS

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910—AB82

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

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

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

**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

**CFR Citation:** 21 CFR 111

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) announced in an advance notice of proposed rulemaking (ANPRM) of February 6, 1997 (62 FR 5700), its plans to consider developing regulations establishing current good manufacturing practices (CGMP) for dietary supplements and dietary

ingredients. The ANPRM was published in order for FDA to solicit comments on whether it should initiate action to establish CGMP regulations and if so, what constitutes CGMP for these products. FDA announced that this effort was in response to the section of the Federal Food, Drug, and Cosmetic Act (the Act) that provides authority to the Secretary of Health and Human Services to promulgate CGMP regulations and to a submission from the dietary supplement industry asking that FDA consider an industry-proposed CGMP framework as a basis for CGMP regulations. The ANPRM also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding; which have the identity and provide the quantity of dietary ingredients declared in labeling; and which meet the quality specifications that the supplements are represented to meet.

**Timetable:**

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	06/00/01	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Karen Strauss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, (HFS-820), 200 C Street SW, Washington, DC 20204  
Phone: 202 205-4168  
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**RIN:** 0910—AB88

### 854. SUBMISSION IN ELECTRONIC FORMAT OF CERTAIN LABELING INFORMATION

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AB91

**855. FEES RELATING TO DRUGS; WAIVER AND REDUCTION OF FEES**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AB92

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

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Carol Drew, Regulatory Counsel, Regulatory Policy

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**RIN:** 0910-AB93

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

**Priority:** Routine and Frequent

**Legal Authority:** 21 USC 331; 21 USC 333; 21 USC 334; 21 USC 335b; 21 USC 335c; 21 USC 342; 21 USC 343; 21 USC 351; 21 USC 352; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381

**CFR Citation:** 21 CFR 59

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857

## HHS—FDA

## Proposed Rule Stage

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RIN: 0910-AB96

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Bryan H. Benesch, Special Assistant to the Director, Office of Compliance, Department of Health and Human Services, Food and Drug Administration, HFZ-300, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, MD 20850  
 Phone: 301 549-4699  
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RIN: 0910-AB99

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

**Priority:** Other Significant

**Legal Authority:** 5 USC 552; 21 USC 331(j); 18 USC 1905; 21 USC 355(i); 21 USC 371(a); 42 USC 264

**CFR Citation:** 21 CFR 20.100; 21 CFR 312.42; 21 CFR 312.130; 21 CFR 601.50; 21 CFR 601.51; 21 CFR 601.52; 21 CFR 601.53

**Legal Deadline:** None

**Abstract:** The proposed regulation would require sponsors of human trials involving human gene therapy or xenotransplantation to submit a redacted version for public disclosure of an investigational new drug application (IND), an amendment to an IND, or other related documents. The submission would be redacted to exclude trade secret information and personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. FDA would then make the redacted documents available to the general public and the information would be able to be discussed in open session at scientific advisory committee meetings and at other suitable fora.

#### Timetable:

Action	Date	FR Cite
NPRM	01/18/01	66 FR 4688
NPRM Comment Period End	04/18/01	
Final Action	02/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

RIN: 0910-AC00

### 860. REPORTING INFORMATION REGARDING POTENTIAL FABRICATION OR FALSIFICATION OF DATA

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 349; 21 USC 352; 21 USC 355i; 21 USC 360b; 21 USC 360c; 21 USC 360e; 21 USC 360i; 21 USC 360j; 21 USC 360k; 21 USC 371; 21 USC 379e; 42 USC 262

**CFR Citation:** 21 CFR 70.3; 21 CFR 71.1; 21 CFR 170.3; 21 CFR 171.1; 21 CFR 312.3; 21 CFR 312.56; 21 CFR 510.3; 21 CFR 511.1; 21 CFR 812.46

**Legal Deadline:** None

**Abstract:** The proposed rule would require sponsors to promptly report any information indicating that any person has or may have falsified data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

#### Timetable:

Action	Date	FR Cite
NPRM	06/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Christine Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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RIN: 0910-AC02

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 360b

**CFR Citation:** 21 CFR 524

**Legal Deadline:** None

**Abstract:** After approving a new animal drug application, the Food and Drug Administration (FDA) requires the

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

**Timetable:**

Action	Date	FR Cite
NPRM	02/00/02	

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

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

**RIN:** 0910-AC04**862. LABELING DIETARY SUPPLEMENTS FOR WOMEN WHO ARE OR MAY BECOME PREGNANT**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321(n); 21 USC 342(f); 21 USC 343(a)(1); 21 USC 343(r)(6); 21 USC 371(a)

**CFR Citation:** Not Yet Determined**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

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

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AC09**863. OVERWRAP FOR INHALATION PRODUCTS PACKAGED IN LOW DENSITY POLYETHYLENE (LDPE) CONTAINERS**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375

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

**Abstract:** The proposed rule would require overwrap on all inhalation

products packaged in low density polyethylene (LDPE) containers to prevent ingress of contaminants.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/01	

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

**Agency Contact:** Carol Drew, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AC10**864. REGULATION OF CARCINOGENIC COMPOUNDS USED IN FOOD-PRODUCING ANIMALS; DEFINITION OF "NO RESIDUE"****Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360b; 21 USC 371

**CFR Citation:** 21 CFR 500.82; 21 CFR 500.84; 21 CFR 500.88

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations relating to the operational definition of the term "no residue." The definition is used in determining whether any residue of carcinogenic compounds used in food-producing animals would "be found in food produced from those animals under conditions of use reasonably certain to be followed in practice" (21 CFR 500.80(a)). Under the current operational definition of no residue, it is possible for a residue detected by a method approved by FDA to be considered "no residue." FDA is revising its regulations to make them consistent with a 1995 Department of Justice opinion regarding this definition. The proposed changes would revise the definition of "no residue" to mean that no residue is detected with an approved regulatory method. FDA would propose several conditions that sponsors of

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carcinogenic compounds must satisfy with respect to the sponsors' proposed regulatory methods.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/01	

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

**Agency Contact:** Steven Brynes, Regulatory Scientist, Department of Health and Human Services, Food and Drug Administration, HFV-151, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855  
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**RIN:** 0910-AC13

**865. CONTROL OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION AND RETAIL**

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

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

**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 264; 42 USC 343; 42 USC 264; 42 USC 271

**CFR Citation:** 21 CFR 116; 21 CFR 118

**Legal Deadline:** None

**Abstract:** The President's Council on Food Safety was established in August 1998 to improve the safety of the food supply through science-based regulations and well-coordinated inspection, enforcement, research, and education programs. The Council has identified egg safety as one component of the public health issue of food safety that warrants immediate Federal, interagency action.

In July 1999, FDA and FSIS committed to developing an action plan to address the presence of salmonella enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced by the President on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent

by 2005 and eliminate egg-related SE illnesses by 2010.

The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), and April 6, 2000 (Sacramento, CA), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

In accordance with discussions at the public meetings, FDA intends to publish a proposed rule to require that shell eggs be produced under an SE risk reduction plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

Because egg safety is a farm-to-table effort, FDA intends to include in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at retail establishments. In addition, the agency intends to propose specific requirements for retail establishments that serve populations most at-risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-306, Center for Food Safety and Applied Nutrition, 200 C Street SW., Washington, DC 20204  
Phone: 202 205-4081  
Fax: 202 205-4422  
Email: rebecca.buckner@cfsan.fda.gov

Nancy Bufano, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-306, Center for Food Safety and Applied Nutrition, 200 C Street SW., Washington, DC 20204  
Phone: 202 401-2022  
Fax: 202 205-4422

Email: nancy.bufano@cfsan.fda.gov

**RIN:** 0910-AC14

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

**Priority:** Other Significant

**Legal Authority:** 21 USC 352; 21 USC 321(n); 21 USC 371(a); 21 CFR 201.51; 21 CFR 201.100; 21 CFR 314.125

**CFR Citation:** 21 CFR 201.323(c)

**Legal Deadline:** None

**Abstract:** The proposed rule would revise 21 CFR 323(c) to permit small volume parenterals and pharmacy bulk packages that contain less than 25 ug/L of aluminum to state "contains less than 25ug/L" rather than the exact amount of aluminum.

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0910-AC18

**867. • USE OF MATERIALS DERIVED FROM RUMINANT ANIMALS IN FDA REGULATED PRODUCTS**

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

**Legal Authority:** Not Yet Determined

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The U.S. Department of Agriculture's Animal and Plant Health Inspection Service maintains, by regulation in 9 CFR 94.18(a), a list of countries: (1) where bovine spongiform encephalopathy (BSE) exists; and (2) that present an undue risk of introducing BSE into the United States. This proposed rule would restrict, in FDA regulated products, the use of

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most materials derived from ruminant animals born, raised, or slaughtered in a country listed in 9 CFR 94.18(a). In addition, there would be a waiver provision that could be used under appropriate criteria.

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

Fax: 301 827-5562

**RIN:** 0910-AC19

**868. • POSTMARKETING REPORTS OF SUBSTANDARD OR INEFFECTIVE BULK INGREDIENTS AND BULK INGREDIENTS FROM UNAPPROVED SOURCES**

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

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The proposed rule would address reporting and other issues relating to the importation or receipt of bulk ingredients that are substandard, ineffective, or come from unapproved sources. The proposal is intended to enhance FDA's ability to

help ensure that human drug products have the strength, quality, and purity appropriate for an approved human drug product.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov

**RIN:** 0910-AC20

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Final Rule Stage

## Food and Drug Administration (FDA)

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

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

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

**CFR Citation:** 21 CFR 514

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

**Abstract:** On December 17, 1991, the Agency published a proposed revision of the existing regulations that is consistent with the current procedural regulations for human drugs, where appropriate. The New Animal Drug Application (NADA) revisions articulate general requirements in regulations containing performance standards and would complement these regulations through detailed guidance on, among other matters, appropriate ways of meeting requirements for submission of chemistry,

pharmacology, and statistical data that would better address the intricate scientific issues involved. A separate proposed rule for reporting requirements for marketed animal drugs also was published on that date. The agency intends to repropose the NADA proposed rule to incorporate some recent changes in procedure. The NADA revisions are expected to include regulations to implement the provisions of the Animal Drug Availability Act of 1996, specifically the definition of flexible labeling, and implement parts of the President's National Performance Report "Reinventing the Regulation of Animal Drugs," May 1996. In the reinventing regulations report, FDA proposed to revise its regulations to reflect numerous new process changes and programs that will maintain the safety and effectiveness of new animal drugs and enable a more streamlined animal drug application review and approval process which will result in less regulatory burden upon industry and FDA. The Agency also proposes to amend its regulations to implement title I of the Generic Animal Drug and Patent Term Restoration Act, which established new standards for

marketing approval of generic copies of animal drugs approved after 1962.

**Timetable:**

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

**New Animal Drug Approval Process**

NPRM 12/17/91 (56 FR 65544)

NPRM To Be Determined

**Records and Reports Concerning Experience with Approved New Animal Drugs**

NPRM 12/17/91 (56 FR 65581)

Final Action 05/00/01

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** For information concerning reporting requirements for marketed animal drugs, contact William C. Keller, Director, Division of Surveillance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301 827-6642.

For further information concerning generic animal drugs, contact Lonnie W. Luther, Chief, Quality Assurance

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Support Team, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301 827-0209.

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

**RIN:** 0910-AA02

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 210.3; 21 CFR 211.113; 21 CFR 211.160; 21 CFR 211.165; 21 CFR 211.166; 21 CFR 211.180; 21 CFR 211.192; 21 CFR 211.220; 21 CFR 211.222; 21 CFR 211.240; 21 CFR 211.22; 21 CFR 211.68; 21 CFR 211.82; 21 CFR 211.84; 21 CFR 211.101; 21 CFR 211.103; 21 CFR 211.110; 21 CFR 211.111; ...

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	05/03/96	61 FR 20104
NPRM Comment Period End	09/30/96	
Final Action	12/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

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

**RIN:** 0910-AA45

### 871. BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 320

**Legal Deadline:** None

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

#### Timetable:

Action	Date	FR Cite
NPRM	11/19/98	63 FR 64222
NPRM Comment Period End	02/02/99	
Final Action	07/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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

**RIN:** 0910-AA51

### 872. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

**CFR Citation:** 21 CFR 201

**Legal Deadline:** None

**Abstract:** The proposed regulation would amend the regulations governing the format and content of professional labeling for human prescription drug and biologic products, 21 CFR 201.56 and 201.57. The proposal would require that professional labeling include a section containing highlights of prescribing information, and a section containing an index to prescribing information; reorder currently required information and make minor changes to its content, and establish minimum graphical requirements for professional labeling. The proposal would also eliminate certain unnecessary statements that are currently required to appear on prescription drug labels and move certain information to professional labeling.

#### Timetable:

Action	Date	FR Cite
NPRM	12/22/00	65 FR 81082
Final Action	02/00/02	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

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

**RIN:** 0910-AA94

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**873. CURRENT GOOD MANUFACTURING PRACTICE; REVISION OF CERTAIN LABELING CONTROLS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374**CFR Citation:** 21 CFR 210; 21 CFR 211**Legal Deadline:** None**Abstract:** The final rule amends the labeling control provisions in the current good manufacturing practice regulations to make the provisions less burdensome while still reducing the frequency of drug product mislabeling and drug product recalls associated with cut labeling.**Timetable:**

Action	Date	FR Cite
NPRM	07/29/97	62 FR 40489
NPRM Comment Period End	10/27/97	
Final Action	10/00/01	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Fax: 301 827-5562**RIN:** 0910-AA98**874. USE OF OZONE-DEPLETING SUBSTANCES****Priority:** Other Significant**Legal Authority:** 15 USC 402; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 371; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351**CFR Citation:** 21 CFR 2**Legal Deadline:** None**Abstract:** FDA is amending the regulation that permits the use of ozone-depleting substances in particular circumstances to set the standard FDA will use to determine when the use of ozone-depleting substances (ODS) is no longer essential under the Clean Air Act (CAA) and set

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

**Timetable:**

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

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Fax: 301 827-5562  
Email: mitchellw@cder.fda.gov**RIN:** 0910-AA99**875. EXPORTS; NOTIFICATION AND RECORDKEEPING REQUIREMENTS****Priority:** Routine and Frequent**Legal Authority:** 15 USC 1453 to 1455; 21 USC 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 381**CFR Citation:** 21 CFR 1.101**Legal Deadline:** None**Abstract:** The final rule would establish the notification recordkeeping requirements for persons exporting human drugs, animal drugs, biological products, and devices under the FDA Export Reform and Enhancement Act.**Timetable:**

Action	Date	FR Cite
NPRM	04/02/99	64 FR 15944
Extension	06/17/99	64 FR 32442
NPRM Comment Period End	07/16/99	
Final Action	06/00/01	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov**RIN:** 0910-AB16**876. FOREIGN ESTABLISHMENT REGISTRATION AND LISTING****Priority:** Routine and Frequent**Legal Authority:** 21 USC 321; 21 USC 374; 42 USC 216; 42 USC 262; 21 USC 331; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b to 360c; 21 USC 360e; 21 USC 360i to 360j; 21 USC 371**CFR Citation:** 21 CFR 207; 21 CFR 607; 21 CFR 807**Legal Deadline:** None**Abstract:** The final rule would amend the establishment registration and product listing regulations for human drugs, biological products, animal drugs, and devices to require foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of such products that are imported or offered for import into the United States to register and to register the name of a United States agent for the foreign establishment.**Timetable:**

Action	Date	FR Cite
NPRM	05/14/99	64 FR 26330
NPRM Comment Period Reopen	08/09/99	
NPRM Comment Period End	10/08/99	
Final Action	06/00/01	

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

## HHS—FDA

## Final Rule Stage

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
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Email: pchao@oc.fda.gov

**RIN:** 0910-AB21

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 1.84

**Legal Deadline:** None

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

complies with section 361 of the PHS Act.

**Timetable:**

Action	Date	FR Cite
NPRM	11/24/98	63 FR 64930
NPRM Comment Period End	02/08/99	
Final Action	09/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov

**RIN:** 0910-AB24

**878. BLOOD INITIATIVE**

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

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

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

**Legal Deadline:** None

**Abstract:** In multiple rulemakings, the Food and Drug Administration is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma and blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on a comprehensive review of the regulations that has been performed by FDA. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on House Resources and Intergovernmental Relations; the General Accounting Office; the Institute of Medicine, as well as public comments. Some of the subjects intended to be addressed in the rulemakings include: 1) labeling; 2) notification of consignees and end

users of product safety information for plasma derivative products; 3) notification of deferred donors; 4) requirements for donor suitability and testing; and 5) infectious agent clearance. These actions are intended to help ensure the continued safety of the Nation's blood supply.

**Timetable:**

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

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

**Current Good Manufacturing Practice for Blood and Blood Components; Blood Labeling Standards**  
NPRM 12/00/01

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

NPRM 08/19/99 (64 FR 45355)  
Final Action 05/00/01

**Infectious Agent Clearance**  
NPRM 06/00/02

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

ANPRM 08/19/99 (64 FR 45383)  
NPRM 06/00/02

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

NPRM 08/19/99 (64 FR 45340)  
Final Action 05/00/01

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

Direct Final Rule 08/19/99 (64 FR 45366)  
NPRM 08/19/99 (64 FR 45375)  
Final Action 05/00/01

**Suitability Reqs. for Whole Blood and Source Plasma Donors**  
NPRM 12/00/01

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Additional Information:** See RIN 0910-AB76. CGMP for Blood and Blood Components; Blood Labeling Standards formerly listed under 0910-AB89

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

## HHS—FDA

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Email: falter@cber.fda.gov

RIN: 0910–AB26

### 879. ANTIBIOTIC DRUG APPROVAL AND EXCLUSIVITY

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	01/24/00	65 FR 3623
NPRM Comment Period End	04/24/00	
Final Action	10/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Paul C. Varki, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037, (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
Email: varkip@cder.fda.gov

RIN: 0910–AB33

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

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

**Abstract:** This final rule revises 21 CFR parts 10, 201, 250, 310, 329, 361, 606, and 610 by removing the requirement that prescription drugs be labeled “Caution: Federal law prohibits dispensing without prescription” and substituting a requirement that prescription drugs be labeled “Rx only.” The rule also revises 21 CFR parts 201, 329, and 369 by removing the requirement that certain habit-forming drugs bear the statement “Warning—May be habit forming.” The rule also revises 21 CFR part 290 to clarify that drugs that are controlled substances under the Federal Controlled Substances Act are prescription drugs.

**Timetable:**

Action	Date	FR Cite
NPRM	04/21/00	65 FR 21378
Final Action	08/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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

RIN: 0910–AB39

### 881. SUPPLEMENTS AND OTHER CHANGES TO APPROVED NEW ANIMAL DRUG APPLICATIONS

**Priority:** Other Significant

**Legal Authority:** 21 USC 356a

**CFR Citation:** 21 CFR 514.8

**Legal Deadline:** None

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

these changes may be distributed. The Center for Veterinary Medicine is amending the regulations regarding supplementary new animal drug regulations to incorporate the requirements of section 116.

**Timetable:**

Action	Date	FR Cite
NPRM	10/01/99	64 FR 53281
Final Rule	12/00/01	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

RIN: 0910–AB49

### 882. REVISIONS TO THE GENERAL SAFETY REQUIREMENTS FOR BIOLOGICAL PRODUCTS; DIRECT FINAL RULE

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 351

**CFR Citation:** 21 CFR 610.11(g)

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) issued a direct final rule and companion proposed rule to amend the biologics regulations by adding “cellular therapy products” to the list of products excepted from the general safety test (GST) and by adding an administrative procedure for obtaining an exemption from the GST requirements for other biological products. Because the agency received significant adverse comment on the administrative procedure portion of the direct final rule, FDA withdrew that portion of the rule and confirmed the remaining portion. FDA intends to finalize the companion proposed rule to respond to the significant adverse comment on the administrative procedure portion of the rule. FDA is taking this action because the GST may not be relevant or necessary for all biological products, including cellular therapy products, currently in various

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stages of development. This action is part of FDA's continuing effort to achieve the objectives of the "Reinventing Government" initiative, and is intended to reduce the burden of unnecessary regulations on biological products without diminishing the protection of the public health.

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

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

**RIN:** 0910-AB51

**883. DISCONTINUATION OF A LIFESAVING PRODUCT**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 356(c)

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/07/00	65 FR 66665
Final Action	06/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

**Agency Contact:** Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910-AB60

**884. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION**

**Priority:** Other Significant

**Legal Authority:** 21 USC 356a

**CFR Citation:** 21 CFR 314

**Legal Deadline:** None

**Abstract:** Section 116 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) added section 506A to the Food, Drug, and Cosmetic Act (21 U.S.C. 356a). Pursuant to section 116, the rulemaking will revise current procedures for approving manufacturing changes and generally classify such changes into four categories. Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency of the drug as they may relate to the safety and effectiveness of a drug, require prior approval of a supplemental application. A second category of changes may be made if FDA has not notified the company within 30 days after the submission of a supplement that prior approval is required. A third category of changes may be made upon submission of a supplement to the agency. The rule will also identify another category of changes that may be made without the submission of a supplement but which must be reported in an annual report.

**Timetable:**

Action	Date	FR Cite
NPRM	06/28/99	64 FR 34608
Final Action	10/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Howard P. Muller, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AB61

**885. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS**

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

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

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

**CFR Citation:** 21 CFR 101

**Legal Deadline:** None

**Abstract:** Section 403(q) of the Federal Food, Drug, and Cosmetic Act, which was added by the Nutrition Labeling and Education Act of 1990, requires that the label or labeling of food products bear nutrition information. Among other things, section 403(q) authorizes the Food and Drug Administration (FDA) to add or delete nutrients that are to be declared on the labels or labeling of food products by regulation if it finds such action necessary to assist consumers in maintaining healthy dietary practices. FDA issued final regulations implementing these provisions in 1993. FDA subsequently received a citizen petition requesting that FDA amend its regulations on food labeling to require that the amount of trans fatty acids be listed in the nutrition label and be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disqualifying levels and disclosure levels. In response to this petition and based on new evidence, FDA proposed the actions requested in the petition on November 17, 1999 (64 FR 62746). In addition, FDA proposed to define the claim "trans fat free."

**Timetable:**

Action	Date	FR Cite
NPRM	11/17/99	64 FR 62746

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Action	Date	FR Cite
NPRM Comment Period Reopened	12/05/00	65 FR 75887
Final Rule	09/00/01	

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

**Agency Contact:** Susan Thompson, Chemist, Department of Health and Human Services, Food and Drug Administration, (HFS-832), Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204

Phone: 202 205-5587

Email: [snt@cfsan.fda.gov](mailto:snt@cfsan.fda.gov)**RIN:** 0910-AB66**886. PRESUBMISSION CONFERENCES****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 360b**CFR Citation:** 21 CFR 514**Legal Deadline:** None

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

**Timetable:**

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

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

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

Phone: 301 594-1620

**RIN:** 0910-AB68**887. SURGEON'S AND PATIENT EXAMINATION GLOVES; RECLASSIFICATION****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	07/30/99	64 FR 41710
Final Action	10/00/01	

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

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

Phone: 301 827-2974

**RIN:** 0910-AB74**888. CGMPS FOR BLOOD AND BLOOD COMPONENTS; NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV (LOOKBACK)****Priority:** Economically Significant. Major under 5 USC 801.

**Legal Authority:** 21 USC 321; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa-25;

21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374

**CFR Citation:** 21 CFR 606; 21 CFR 610**Legal Deadline:** None

**Abstract:** This rulemaking is one of a number of actions being taken to amend the biologics regulations to remove, revise, or update the regulations applicable to blood, blood components, and blood derivatives. These actions are based on a comprehensive review of the regulations performed by FDA, and are also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as public comments. In this rulemaking, FDA will propose to amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested repeatedly reactive for evidence of HCV.

**Timetable:**

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69377
NPRM Comment Period End	02/14/01	
Final Action	03/00/02	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Additional Information:** See RIN 0910-AB26.

**Agency Contact:** Steven F. Falter, Director, Regulations and Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448

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Email: [falter@cber.fda.gov](mailto:falter@cber.fda.gov)**RIN:** 0910-AB76

HHS—FDA

Final Rule Stage

**889. ANTIBIOTIC RESISTANCE LABELING**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 201.24

**Legal Deadline:** None

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

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910-AB78

**890. 180-DAY GENERIC DRUG EXCLUSIVITY FOR ABBREVIATED NEW DRUG APPLICATIONS**

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 314.107

**Legal Deadline:** None

**Abstract:** The final rule will amend regulations governing 180-day generic drug exclusivity to clarify existing eligibility requirements and conditions for abbreviated new drug application

sponsors, to modify current eligibility requirements, and to impose new eligibility conditions. These revisions are the result of recent court decisions, including *Mova Pharmaceutical v. Shalala*, 140 F. 3d 1060 (D.C. Cir. 1998), invalidating an eligibility requirement for exclusivity.

**Timetable:**

Action	Date	FR Cite
NPRM	08/06/99	64 FR 42873
NPRM Comment Period End	10/04/99	
Final Action	11/00/01	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:**

Undetermined

**Agency Contact:** Virginia G. Beakes, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AB80

**891. FOOD ADDITIVES: FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321 et seq

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

**Legal Deadline:** None

**Abstract:** In November 1997, Congress amended the Federal Food, Drug, and Cosmetic Act (FFD&C) to establish a notification process whereby manufacturers and suppliers of components of food contact materials may notify FDA 120 days prior to marketing a new food contact substance. If FDA does not object to the notification within 120 days, the substance may be marketed with the same status as a regulated food additive. FDA is authorized to publish

regulations outlining the information required to be submitted in premarket notifications for food-contact substances submitted to the agency. FDA is also authorized to publish regulations that identify when a food additive petition is required in lieu of a premarket notification. FDA is not required to accept a premarket notification in any fiscal year for which an appropriation is not specifically made for this program. FDA expects that the majority of food-contact substances that are currently the subject of food additive petitions will be the subject of premarket notifications. FDA also expects that substances currently reviewed under the agency's threshold of regulation process will be reviewed as premarket notifications under the new process. Unlike food additive regulations, premarket notifications will be specific to the notifier. The proposed use of a similar or identical substance produced by another manufacturer will require a separate premarket notification submission. Also unlike food additive petitions, the existence of the notification and any otherwise releasable data within the notification is not publicly available until the 120-day period has expired. FDA expects to keep a publicly available list of effective premarket notifications to assist manufacturers, distributors, and users of food packaging and other food-contact materials. FDA published a proposed rule on the notification process for food contact substances on July 13, 2000. The comment period on the proposed rule ended on September 26, 2000.

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Mitchell Alan Cheeseman, Team Leader, Department of Health and Human Services, Food and Drug Administration, HFS-215, Center for Food Safety and Applied Nutrition, 200 C Street SW, Washington, DC 20204  
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**RIN:** 0910-AB94

HHS—FDA

Final Rule Stage

**892. STATE CERTIFICATION OF MAMMOGRAPHY FACILITIES****Priority:** Other Significant**Legal Authority:** 21 USC 360i; 21 USC 360nn; 21 USC 374; 42 USC 263b**CFR Citation:** 21 CFR 900.2; 21 CFR 900.20; 21 CFR 900.21; 21 CFR 900.22; 21 CFR 900.23; 21 CFR 900.24; 21 CFR 900.25**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	03/30/00	65 FR 16847
NPRM Comment Period End	06/28/00	
Final Rule	06/00/01	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.

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

**RIN:** 0910-AB98**893. EXAMINATION OF ADMINISTRATIVE RECORD AND OTHER ADVISORY COMMITTEE RECORDS****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321**CFR Citation:** 21 CFR 14.75**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	01/08/01	66 FR 1275
Direct Final Rule	01/08/01	66 FR 1257
Direct Final Rule Withdrawn	05/00/01	
Final Rule	09/00/01	

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

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

**RIN:** 0910-AC03**894. EFFICACY EVIDENCE NEEDED FOR PRODUCTS TO BE USED AGAINST TOXIC SUBSTANCES WHEN HUMAN STUDIES ARE UNETHICAL****Priority:** Other Significant

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

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

**Abstract:** The agency plans to publish a final rule that would amend its new

drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, or radiological, substances when adequate and well-controlled efficacy studies in humans cannot be conducted ethically. Efficacy studies in humans cannot be conducted ethically if: 1) the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers without a proven treatment; and 2) field trials (assessment of the product after natural accidental, or malicious exposure to the substance) are not feasible. FDA is taking this action because it recognizes the importance of improving medical responses to the use of lethal or permanently disabling chemical, biological, radiological, and nuclear substances in order to protect individuals exposed to these substances.

**Timetable:**

Action	Date	FR Cite
NPRM	10/05/99	64 FR 53960
Final Action	08/00/01	

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

**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AC05**895. ADDITIONAL SAFEGUARDS FOR CHILDREN IN CLINICAL INVESTIGATIONS OF FDA REGULATED PRODUCTS****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 343; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 350a; 21 USC 350b; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC

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371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

**CFR Citation:** 21 CFR 50; 21 CFR 56

**Legal Deadline:** Other, Statutory, April 17, 2001, The Children's Health Act of 2000 requires FDA to adopt existing HHS regulations within 6 months of the date of its enactment on 10/17/2000. Thus FDA is required to adopt HHS Subpart D by 4/17/2001.

**Abstract:** The interim rule would provide additional protections for children involved as subjects in clinical investigations of FDA-regulated products, as required by the Children's Health Act of 2000.

**Timetable:**

Action	Date	FR Cite
Interim Rule	04/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Carol Drew, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910-AC07

**896. IMPLEMENTING COURT DECISIONS, ANDA APPROVALS, AND 180-DAY EXCLUSIVITY**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 314.107(e)

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	07/13/00	65 FR 43233
Final Rule	11/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**897. REVOCATION OF CONDITIONS FOR MARKETING DIGOXIN PRODUCTS FOR ORAL USE**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 310.500

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/24/00	65 FR 70538
Final Rule	12/00/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Mary E. Catchings, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, HFD-7, Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AC12

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Long-Term Actions

## Food and Drug Administration (FDA)

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

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 106; 21 CFR 107

**Legal Deadline:** None

**Abstract:** The agency published a proposed rule on July 9, 1996 that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. Two final rules will be published: one, on Quality Factors and the second, on Good Manufacturing Practice, Quality Control Procedures

Notification Requirements, and Records and Reports.

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

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

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

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

## HHS—FDA

## Long-Term Actions

**Infant Formula Quality Factors**

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

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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**RIN:** 0910-AA04

**899. FOOD LABELING REVIEW**

**Priority:** Routine and Frequent

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

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

**Legal Deadline:** None

**Abstract:** The Nutrition Labeling and Education Act of 1990 (NLEA) requires that most foods bear nutrition labeling. The agency issued final rules implementing most of the provisions contained in the NLEA on January 6, 1993. Subsequently, however, the agency has identified additional areas that should be the subject of rulemaking. FDA issued a proposal on January 6, 1993, to establish requirements for the identification of certain ingredients on food labels. FDA proposed on June 15, 1993, to amend its January 6, 1993, final rules on nutrient content and health claims to remove the provisions that exempted restaurant menus from the requirements for how nutrient content claims and health claims are to be made. The agency proposed on January 4, 1994, to establish reference daily intakes based on the 9th and 10th editions of the National Research Council's Recommended Dietary Allowances. On March 14, 1994, FDA published a proposal implementing the provisions for exemptions from nutrition labeling for low-volume food products of small businesses that were established by the Nutrition Labeling and Education Act Amendments of 1993. On August 18, 1993, FDA published a proposal

concerning the placement of the nutrition facts panel on food labels. Finally, on July 18, 1994, FDA published proposed revised guidelines for the voluntary declaration of nutrition labeling for raw produce and fish. A final rule concerning the placement of the nutrition facts panel was published on April 5, 1995. A final rule establishing reference daily intakes based on the 9th and 10th editions of Recommended Dietary Allowances was published on December 28, 1995.

FDA published a final rule on August 2, 1996, on nutrient content claims and health claims to remove the provisions that exempted restaurant menus from the requirements for how nutrient content claims and health claims are to be made. FDA published a final rule on August 7, 1996, implementing the exemption for small businesses from the requirements for nutrition labeling and providing instructions on how to file a notice claiming the exemption. FDA published on August 16, 1996, final guidelines on the voluntary declaration of nutrition labeling for raw produce and fish.

**Timetable:****Amend Standard of Identity for Grain Products (Folic Acid)**

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

**Health Claims and Label Statements**

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

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

**Misleading Containers; Nonfunctional Slack Fill**

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

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

NPRM 06/15/93 (58 FR 33055)  
 Final Action 08/02/96 (61 FR 40320)

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

NPRM 01/06/93 (58 FR 2944)  
 Final Action 05/10/94 (59 FR 24232)

**Placement of Nutrition Facts Panel**

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

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

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

**Reference Daily Intakes**

NPRM 01/04/94 (59 FR 427)  
 Final Action 12/28/95 (60 FR 67164)

**Small Business Exemption, Nutrition Labeling**

NPRM 03/14/94 (59 FR 11872)  
 Final Action 08/07/96 (61 FR 40963)

**Voluntary Guidelines for Nutrition Labeling Produce**

NPRM 07/18/94 (59 FR 36379)  
 Final Action 08/16/96 (61 FR 42742)

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State,  
 Federal

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

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

**Agency Contact:** Christine L. Lewis,  
 Director, Office of Nutritional Products,  
 Labeling and Dietary Supplements,  
 Department of Health and Human  
 Services, Food and Drug  
 Administration, (HFS-800), Center for  
 Food Safety and Applied Nutrition, 200  
 C Street SW, Washington, DC 20204  
 Phone: 202 205-4561

**RIN:** 0910-AA19

**900. MEDICAL FOODS**

**Priority:** Other Significant

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

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

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** Yes

## HHS—FDA

## Long-Term Actions

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Federal

**Federalism:** Undetermined

**Agency Contact:** Sue A. Anderson, Department of Health and Human Services, Food and Drug Administration, (HFS-831), Center for Food Safety and Applied, Nutrition, 200 C Street SW, Washington, DC 20204  
Phone: 202 205-4240

**RIN:** 0910-AA20

### 901. CLASSIFICATION OF COMPUTER SOFTWARE PROGRAMS THAT ARE MEDICAL DEVICES

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** FDA is considering whether to classify stand-alone computer software products that fit the definition of a medical device under the Federal Food, Drug, and Cosmetic Act. Although the Secretary has not made a final decision to initiate such a program, the agency is considering classifying these devices by using a risk-based approach as required under the Medical Device Amendments to the Act. In addition, the agency would use existing exemptions from regulation where appropriate. Under this approach, low risk medical software devices would be subject only to the adulteration and misbranding provisions of the Act. Moderate risk devices would additionally be subject to the registration, listing, good manufacturing practice requirements, and reporting and recordkeeping requirements. High risk devices would be the only products to require premarket submissions. FDA would seek comment on potential criteria related to the intended uses of medical software devices that might be used in determining the level of risk.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

### Regulatory Flexibility Analysis

**Required:** Undetermined

**Government Levels Affected:** None

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

**RIN:** 0910-AA41

### 902. REINVENTING FDA FOOD REGULATIONS

**Priority:** Substantive, Nonsignificant

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

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

**Legal Deadline:** None

**Abstract:** In response to President Clinton's memorandum to heads of departments and agencies entitled "Regulatory Reinvention Initiative," FDA has initiated rulemaking to retain, revise, or revoke certain of its regulations for food. FDA published an advance notice of proposed rulemaking (ANPRM) on December 29, 1995, requesting information on the need to retain, revise, or revoke its food standards of identity regulations and its common or usual name regulations. In the same issue of the Federal Register, FDA proposed to improve the coordination of the food additive, GRAS, and color additive approval process with USDA for substances used in meat and poultry products. FDA proposed to revoke several lower fat milk standards on November 9, 1995. On June 12, 1996, FDA published an ANPRM announcing its intention to review: 1) its human food labeling regulations pertaining to the exemption for soft drinks from requirements for the type size and placement of certain information on the information panel, requirements for listing "statements of identity," and requirements for flavor labeling; 2) its infant formula regulations to ensure that they fully reflect the Federal Food, Drug, and Cosmetic Act; 3) its regulations pertaining to the discharge of waste aboard casino ships, passenger ships,

and ferries; and 4) its food additive regulations to consolidate certain existing regulations. In the same June 12 issue of the Federal Register, FDA published a second ANPRM seeking public comment on possible ways to streamline various food additive regulations. FDA also proposed on June 12, 1996, to revoke certain food labeling regulations pertaining to labeling of food with number of servings and labeling Kosher and Kosher-style foods and to revoke the agency's voluntary filing of cosmetic product experiences. The latter was published August 12, 1997.

On October 13, 1995, FDA proposed to revoke certain agency regulations that were obsolete or no longer necessary to achieve public health goals. The final rule (pertaining to food regulations only) was published on June 3, 1996. A confirmation of effective date on those regulations, promulgated under the formal rulemaking procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 USC 371(e)), pertaining to diabetic labeling (21 CFR 105.67) and sodium intake labeling (21 CFR 105.69), was published on August 27, 1996.

In the Federal Register of April 17, 1997 (62 FR 18938), FDA proposed to establish a notification procedure for companies to use to inform FDA of a company's determination that use of a substance in food is generally recognized as safe (GRAS).

**Timetable:**

**Exempt Infant Formula; Plan for Revisions**

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

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

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

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

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

**Notification Procedures for GRAS**

**Determinations**

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

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

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

## HHS—FDA

## Long-Term Actions

**Revocation of Lower Fat Milk Standards**

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

**Revocation of Lower Fat Yogurt Standards**

NPRM 11/09/95 (60 FR 56541)  
 Confirmation of Effective Date To Be  
 Determined  
 Final Action (Yogurt) To Be Determined

**Revocation of Obsolete Regulations**

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

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

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

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

Phone: 202 205-4561

**RIN:** 0910-AA58

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

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 42 USC 241; 42 USC 262; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 42 USC 216; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 360c; 21 USC 360d; 21 USC 360e; 21 USC 360f; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 379e; 21 USC 381; 42 USC 263b; 42 USC 263e; 42 USC 263f; 42 USC 263g; 42 USC 263h; 42 USC 263i; 42 USC 263j; 42 USC 263k; 42 USC 263l; 42 USC 263m; 42 USC 263n; 42 USC 263c; 42 USC 263d

**CFR Citation:** 21 CFR 50; 21 CFR 312

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration is planning to publish a final rule that would finalize its 1999

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

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	10/05/99	64 FR 54180
Final Action	04/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** Federal

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

**RIN:** 0910-AA89

**904. DIRECT-TO-CONSUMER PROMOTION REGULATIONS**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 321; 21 USC 360k; 21 USC 361; 21 USC 362; 21 USC

371; 21 USC 331; 21 USC 334; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360e to 360i

**CFR Citation:** 21 CFR 200; 21 CFR 800

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

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

**RIN:** 0910-AA90

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

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

**Unfunded Mandates:** Undetermined

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

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

**Legal Deadline:** None

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

## HHS—FDA

## Long-Term Actions

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

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910-AB02

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

**Priority:** Other Significant

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

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	09/30/99	64 FR 52696
NPRM Comment Period Reopened	04/18/00	65 FR 20774
NPRM Comment Period End	07/17/00	
Final Action	01/00/03	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

**Agency Contact:** Astrid L. Szeto, Senior Regulatory Review Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448  
Phone: 301 827-6210

**RIN:** 0910-AB27

**907. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE-CHOICE MEDICATED FEED**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 558.5; 21 CFR 510.455

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	To Be Determined	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910-AB50

**908. BULK DRUG SUBSTANCES FOR USE IN PHARMACY COMPOUNDING**

**Priority:** Other Significant

**Legal Authority:** PL 105-115, sec 127; 21 USC 351; 21 USC 352; 21 USC 353a; 21 USC 355; 21 USC 371

**CFR Citation:** 21 CFR 216

## HHS—FDA

## Long-Term Actions

**Legal Deadline:** None

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

**Timetable:**

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

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** None

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

**RIN:** 0910-AB57

**909. PHARMACY AND PHYSICIAN COMPOUNDING OF DRUG PRODUCTS**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353a; 21 USC 355; 21 USC 360; 21 USC 371

**CFR Citation:** 21 CFR 216

**Legal Deadline:** None

**Abstract:** Section 503A of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353a) describes the circumstances under which compounded drugs may qualify for

exemption from three requirements of the Act: (1) that a drug be manufactured according to current good manufacturing practice; (2) that a drug have adequate directions for use; and (3) that a marketing application be approved by FDA before a new drug product is introduced for sale (i.e., sections 501(a)(2)(B), 502(f)(1), and 505 of the Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355)). To qualify for the exemption, a pharmacist or physician must meet statutory conditions for compounding, including the following: (1) there generally must be a prescription for an identified individual patient before compounding; (2) compounding before receiving a prescription is allowed only under limited circumstances; (3) the quantity of drugs that may be shipped out of state is limited and may vary depending on whether the compounder is located in a state that has entered into a memorandum of understanding (MOU) with FDA; (4) drug products may only be compounded using a bulk drug substance (which is essentially the active ingredient) that is listed in the United States Pharmacopoeia (USP) or National Formulary (NF), or a bulk drug substance that is a component of an FDA-approved drug product, or a bulk drug substance that is listed in the regulation as one that FDA has found to be suitable for compounding; (5) the bulk drug substance must be made in a facility registered with FDA and the bulk drug substance must be accompanied by a certificate of analysis; (6) they cannot compound regularly or in inordinate amounts of any drug products that are essentially copies of commercially available products; (7) drug products may not be compounded if they are listed in a regulation as having been removed from the market or had their FDA-approval withdrawn because they were found to be not safe or not effective; (8) drug products that are listed in the regulations as "demonstrably difficult to compound" may not be compounded. The regulations will amplify and explain the statutory requirements as well as execute tasks Congress assigned FDA in section 503A. This proposed rule will be one of several rulemakings implementing section 503A. Related regulatory initiatives are described below: (1) FDA has issued a final rule listing drug products that may not be compounded because they were found to be not safe

or not effective and were removed from the market or had their FDA approval withdrawn; (2) FDA has also issued a proposed rule and is preparing a final rule listing drugs that are not the subject of a USP or NF monograph, and are not components of an FDA-approved drug product but are suitable for compounding; (3) FDA is currently preparing a proposed rule listing those drugs that are demonstrably difficult to compound and are not allowed to be compounded; and (4) FDA has published a Federal Register notice announcing the availability of a draft MOU between FDA and State boards of pharmacy.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Federal

**Federalism:** Undetermined

**Additional Information:** See RINs 0910-AB57, 0910-AB59

**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
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**RIN:** 0910-AB58

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 105-115, sec 127

**CFR Citation:** 21 CFR 216

**Legal Deadline:** None

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

## HHS—FDA

## Long-Term Actions

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

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

**Agency Contact:** Andrea C. Masciale, Regulatory Counsel, Regulatory Policy Staff, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910-AB59

### 911. MANDATORY HACCP REGULATIONS FOR MANUFACTURERS OF RENDERED PRODUCTS

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 21 CFR 589

**Legal Deadline:** None

**Abstract:** During the notice and comment rulemaking for 21 CFR part 589, "Listing of Specific Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed," FDA received several comments supporting the application of mandatory Hazard Analysis Critical Control Point (HACCP) regulations for renderers. Some of these comments were from renderers. Because of the

need to expedite the rulemaking for 21 CFR part 589, FDA stated that it would take up the HACCP regulations for renderers as a separate initiative. This rulemaking is to address the need expressed in the comments to 21 CFR part 589 by promulgating mandatory HACCP regulations for renderers.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910-AB72

### 912. CITIZEN PETITIONS; ACTIONS THAT CAN BE REQUESTED BY PETITION; DENIALS, WITHDRAWALS, AND REFERRALS FOR OTHER ADMINISTRATIVE ACTION

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

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

**CFR Citation:** 21 CFR 10

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	11/30/99	64 FR 66822

Action	Date	FR Cite
NPRM Comment Period End	02/28/00	
Final Action	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
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**RIN:** 0910-AB73

### 913. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 589

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
ANPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State

**Federalism:** Undetermined

## HHS—FDA

## Long-Term Actions

**Agency Contact:** Randall A. Lovell, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, HFV-222, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855  
Phone: 301 827-0176  
Fax: 301 827-1484  
Email: rlovell@cvm.fda.gov

**RIN:** 0910—AB90

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

**Priority:** Routine and Frequent

**Legal Authority:** 15 USC 1453, 1454, 1455; 21 USC 321, 343, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 USC 216, 241, 243, 262, 264

**CFR Citation:** 21 CFR 1.98

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	01/22/01	66 FR 6502
NPRM Comment Period End	04/09/01	
Final Rule	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-3380  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov

**RIN:** 0910—AB95

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 216.24

**Legal Deadline:** None

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

**Timetable:**

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

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0910—AC01

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

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 353a

**CFR Citation:** 21 CFR 216.24

**Legal Deadline:** None

**Abstract:** The NPRM proposes to amend 21 CFR 216.24 by adding three

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

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0910—AC08

#### 917. PREMARKET NOTICE CONCERNING BIOENGINEERED FOODS

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 192; 21 CFR 592

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is requiring the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is requiring that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA took this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The action will permit the agency to assess on an ongoing basis whether plant-derived

## HHS—FDA

## Long-Term Actions

bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act.

**Timetable:**

Action	Date	FR Cite
NPRM Final Action	01/18/01 To Be	66 FR 4706 Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Phone: 202 418-3101

Fax: 202 418-3131

Email: lkahl@cfsan.fda.gov

**RIN:** 0910-AC15

**918. • RESCISSION OF SUBSTANTIALLY EQUIVALENT DECISIONS AND RESCISSION APPEAL PROCEDURES**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 15 USC 1451 to 1461; 21 USC 141 to 149; 21 USC 321 to 394; 21 USC 467f; 21 USC 679; 21 USC 821; 21 USC 1034; 28 USC 2112; 42 USC 201 to 262; 42 USC 263b; 42 USC 364; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

**CFR Citation:** 21 CFR 16; 21 CFR 807

**Legal Deadline:** None

**Abstract:** FDA may rescind a decision issued under the Federal Food, Drug, and Cosmetic Act (the Act) that a device is substantially equivalent to a legally marketed device, and therefore, may be marketed. In addition, under this rule a premarket notification (commonly known as a 510(k)) holder may request administrative review of a proposed rescission action. This rule would standardize the procedures for considering rescissions.

**Timetable:**

Action	Date	FR Cite
Proposed Rule Final Rule	01/26/01 To Be	66 FR 3526 Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

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

Phone: 301 827-2974

**RIN:** 0910-AC16

**919. • INSTITUTIONAL REVIEW BOARDS: REGISTRATION REQUIREMENTS**

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

**Legal Authority:** 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 306c to 306f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n; 42 USC 264

**CFR Citation:** 21 CFR 56.106

**Legal Deadline:** None

**Abstract:** The proposed rule would require institutional review boards (IRB) to register with FDA. The registration information would include the names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the responsible institutional official (if the IRB is affiliated with an institution) and IRB chair or contact, the range of active protocols (small, medium, or large) involving FDA-regulated products reviewed in the previous calendar year, and a description of the types of FDA-regulated products reviewed. The proposed rule would make it easier for FDA to inspect IRB's and to convey information to IRB's.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 827-3380

Fax: 301 827-4774

Email: pchao@oc.fda.gov

**RIN:** 0910-AC17

**920. • CHRONIC WASTING DISEASE: CONTROL OF FOOD PRODUCTS AND COSMETICS DERIVED FROM EXPOSED ANIMAL POPULATIONS**

**Priority:** Other Significant

**Legal Authority:** 42 USC 264; 21 USC 301 et seq

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to prohibit the use for food, including dietary supplements, and cosmetics derived from any part of cervids, such as deer and elk, that have been exposed to chronic wasting disease (CWD). FDA is proposing this regulation because of potential risks to health.

CWD is a type of transmissible spongiform encephalopathy (TSE), a group of fatal, neurodegenerative diseases that include bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep, and Creutzfeldt-Jakob disease (CJD) in humans. CWD affects cervids in the United States and Canada.

CWD is endemic in cervid populations in certain areas of Colorado, Nebraska, and Wyoming. The disease has been identified in wild and farmed elk and wild deer populations. At least one published scientific article has reported that infectious CWD prion proteins in vitro can convert normal, non-infectious human prion proteins into abnormal, infectious forms. These data suggest that the agent of CWD could be transmitted to humans.

Currently, there are no analytical tests to identify animals in the pre-clinical phase of CWD, or any other TSE. CWD typically exhibits a long incubation period, during which time animals appear normal but are likely to be infectious. Therefore, FDA is proposing to require that food or cosmetic products derived from animals exposed to CWD not enter into commerce until scientific evidence indicates that these products do not represent a threat to public health.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

## HHS—FDA

## Long-Term Actions

**Regulatory Flexibility Analysis**

Required: Yes

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

Undetermined

**Federalism:** Undetermined**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-306, Center for Food Safety and Applied Nutrition,

200 C Street SW., Washington, DC 20204

Phone: 202 205-4081

Fax: 202 205-4422

Email: rebecca.buckner@cfsan.fda.gov

**RIN:** 0910-AC21

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Completed Actions

## Food and Drug Administration (FDA)

**921. BIOLOGICAL PRODUCTS: REPORTING OF BIOLOGICAL PRODUCT DEVIATIONS IN MANUFACTURING****Priority:** Other Significant**CFR Citation:** 21 CFR 600; 21 CFR 606**Completed:**

Reason	Date	FR Cite
Final Action	11/07/00	65 FR 66621

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Paula S. McKeever  
Phone: 301 827-6210**RIN:** 0910-AA12**Government Levels Affected:** State, Federal**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Elsworth Dory  
Phone: 301 827-7264**RIN:** 0910-AA52**926. SHELL EGGS: WARNING, NOTICE AND SAFE HANDLING LABELING STATEMENTS AND REFRIGERATION REQUIREMENTS****Priority:** Other Significant. Major under 5 USC 801.**CFR Citation:** 21 CFR 101.17(h); 21 CFR 115.50; 21 CFR 16.5**Completed:**

Reason	Date	FR Cite
Final Action	12/05/00	65 FR 76092

**Regulatory Flexibility Analysis**

Required: Yes

**Government Levels Affected:** State, Federal**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Geraldine A. June  
Phone: 202 205-4168  
Email: gaj@cfsan.fda.gov**RIN:** 0910-AB30**922. FRUIT AND VEGETABLE JUICES: DEVELOPMENT OF HACCP AND LABEL WARNING STATEMENTS FOR JUICES****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 21 CFR 120**Completed:**

Reason	Date	FR Cite
Final Action	01/19/01	66 FR 6138

**Regulatory Flexibility Analysis**

Required: Yes

**Government Levels Affected:** Federal**Agency Contact:** Shellee Anderson  
Phone: 202 205-5023  
Email: shellee.anderson@cfsan.fda.gov**RIN:** 0910-AA43**924. ESTABLISHMENT REGISTRATION AND LISTING OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS****Priority:** Other Significant**CFR Citation:** 21 CFR 207; 21 CFR 807; 21 CFR 1271**Completed:**

Reason	Date	FR Cite
Final Action	01/19/01	66 FR 5447

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Valerie Butler  
Phone: 301 827-6210**RIN:** 0910-AB05**927. POSTMARKETING STUDIES FOR HUMAN DRUGS AND LICENSED BIOLOGICAL PRODUCTS: STATUS REPORTS****Priority:** Substantive, Nonsignificant**CFR Citation:** 21 CFR 314.81; 21 CFR 601.37; 21 CFR 601.70**Completed:**

Reason	Date	FR Cite
Final Action	10/30/00	65 FR 64607
60-Day Delay of Effective Date	02/21/01	66 FR 10815

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Nathaniel Geary  
Phone: 301 827-6210**RIN:** 0910-AB83**923. DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS****Priority:** Substantive, Nonsignificant**CFR Citation:** 21 CFR 291; 42 CFR 8**Completed:**

Reason	Date	FR Cite
Final Action	01/17/01	66 FR 4076

**Regulatory Flexibility Analysis**

Required: Yes

**925. VETERINARY FEED DIRECTIVES****Priority:** Other Significant**CFR Citation:** 21 CFR 510; 21 CFR 514; 21 CFR 558**Completed:**

Reason	Date	FR Cite
Final Action	12/08/00	65 FR 76924

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** George Graber  
Phone: 301 827-6651  
Email: ggrabr@cvm.fda.gov**RIN:** 0910-AB09

## HHS—FDA

## Completed Actions

**928. CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS; BLOOD LABELING STANDARDS****Priority:** Other Significant**CFR Citation:** 21 CFR 606.121; 21 CFR 606.122**Completed:**

Reason	Date	FR Cite
Withdrawn--See RIN 0910-AB26	02/22/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Sharon Carayiannis  
Phone: 301 827-6210**RIN:** 0910-AB89**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)  
Health Resources and Services Administration (HRSA)**

## Proposed Rule Stage

**929. DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 254b; 42 USC 254e**CFR Citation:** 42 CFR 5; 42 CFR 51c**Legal Deadline:** None

**Abstract:** This rule would consolidate the process for designating areas of health professional shortage and medical underservice that apply in several department programs, and would improve the criteria for designating medically underserved populations (MUPs) and Primary Care Health Professional Shortage Areas (HPSAs). This NPRM will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

**Timetable:**

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
NPRM Comment Period End	01/04/99	
Second NPRM	10/00/01	
NPRM Comment Period End	12/00/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Richard C. Lee, Public Health Analyst, Bureau of Primary Health Care, Department of Health and Human Services, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, MD 20814

Phone: 301 594-4280

**RIN:** 0906-AA44**930. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE****Priority:** Substantive, Nonsignificant**Legal Authority:** PL 106-170; 42 USC 300aa-14**CFR Citation:** 42 CFR 100**Legal Deadline:** None

**Abstract:** This NPRM proposes several changes to the Vaccine Injury Table (Table) (42 CFR 100.3), which will have an effect upon petitions for compensation under the National Childhood Vaccine Injury Compensation Program including the following: 1) amending the Table by adding the injury of intussusception to

the Table for vaccines containing live, oral, rhesus-based rotavirus, a category of rotavirus vaccines; 2) removing residual seizure disorder and early onset Hib disease from the Table's Qualifications and Aids to Interpretation; 3) removing hemophilus influenzae type b polysaccharide vaccines from and adding pneumococcal conjugate vaccines to the Table; and 4) changing certain dates of coverage under the Table.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/01	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, BHP, Department of Health and Human Services, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857

Phone: 301 443-4198

Fax: 301 443-8196

Email: ge Evans@hrsa.gov

**RIN:** 0906-AA55**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)  
Health Resources and Services Administration (HRSA)**

## Final Rule Stage

**931. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 11131**CFR Citation:** 45 CFR 60.7**Legal Deadline:** None

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

judgments or settlements but who furnished or failed to furnish the health care services upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to "shield" practitioners. It would also require malpractice payers,

## HHS—HRSA

## Final Rule Stage

in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified and to provide the name of the corporate health care entity.

**Timetable:**

Action	Date	FR Cite
NPRM	12/24/98	63 FR 71255
NPRM Comment Period End	02/22/99	
Final Rule	07/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** John M. Heyob, Acting Director, Division of Medicine, Bureau of Health Professions, Department of Health and Human Services, Public Health Service, Room 4C-25, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 443-6190

**RIN:** 0906-AA41

### 932. COMPLIANCE ALTERNATIVES FOR PROVISION OF UNCOMPENSATED SERVICES

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 124, subpart F

**Legal Deadline:** None

**Abstract:** The rules apply to facilities obligated under the Hospital Survey and Construction Act, commonly known as the Hill-Burton Act. The rules will revise a compliance alternative that provides more flexible compliance standards for facilities that principally serve nonpaying patient populations by reducing the amount of time needed to qualify for certification under the alternative and by providing for provisional certification, where a facility is unable to qualify for full certification. The rules will also

provide a compliance alternative for facilities with histories of uncompensated services deficits, to enable them to make up the deficits on a timely basis. These revisions will have the effect of making it easier for facilities with an uncompensated services obligation to meet that obligation, while still ensuring the availability of uncompensated services to persons unable to pay.

**Timetable:**

Action	Date	FR Cite
NPRM	10/19/00	65 FR 68975
NPRM Comment Period End	12/18/00	
Final Action	07/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Eulas Dortch, Director, Division of Facilities Compliance and Recovery, OSP, Department of Health and Human Services, Health Resources and Services Administration, Room 10C-16, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 443-8007  
Fax: 301 443-0619  
Email: edortch@hrsa.gov

**RIN:** 0906-AA52

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

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 105-392

**CFR Citation:** 42 CFR 57; 42 CFR 58

**Legal Deadline:** None

**Abstract:** This final rule rescinds and removes various Public Health Service health professions, nursing, public health, and allied health training grant regulations from the CFR at 42 CFR parts 57 and 58. The existing training grant regulations are fundamentally and

extensively inconsistent with the new law, Health Professions Education Partnerships Act of 1998 (Pub. L. 105-392), enacted November 13, 1998. There are structural problems in implementing the new statute under the current program regulations. The general focus of this legislation is to reauthorize and consolidate 44 different Federal health professions training programs currently authorized under titles VII and VIII, PHS Act. These 44 programs are consolidated into seven general categories of authorities and offer more flexibility for program implementation. These categories are designed to train health practitioners most inclined to enter practice in rural and other medically underserved areas. Because the statute always take precedence over regulations, and the existing regulations are inconsistent with the new law that takes an interdisciplinary approach (and thus inhibits the achievement of the statute's clustered objectives), we are removing 19 grant regulations from the Code of Federal Regulations. Program specific guidance and information for preparing applications are now provided in the grant application materials (which makes them now self-contained).

**Timetable:**

Action	Date	FR Cite
Final Action	06/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

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

**RIN:** 0906-AA53

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Health Resources and Services Administration (HRSA)**
**Completed Actions**
**934. RICKY RAY HEMOPHILIA RELIEF  
FUND PROGRAM**
**Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 130**Completed:**

Reason	Date	FR Cite
Final Rule	08/02/00	65 FR 47438

**Regulatory Flexibility Analysis  
Required:** No**Government Levels Affected:** None**Agency Contact:** Neil H. Sampson  
Phone: 301 443-5974**RIN:** 0906-AA56
**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Indian Health Service (IHS)**
**Proposed Rule Stage**
**935. • TRIBAL SELF-GOVERNANCE  
AMENDMENTS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** PL 106-260, Sec  
517(a)(2); 25 USC 450, Tribal Self-  
Governance Amendments**CFR Citation:** None**Legal Deadline:** NPRM, Statutory,  
August 18, 2001.**Abstract:** Section 517(a)(2) requires  
that proposed regulations be published  
in the Federal Register no later than  
one year after the date of enactment**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis  
Required:** Undetermined**Government Levels Affected:**  
Undetermined**Agency Contact:** Paula K. Williams,  
Director of Tribal Self-Governance,  
Department of Health and Human  
Services, Indian Health Service, Room  
54-55, Parklawn Building, 5600 Fishers  
Lane, Rockville, MD 20857  
Phone: 301 443-7821**RIN:** 0917-AA05
**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Indian Health Service (IHS)**
**Final Rule Stage**
**936. INDIAN CHILD PROTECTION AND  
FAMILY VIOLENCE PREVENTION ACT  
MINIMUM STANDARDS OF  
CHARACTER**
**Priority:** Info./Admin./Other**Legal Authority:** 25 USC 3201 et seq**CFR Citation:** 42 CFR 36**Legal Deadline:** None**Abstract:** The Indian Health Service  
(IHS) is proposing to establish  
regulations as mandated by the Indian  
Child Protection and Family ViolenceProtection Act, Public Law 101-630, 25  
U.S.C. 3201-3211, that prescribe  
minimum standards of character for  
individuals whose duties and  
responsibilities involve regular contact  
with, or control over, Indian children.**Timetable:**

Action	Date	FR Cite
NPRM	03/25/99	64 FR 14559
NPRM Comment Period End	07/26/99	
Final Action	10/00/01	

**Regulatory Flexibility Analysis  
Required:** No**Government Levels Affected:** Tribal**Agency Contact:** Ramona D. Williams,  
Child Protection Coordinator,  
Department of Health and Human  
Services, Indian Health Service, Suite  
605, 12302 Twinbrook Parkway,  
Rockville, MD 20857  
Phone: 301 443-1589**RIN:** 0917-AA02
**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Indian Health Service (IHS)**
**Completed Actions**
**937. CONTRACTS UNDER THE INDIAN  
SELF-DETERMINATION ACT**
**Priority:** Info./Admin./Other**CFR Citation:** 42 CFR 36.201-237**Completed:**

Reason	Date	FR Cite
Final Rule	10/03/00	65 FR 58918

**Regulatory Flexibility Analysis  
Required:** No**Government Levels Affected:** Tribal**Agency Contact:** Betty J. Penn  
Phone: 301 443-1116  
Email: bpenn@hqe.ihs.gov**RIN:** 0917-AA04

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

Proposed Rule Stage

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

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

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined
**Additional Information:** RFA: N

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA02
**939. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NIH**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 288-4**CFR Citation:** 42 CFR 68b**Legal Deadline:** None

**Abstract:** Section 487D of the Public Health Service Act, as added by the National Institutes of Health Revitalization Act of 1993, creates a program offering scholarships, in an amount not to exceed \$20,000 per year of academic study, to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by the NIH. For each year of scholarship support, the recipient agrees to service (employment) after graduation, at the

NIH, for one year. Additionally, the individual agrees to at least 10 consecutive weeks of service (employment) at the NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will cover this program.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

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

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA10
**940. NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM**
**Priority:** Info./Admin./Other**Legal Authority:** 42 USC 216**CFR Citation:** 42 CFR 52d**Legal Deadline:** None

**Abstract:** Current regulations relating to the National Cancer Institute (NCI) Clinical Cancer Education Program will be amended to update various aspects of the regulation.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/01	

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

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA17
**941. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 288-3**CFR Citation:** 42 CFR 68d**Legal Deadline:** None

**Abstract:** Regulations will be issued to govern the awarding of educational loan repayments to qualified health professionals who agree to conduct research as employees of the National Institutes of Health.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

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

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA18
**942. • NIH CENTER GRANTS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 216; PL 106-310; PL 106-525; PL 106-505**CFR Citation:** 42 CFR 52a**Legal Deadline:** None

**Abstract:** NIH proposes to amend the current center grants regulations to reflect new authorities set forth in sections 409C, 452E, 485F and 445I of the PHS Act. Section 409C concerns centers of excellence regarding research on autism; section 452E concerns centers regarding research on "fragile x;" section 452F concerns centers of excellence for research education and training for individuals who are members of minority health disparity populations, and section 445I concerns centers of excellence in Alzheimer's disease research and treatment.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis Required:** No

HHS—NIH

Proposed Rule Stage

**Small Entities Affected:** Governmental Jurisdictions

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA24

**943. • NATIONAL INSTITUTES OF HEALTH CLINICS RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; PL 105-392; PL 106-554

**CFR Citation:** 42 CFR 68a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the current regulations by revising sections 68a.8(a) to reflect the increase in the maximum annual loan repayment from \$20,000 to \$35,000, and other sections to reflect expansion of the program to include extramural investigators from disadvantaged backgrounds. This action is necessary because of the enactment of the Health Professions Education Partnership Act of 1998, Public Law 105-392, and enactment of the Consolidated Appropriations Act of 2001, Public Law 106-554. Section 410 of Public Law 105-392 amends section 487E(a) of the PHS Act to increase the maximum annual amount.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA25

**944. • NIH LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; PL 106-525

**CFR Citation:** 42 CFR 68f

**Legal Deadline:** None

**Abstract:** NIH proposes to establish regulations to implement the program authorized under section 485G of the PHS Act. Section 103 of the Minority Health and Health Disparities Research and Education Act of 2000 amends the PHS Act by adding a new section 485G which authorizes the program.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA26

**945. • PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; PL 106-310

**CFR Citation:** 42 CFR 68f

**Legal Deadline:** None

**Abstract:** NIH proposes to establish regulations to implement the Pediatric Research Loan Repayment Program authorized under section 487F of the PHS Act. Section 1002 of Public Law 106-310 amends the PHS Act by adding a new section 487F which authorizes the program.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA27

**946. • NIH TRAINING GRANTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 216; PL 106-310

**CFR Citation:** 42 CFR 63a

**Legal Deadline:** None

**Abstract:** NIH proposes to amend the training grants regulations to implement the new authority under section 452G of the PHS Act. This action is necessitated by enactment of the Children's Act of 2000. Section 1002 of this act adds a new section 452G that authorizes the Director of NICHD in consultation with the Administrator of HRSA, to support activities to provide for an increase in the number and size of institutional training grants to institutions supporting pediatric training.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

**RIN:** 0925-AA28

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

Final Rule Stage

**947. NATIONAL RESEARCH SERVICE AWARDS**

Priority: Info./Admin./Other

Legal Authority: 42 USC 216; 42 USC 288

CFR Citation: 42 CFR 66

Legal Deadline: None

**Abstract:** Current HHS regulations will be amended to reflect provisions of the ADAMHA Reorganization Act and the National Institutes of Health Revitalization Act of 1993. New language concerning the service payback obligation will be set forth, specifically, that a service payback obligation is incurred only during the first 12 months of postdoctoral support and individuals may pay back this service obligation by engaging in an equal period of health-related teaching or, if the individual finished the first 12 months of support, by engaging in a second year of NRSA supported research training.

**Timetable:**

Action	Date	FR Cite
NPRM	06/30/99	64 FR 35119
Final Rule	06/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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

Email: jm40z@nih.gov

RIN: 0925-AA16

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

Priority: Substantive, Nonsignificant

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

CFR Citation: 42 CFR 68c

Legal Deadline: None

**Abstract:** Section 487B of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of education loans by conducting research with respect to contraception and/or infertility.

**Timetable:**

Action	Date	FR Cite
NPRM	12/10/99	64 FR 69213
Final Rule	05/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

RIN: 0925-AA19

**949. SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 282(b)(6); 42 USC 284(c)(3); 42 USC 289a; 42 USC 290aa-3

CFR Citation: 42 CFR 52h

Legal Deadline: None

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

**Timetable:**

Action	Date	FR Cite
NPRM	09/21/00	65 FR 57132
Final Action	06/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore, NIH Regulations Officer, Department of Health and Human Services, National Institutes of Health, Room 601 MSC 7669, 6011 Executive Boulevard, Rockville, MD 20852  
Phone: 301 496-4606  
Email: jm40z@nih.gov

RIN: 0925-AA20

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

Completed Actions

**950. TRAINEESHIPS**

Priority: Info./Admin./Other

CFR Citation: 42 CFR 63

**Completed:**

Reason	Date	FR Cite
Final Rule	11/06/00	65 FR 66511

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Jerry Moore  
Phone: 301 496-4606

Email: jm40z@nih.gov

RIN: 0925-AA11

**951. ADDITIONAL PROTECTIONS FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED IN RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION**
**Timetable:**

Action	Date	FR Cite
Transferred to RIN 0940-AA02	03/12/01	

RIN: 0925-AA14

**952. FEDERAL POLICY (COMMON RULE) FOR THE PROTECTION OF HUMAN SUBJECTS**
**Timetable:**

Action	Date	FR Cite
Transferred to RIN 0940-AA03	03/12/01	

RIN: 0925-AA21

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Office of Public Health and Science (OPHS)**

Final Rule Stage

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 94

**Legal Deadline:** None

**Abstract:** To implement section 493(e) of the Public Health Service Act (added by section 163 of the National Institutes of Health Revitalization Act of 1993, Public Law 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: (1) persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to, an allegation of research misconduct; and (2) persons who cooperate in good faith with an investigation of research misconduct.

**Timetable:**

Action	Date	FR Cite
NPRM	11/28/00	65 FR 70830

Action	Date	FR Cite
NPRM Comment	01/29/01	
Period End		
Final Rule	06/00/01	

**Regulatory Flexibility Analysis Required:** Yes

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

**Government Levels Affected:** State

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

**RIN:** 0940-AA01

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

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	12/00/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Dr. Clifford Scharke, Department of Health and Human Services, Office of Public Health and Science, Suite 3B01, 6100 Executive Boulevard, Rockville, MD 20852  
Phone: 301 435-5647

**RIN:** 0940-AA03

**954. FEDERAL POLICY (COMMON RULE) FOR THE PROTECTION OF HUMAN SUBJECTS**

**Priority:** Other Significant

**Legal Authority:** 5 USC 301; 42 USC 289

**CFR Citation:** 45 CFR 46

**Legal Deadline:** None

**Abstract:** In compliance with the President's Memorandum of March 27, 1997, this interim final rule would amend the Federal Policy (common rule) for the Protection of Human

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Office of Public Health and Science (OPHS)**

Completed Actions

**955. ADDITIONAL PROTECTIONS FOR PREGNANT WOMEN AND HUMAN FETUSES INVOLVED IN RESEARCH, AND PERTAINING TO HUMAN IN VITRO FERTILIZATION**

**Priority:** Other Significant

**CFR Citation:** 45 CFR 46, subpart B

**Completed:**

Reason	Date	FR Cite
Final Rule	01/17/01	66 FR 3878
60-Day Delay of Effective Date To 05/18/2001	03/19/01	66 FR 15352

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Melody Lin  
Phone: 301 435-5647

**RIN:** 0940-AA02

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

Proposed Rule Stage

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

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395rr

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

42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 489; 42 CFR 494

**Legal Deadline:** None

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

update the conditions to reflect developments in technology and equipment, emphasize the total patient experience and develop performance expectations for the facility that result in quality, comprehensive care for the dialysis patient.

## HHS—HCFA

## Proposed Rule Stage

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/01	

**Regulatory Flexibility Analysis**

Required: No

**Small Entities Affected:** Governmental Jurisdictions, Businesses, Organizations**Government Levels Affected:** None**Agency Contact:** Robert Miller, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-6797

Email: rmiller1@hcfa.gov

RIN: 0938-AG82

**957. ● RECOGNITION OF THE AMERICAN OSTEOPATHIC ASSOCIATION FOR CRITICAL ACCESS HOSPITALS (HCFA-2099-PN)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Legal Authority:** Social Security Act, sec 1865(b)**CFR Citation:** 42 CFR 488.4**Legal Deadline:** Final, Statutory, September 14, 2001.**Abstract:** This notice announces the application of the AOA for deeming authority to survey critical access hospitals (CHAs) for Medicare participation in lieu of survey by a State survey agency.**Timetable:**

Action	Date	FR Cite
Proposed Notice	04/16/01	66 FR 19509
Final Action	09/00/01	

**Regulatory Flexibility Analysis**

Required: No

**Small Entities Affected:** Businesses**Government Levels Affected:** State**Agency Contact:** Irene Dustin, Health Program Evaluation Officer, Department of Health and Human Services, Health Care Financing Administration, S3-13-21, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0495

Email: idustin@hacf.gov

RIN: 0938-AK84

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Final Rule Stage

## Health Care Financing Administration (HCFA)

**958. ● PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES-UPDATE (HCFA-1163-P)****Priority:** Other Significant. Major under 5 USC 801.**Legal Authority:** Social Security Act, sec 1888(e); 42 USC 1395yy(e)**CFR Citation:** 42 CFR 411.15; 42 CFR 489.20**Legal Deadline:** None**Abstract:** This rule sets forth updates to the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs), for fiscal year 2002.**Timetable:**

Action	Date	FR Cite
Final Action	07/00/01	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses, Organizations**Government Levels Affected:** None**Agency Contact:** William Ullman, Department of Health and Human Services, Health Care Financing Administration, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 401 786-5667

RIN: 0938-AK47

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

## Long-Term Actions

## Health Care Financing Administration (HCFA)

**959. "WITHOUT FAULT" AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (HCFA-6007-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395gg**CFR Citation:** 42 CFR 401; 42 CFR 466.86; 42 CFR 466.94; 42 CFR 473.14; 42 CFR 493.1834; 42 CFR 403.310; 42 CFR 405; 42 CFR 410.1; 42 CFR 411.23; 42 CFR 411.28; 42 CFR 413.20; 42 CFR 413.153; 42 CFR 447.31**Legal Deadline:** None**Abstract:** This rule would amend the Medicare regulations to clarify our interpretation of "without fault" as it applies to physician, provider, supplier,

and beneficiary liability for overpayments. This definition would result in greater uniformity of determinations by carriers and intermediaries. Additionally, this rule would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with HCFA regulations more specific to circumstances involving Medicare overpayments.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Barbara Wright, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C3-14-00, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4292

RIN: 0938-AD95

**960. MEDICAID PAYMENT FOR COVERED OUTPATIENT DRUGS UNDER REBATE AGREEMENTS (HCFA-2046-FC)****Priority:** Other Significant**Legal Authority:** 42 USC 1396a(a); 42 USC 1396r-8; 42 USC 1396b(a); 42 USC 1302

## HHS—HCFA

## Long-Term Actions

**CFR Citation:** 42 CFR 447; 42 CFR 441

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	09/19/95	60 FR 48442
NPRM Comment Period End	11/20/95	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** Larry Reed, Chief, Medicaid Noninstitutional Payment Policy Branch, Department of Health and Human Services, Health Care Financing Administration, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3325

Peggy Rahn, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3284

**RIN:** 0938-AF42

**961. REVISION OF MEDICARE/MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION (HCFA-3745-F)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395x; 42 USC 1302; 42 USC 1395(cc); 42 USC 1395hh; 42 USC 13206-8

**CFR Citation:** 42 CFR 416; 42 CFR 482; 42 CFR 485; 42 CFR 489

**Legal Deadline:** None

**Abstract:** This rule will revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in health care practices since the requirements were last revised in 1986.

**Timetable:**

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66726
NPRM Comment Period End	03/20/98	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Stephanie Dyson, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9226

**RIN:** 0938-AG79

**962. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (HCFA-3819-F)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bbb

**CFR Citation:** 42 CFR 484

**Legal Deadline:** None

**Abstract:** This rule will revise home health agency conditions of participation to center on the patient, using outcome-oriented measures. Most of the current HHA conditions of participation have remained unchanged since home health services became a Medicare benefit in 1966. Some limited modifications have been made over the years to comply with legislative

changes. As a result, most of the conditions of participation continue to be structure- and process-oriented.

**Timetable:**

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Federalism:** Undetermined

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

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6775

**RIN:** 0938-AG81

**963. LIABILITY FOR THIRD PARTIES TO PAY FOR SERVICES (HCFA-2080-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1396a(a)(25)(A); 42 USC 1396b(o)

**CFR Citation:** 42 CFR 433

**Legal Deadline:** None

**Abstract:** This rule would incorporate provisions of OBRA '93 by amending the regulations governing third party liability. It would add ERISA plans, service benefit plans, and health maintenance organizations to the definition of liable third parties. It would require States to prohibit any health insurer from taking into account, when enrolling or making payments, that an individual is eligible for or receiving Medicaid. It would also require States to enact a law under which the State is deemed to have acquired an individual's right to payment by a third party.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

## HHS—HCFA

## Long-Term Actions

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Federal

**Agency Contact:** Robert Nakielny, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4466

**RIN:** 0938-AH01

**964. CRITERIA FOR APPROVAL OF FACILITIES TO PERFORM COVERED HEART, LIVER, LUNG, PANCREAS AND INTESTINAL TRANSPLANTS (HCFA-3835-P)**

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 482

**Legal Deadline:** None

**Abstract:** The rule establishes conditions of participation for facilities to perform Medicare-covered transplants.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Marty Abeln, Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1032

Kathy Linstromberg, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-8279

Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S3-06-6, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7539

**RIN:** 0938-AH17

**965. HOSPICE CARE-CONDITIONS OF PARTICIPATION (HCFA-3844-P)**

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 418

**Legal Deadline:** None

**Abstract:** This rule would revise the Medicare conditions of participation for hospices to help ensure the provision of quality care through an emphasis on patient-centered outcomes. Areas of change would include, among others, assessment of patient needs, clarification of physician roles, coordination of care for hospice patients residing in nursing homes, clarification of nursing roles, patient rights, and provision of services.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be Determined	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Mary Rossi Coajou, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6051

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6775

**RIN:** 0938-AH27

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 435; 42 CFR 436

**Legal Deadline:** None

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

This rule conforms our regulations to sections 4402 and 4713 of the Omnibus Budget Reconciliation Act of 1990 and section 4741 of the Balanced Budget Act of 1997.

**Timetable:**

Action	Date	FR Cite
NPRM	06/20/94	59 FR 31569
NPRM Comment Period End	08/19/94	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Additional Information:** Previously published under RIN 0938-AF64.

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

Phone: 410 786-5928  
Email: gtalvert@hcfa.gov

**RIN:** 0938-AH48

**967. TERMS, DEFINITIONS, AND ADDRESSES: TECHNICAL AMENDMENTS (HCFA-9877-FC)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1395x(v)(1)(A); 42 USC 1395hh

**CFR Citation:** 42 CFR 400 to 440; 42 CFR 442 to 447; 42 CFR 455; 42 CFR

## HHS—HCFA

## Long-Term Actions

456; 42 CFR 462 to 466; 42 CFR 473 to 476; 42 CFR 482 to 489; 42 CFR 491 to 498

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Margie Teeters, Department of Health and Human Services, Health Care Financing Administration, Division of Regulation and Issuances  
Phone: 410 786-4678

**RIN:** 0938-AH53

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

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 424

**Legal Deadline:** None

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Additional Information:** Formerly known as HCFA-1023-P

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

**RIN:** 0938-AH73

#### 969. UPDATE OF RATESETTING METHODOLOGY, PAYMENT RATES AND THE LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS (HCFA-1885-FC)

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

**Legal Authority:** 42 USC 13951(i)(2)(A)

**CFR Citation:** 42 CFR 416.61(b); 42 CFR 416.65(a)(4); 42 CFR 416.65(c); 42 CFR 416.120(c)(1); 42 CFR 416.125; 42 CFR 416.130; 42 CFR 416.140(a); 42 CFR 416.140(b); 42 CFR 488.1

**Legal Deadline:** None

**Abstract:** The final rule will update the criteria for determining which surgical procedures can be appropriately and safely performed in an Ambulatory Surgical Center (ASC); make additions to and deletions from the current list of Medicare covered ASC procedures based on the revised criteria; rebase the ASC payment rates using charge and utilization data collected by a 1994 survey of ASCs; refine the ratesetting methodology that was implemented by a final notice published on February 8, 1990 in the Federal Register; require that ASC payment, coverage and wage index updates be implemented annually on January 1, rather than having these updates occur randomly throughout the year; establish a payment rate for Extracorporeal Shock Wave Lithotripsy; reduce regulatory burden; and make several technical policy changes.

**Timetable:**

Action	Date	FR Cite
NPRM	06/12/98	63 FR 32290
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Bob Cereghino, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, C4-03-06, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4645

**RIN:** 0938-AH81

#### 970. REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (HCFA-3887-P)

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 416

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Marcia Newton, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5265

Joan Brooks, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5526

**RIN:** 0938-AH83

## HHS—HCFA

## Long-Term Actions

**971. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (HCFA-4145-P)**

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

**Legal Authority:** 42 USC 1320d-2(b)(1)

**CFR Citation:** 45 CFR 162

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

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

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

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

**Agency Contact:** Faye Broseker, Center for Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, S1-07-06, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3342

**RIN:** 0938-AH87

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

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

**Legal Authority:** 42 USC 1320d-2(h)(1)

**CFR Citation:** 42 CFR 160; 42 CFR 162

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

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

**Timetable:**

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

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

**Additional Information:** None

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

**RIN:** 0938-AH99

**973. MEDICAID: MEDICAL CHILD SUPPORT (HCFA-2081-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1396a(a)(60); 42 USC 1396(a)(25), (45) and (60); 42 USC 1396(a)(60); 42 USC 139b(o)(2); 42 USC 1396g-1

**CFR Citation:** 42 CFR 433; 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.170

**Legal Deadline:** None

**Abstract:** This rule would require States to provide assurances satisfactory to the Secretary that the State has in effect laws relating to medical child support. This requirement would implement section 13623 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66), commonly cited as OBRA 1993. The medical child support laws that the States must have in effect are set forth in section 1908 of the Social Security Act (the Act). These laws would impose requirements on insurers, employers, and State Medicaid agencies that would result in greater enrollment opportunities for children, facilitate the filing of claims by custodial parents, and establish new payment disbursement criteria.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

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

**Government Levels Affected:** State

**Agency Contact:** Sue Knefley, Center for Medicaid and State Operations, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-0488

**RIN:** 0938-AI21

**974. SURETY BOND REQUIREMENTS FOR COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES, REHABILITATION AGENCIES (HCFA-6005-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395x(v); 42 USC 1395hh; 42 USC 1395x(cc)(2); 42 USC 1395x(p)

**CFR Citation:** 42 CFR 405; 42 CFR 413; 42 CFR 489

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

**Abstract:** This rule would require comprehensive outpatient rehabilitation facilities and rehabilitation agencies to furnish us with a surety bond on a continuing basis in order to participate in the Medicare program, in accordance with provisions of the Balanced Budget Act of 1997 (105-33).

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4870  
Email: rgoldberg@hcfa.gov

**RIN:** 0938-AI48

**975. APPEALS OF CARRIER DETERMINATION THAT A PHYSICIAN OR OTHER SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (HCFA-6003-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)

## HHS—HCFA

## Long-Term Actions

**CFR Citation:** 42 CFR 405.874

**Legal Deadline:** None

**Abstract:** This rule would establish an administrative appeal process whereby suppliers can request an appeal for a determination that affects their Medicare part B billing number. The purpose of this rule is to update and clarify our policy and extend administrative appeal rights to all current and prospective suppliers who are denied enrollment in the Medicare program or whose Medicare billing privileges are revoked. This rule does not apply to those suppliers covered under the appeals provisions for our regulations at 42 CFR 498.

**Timetable:**

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Yvonne West, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-6479

**RIN:** 0938-AI49

**976. SECURITY STANDARDS (HCFA-0049-F)**

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

**Legal Authority:** PL 104-191; 42 USC 1320d-2(d)

**CFR Citation:** 45 CFR 162

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

**Abstract:** This rule implements some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. It establishes standards for the security of health information used by health plans, health care clearinghouses, and

certain health care providers. These entities would use the security standards to develop and maintain the security of all electronic health information.

**Timetable:**

Action	Date	FR Cite
NPRM	08/12/98	63 FR 43242
NPRM Comment	10/13/98	
Period End		
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

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

**Federalism:** Undetermined

**Agency Contact:** Barbara Clark, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, N2-14-10, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3017

**RIN:** 0938-AI57

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

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

**Legal Authority:** PL 104-191; 42 USC 1320d to 1320-d-8

**CFR Citation:** 45 CFR 162

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

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/16/98	63 FR 32784
NPRM Comment	08/17/98	
Period End		
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

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

**Agency Contact:** Mary Emerson, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, N2-12-22, Baltimore, MD 21244  
Phone: 410 786-7065  
Email: memerson@hcfa.gov

**RIN:** 0938-AI59

**978. MEDICARE PROGRAM; ADVANCE REFUNDING OF DEBT AND METHODOLOGY FOR REPAYMENT OF LOAN (HCFA-1777-P)**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 42 CFR 413

**Legal Deadline:** None

**Abstract:** This rule would amend current regulations to clarify our policies regarding the treatment of interest expense. The rule would require that, when only part of the interest on a loan is allowable, repayment would be made first to that portion of the loan on which expense is allowable. This rule would also clarify how this policy is to be applied in situations in which there are multiple loans, and one or more of the loans are not related to patient care. In addition, we would define the allowable costs associated with advance refunding of debt, and clarify the treatment of revenue and expenses.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Ann Pash, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4516  
Email: apash@hcfa.gov

**RIN:** 0938-AI75

## HHS—HCFA

## Long-Term Actions

**979. MEDICARE PROGRAM; MEDICARE COVERAGE OF AND PAYMENT FOR BONE MASS MEASUREMENTS (HCFA-3004-F)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1); 42 USC 4106

**CFR Citation:** 42 CFR 410; 42 CFR 414

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

**Abstract:** This rule provides for uniform coverage of, and payment for, bone mass measurements for qualified Medicare beneficiaries for services furnished on or after July 1, 1998. It implements provisions in section 4106(a) of the Balanced Budget Act of 1997.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	06/24/98	63 FR 34320
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** William Larson, Office of Communications and Operations Support, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4639

**RIN:** 0938-AI89

**980. MEDICARE PROGRAM; COVERAGE AND ADMINISTRATIVE POLICIES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS (HCFA-3250-F)**

**Priority:** Other Significant

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

**Legal Authority:** PL 105-33, sec 4554(b)(1)

**CFR Citation:** 42 CFR ch 410

**Legal Deadline:** Final, Statutory, January 1, 1999, BBA Section 4106.

**Abstract:** This rule would establish national coverage and administrative

policies for clinical diagnostic laboratory services payable under Medicare part B to promote Medicare program integrity and national uniformity, and simplify administrative requirements for clinical diagnostic laboratory services. A Negotiated Rulemaking Committee (the Committee) developed the proposed policies as directed by section 4554(b)(1) of the Balanced Budget Act of 1997 (the BBA).

**Timetable:**

Action	Date	FR Cite
Notice of Intent To Negotiate	06/03/98	63 FR 30166
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

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

**Federalism:** Undetermined

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

**RIN:** 0938-AI92

**981. COVERAGE OF RELIGIOUS NON-MEDICAL HEALTH CARE INSTITUTIONS (HCFA-1909-F)**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 42 CFR 403; 42 CFR 440.170; 42 CFR 488.2; 42 CFR 488.6; 42 CFR 489.102; 42 CFR 412.90; 42 CFR 412.98; 42 CFR 431.610; 42 CFR 440.155; 42 CFR 442.12; 42 CFR 456.351; 42 CFR 456.601; 42 CFR 466.1

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

**Abstract:** This rule implements section 4454 of the Balanced Budget Act of 1997 (BBA 1997), which amended section 1861 of the Social Security Act (the Act) and added a new section 1821 to the Act. Section 4454 of BBA 1997 removed all references to Christian Science and Christian sanatoria from the Act and substituted religious nonmedical health care institutions in their place. This change permits any qualified religious, nonmedical, health

care institution to apply for payment for furnishing nonmedical services under Medicare. Section 4454 also authorizes payment for such services as an option benefit under State Medicaid plans. The rule sets forth minimum requirements and conditions of participation to qualify as a religious nonmedical health care institution for purposes of receiving payment for services furnished under Medicare and Medicaid.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	11/30/99	64 FR 67028
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Jean Marie Moore, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3508

**RIN:** 0938-AI93

**982. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (HCFA-2015-F)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1302

**CFR Citation:** 42 CFR 438

**Legal Deadline:** None

**Abstract:** This rule implements section 1932(c) of the Social Security Act, added by section 4705 of the Balanced Budget Act of 1997. It requires State agencies that contract with managed care organizations to implement quality improvement strategies that address access and other aspects of care and services directly related to the quality of care provided by these managed care organizations and performance through annual external, independent reviews conducted by accrediting organizations that are approved by HCFA.

**Timetable:**

Action	Date	FR Cite
NPRM	12/01/99	64 FR 67223

## HHS—HCFA

## Long-Term Actions

Action	Date	FR Cite
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NPRM Comment Period End	01/31/00	
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Next Action Undetermined

**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.

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

**RIN:** 0938-AJ06**983. REPORTING OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA AS PART OF THE CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (HCFA-3006-F)****Priority:** Substantive, Nonsignificant**Unfunded Mandates:** This action may affect State, local or tribal governments and the private sector.**Legal Authority:** 42 USC 1302; 42 USC 1395(hh)**CFR Citation:** 42 CFR 484.11; 42 CFR 484.20; 42 CFR 488.68**Legal Deadline:** None

**Abstract:** This rule requires electronic reporting of data from the Outcome and Assessment Information Set (OASIS) as a condition of participation for Home Health Agencies (HHAs). Specifically, this rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or contractor in collecting and transmitting this information to HCFA. This rule also sets forth provisions concerning the privacy of patient identifiable information generated by the OASIS.

**Timetable:**

Action	Date	FR Cite
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Interim Final Rule	01/25/99	64 FR 3748
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Next Action Undetermined

**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** State, Local, Tribal**Federalism:** Undetermined

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

**RIN:** 0938-AJ10**984. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS, AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (HCFA-1910-F)****Priority:** Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 405; 42 CFR 491**Legal Deadline:** None

**Abstract:** This rule would amend the requirements for certification and payment for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997 (BBA 1997). It would include new refinements of what constitutes a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that can continue to be approved as Medicare RHCs in areas no longer designated as medically underserved; and include recent statutory provisions that provide a temporary waiver of certain nonphysician practitioner staffing requirements. It would impose payment limits on provider based RHCs, and would prohibit the use of RHC space or equipment, and other RHC resources by another Medicare entity. The rule also requires establishment of a quality assessment and performance improvement program.

**Timetable:**

Action	Date	FR Cite
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NPRM	02/28/00	65 FR 10450
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Next Action Undetermined

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

**Agency Contact:** David Worgo, Center for Health Plans and Providers, Division of Integrated Services, Department of Health and Human Services, Health Care Financing Administration, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5919

**RIN:** 0938-AJ17**985. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (HCFA-3014-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 482.27**Legal Deadline:** None

**Abstract:** This rule would require hospitals that transfuse blood and blood products to: 1) prepare and follow written procedures for appropriate action when it is determined that blood and blood products are at increased risk for transmitting hepatitis C virus (HCV); 2) quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; 3) notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and 4) maintain records for at least 10 years.

**Timetable:**

Action	Date	FR Cite
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NPRM	11/16/00	65 FR 69416
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Next Action Undetermined

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

**Agency Contact:** Mary Collins, OCSQ, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3189

**RIN:** 0938-AJ29**986. MEDICARE HOSPICE CARE AMENDMENTS (HCFA-1022-P)****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined

## HHS—HCFA

## Long-Term Actions

**Legal Authority:** PL 105-33, sec 4441(a); PL 105-33, sec 4442 to 4446; PL 105-33, sec 4448

**CFR Citation:** 42 CFR 418

**Legal Deadline:** None

**Abstract:** This rule would implement sections 4441(a), 4442 to 4446, and 4448 of the Balanced Budget Act of 1997. Specific changes include updating hospice payment rates, specifying payment according to the site of service, modifying the hospice benefit periods, clarifying the services covered under the benefit, allowing hospices to contract for physician services, allowing waivers of certain staffing requirements for hospice care provided in non-urbanized areas, and extending the period for physician certification of an individual's terminal illness. Additionally, the rule would clarify other current policies.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

**Agency Contact:** Carol Blackford, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5909  
Email: cblackford@hcfa.gov

**RIN:** 0938-AJ36

### 987. EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) (HCFA-1063-P)

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1395cc; 42 USC 1395dd

**CFR Citation:** 42 CFR 489.24

**Legal Deadline:** None

**Abstract:** This rule clarifies the extent of the applicability of the Emergency Medical Treatment and Labor Act (EMTALA).

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** George Morey, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4653

**RIN:** 0938-AJ39

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 300gg-6; 42 USC 300gg-52

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

**Legal Deadline:** None

**Abstract:** The final rule would implement the requirements of the Women's Health and Cancer Rights Act of 1998 (WHCRA) (Pub. L. 105-277). The rules will provide protection to patients who are receiving benefits in connection with a mastectomy and who elect breast reconstruction. WHCRA provides coverage for all stages of reconstruction of the breast on which the mastectomy has been performed; surgery and reconstruction of the other breast to produce a symmetrical appearance; and coverage for prostheses and treatment of physical complications of a mastectomy, including lymphedema. Group health plans and health insurance issuers that offer medical and surgical benefits for mastectomies are subject to WHCRA's coverage requirements.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Kathryn McCann, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7623

**RIN:** 0938-AJ44

### 989. MEDICARE PROGRAM: PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITAL SERVICES (HCFA-1069-F)

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

**Legal Authority:** PL 105-33, sec 4421; 42 USC 1395ww(j)

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This rule would implement the new prospective payment system for rehabilitation facilities, pursuant to section 1886(j) of the Social Security Act, as added by section 4421 of the Balanced Budget Act, and as amended by section 125 of the Balanced Budget Refinement Act of 1999.

**Timetable:**

Action	Date	FR Cite
Proposed Rule	11/03/00	65 FR 66304
Next Action Undetermined		

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Laurence Wilson, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4603

**RIN:** 0938-AJ55

### 990. DME SURETY BONDS (HCFA-6006-P)

**Priority:** Economically Significant

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

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

**CFR Citation:** 42 CFR 424.57

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

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

## HHS—HCFA

## Long-Term Actions

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4870  
Email: rgoldberg@hcfa.gov

**RIN:** 0938-AJ64

**991. STATE HEALTH INSURANCE ASSISTANCE PROGRAM (SHIP) (HCFA-4005-F)**

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

**Legal Authority:** 42 USC 13956-4; 42 USC 1395w-21(d); 42 USC 1395w-27(e)

**CFR Citation:** 42 CFR 403.502; 42 CFR 403.504; 42 CFR 403.508

**Legal Deadline:** None

**Abstract:** This rule modifies several terms and conditions that apply to State Medicare beneficiary counseling and assistance grants and implements several minor technical clarifications affecting programs compliance. This rule also specifies our policies regarding the treatment of other funds associated with the management of this program, including user fee assessments not in effect when prior regulations were issued.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	06/01/00	65 FR 34983
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State, Local

**Federalism:** Undetermined

**Agency Contact:** Eric Lang, Health Insurance Specialist, Office of Beneficiary Services, Department of Health and Human Services, Health Care Financing Administration, Room 600, EHR, 6325 Security Boulevard, Baltimore, MD 21207  
Phone: 410 966-3193

**RIN:** 0938-AJ67

**992. HHA SURETY BOND (HCFA-6001-P)**

**Priority:** Economically Significant

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

**Legal Authority:** PL 105-33, sec 4312(b); PL 105-33, sec 4724(b); PL 105-33, sec 1861(o)(7); PL 105-33, sec 1861(v)(1); PL 105-33, sec 1891(b); PL 105-33, sec 1903(i)(18); PL 105-33, sec 1128F

**CFR Citation:** 42 CFR 413; 42 CFR 440; 42 CFR 441; 42 CFR 489

**Legal Deadline:** NPRM, Statutory, June 15, 2000.

**Abstract:** This rule would amend our regulations to require an HHA surety bond of \$50,000. We would remove the 15 percent provision based on concerns expressed by Congress, the home health industry, surety association representatives, and comments published in a report by the General Accounting Office. This rule would require that HHAs obtain a surety bond by October 1, 2000. Although the bond must be effective January 1, 1998, we are proposing not to hold sureties liable for excessive interim payments attributable to the implementation of the interim payment systems made between October 1, 1997 and September 30, 2000.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Organizations

**Government Levels Affected:** None

**Additional Information:** RIN 0938-AJ08 in the October 1998 Unified Agenda provides information about rulemaking actions taken and withdrawn in 1998 concerning surety bond requirements for home health agencies.

**Agency Contact:** Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4870  
Email: rgoldberg@hcfa.gov

**RIN:** 0938-AJ81

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

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 105-33, sec 4316

**CFR Citation:** 42 CFR 405

**Legal Deadline:** None

**Abstract:** This rule implements sections 1842(b)(8) and (9) of the Social Security Act, as revised by section 4316 of the Balanced Budget Act of 1997. It sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. This rule describes the factors HCFA (or its carriers) will consider and the procedures that will be followed in establishing realistic and equitable payment amounts.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** William J. Long, Department of Health and Human Services, Health Care Financing Administration, C4-12-18, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21228  
Phone: 410 786-5655  
Email: wlong@hcfa.gov

**RIN:** 0938-AJ97

**994. SUPPLIER STANDARDS RELATED TO TRAINING REQUIREMENTS FOR OXYGEN, THERAPEUTIC SHOES (HCFA-6010-NPRM)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 424.57

**Legal Deadline:** None

**Abstract:** As required by the BBA, this rule proposes service standards for the suppliers of home oxygen therapy and suppliers of therapeutic shoes.

## HHS—HCFA

## Long-Term Actions

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Frank Whelan, Health Insurance Sepicalist, Department of Health and Human Services, Health Care Financing Administration, C3-02-16, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-1302

**RIN:** 0938-AJ98

**995. NON-FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA (HCFA-2033-IFC)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Not Yet Determined

**CFR Citation:** 45 CFR 146

**Legal Deadline:** None

**Abstract:** This rule amends 45 CFR part 146, as promulgated at 62 FR 16894 April 8, 1997 (BPD-890-IFC). This rule makes a correction to 45 CFR 146.150, Guaranteed Availability of Coverage for Employers in the Small Group Market.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Agency Contact:** Dave Holstein, Insurance Standards Team, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1564

**RIN:** 0938-AK00

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

**Priority:** Other Significant

**Legal Authority:** Section 1861(v)(1)(A); 42 USC 1395x(v)(1)(A)

**CFR Citation:** 42 CFR 413.178

**Legal Deadline:** None

**Abstract:** This rule would remove the cap on end stage renal disease bad debts as stated in 42 CFR 413.178, which limits reimbursement of Medicare bad debts to the end stage renal disease facility's unrecovered costs. With respect to hospital-based providers, this regulation permits clearer distinctions to be made between various types of services, and ensures that these services will be paid for in an appropriate manner.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

**RIN:** 0938-AK02

**997. PRACTICE EXPENSE DATA COLLECTION (HCFA-1111-IFC)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 212 of BBRA of 1999; 42 USC 1395w-4

**CFR Citation:** 42 CFR 414

**Legal Deadline:** None

**Abstract:** This interim final rule establishes criteria for physician and non-physician specialty groups for submitting supplemental practice expense survey data for use in determining payments under the physician fee schedule. This interim final rule solicits public comments on the criteria for supplemental surveys.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	05/03/00	65 FR 25664
Final Rule	11/01/00	65 FR 65376
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Kenneth Marsalek, Program Analyst, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 301 786-1115

**RIN:** 0938-AK14

**998. PAYMENT FOR CLINICAL PSYCHOLOGY TRAINING PROGRAMS (HCFA-1089-F)**

**Priority:** Other Significant

**Legal Authority:** Social Security Act, sec 1861(v); Social Security Act, sec 1886(a)(4); PL 105-33

**CFR Citation:** 42 CFR 413.85

**Legal Deadline:** None

**Abstract:** This final rule revises our policy on Medicare payment for approved nursing and allied health education programs to permit payment for the costs incurred by a provider for the clinical training of students enrolled in a clinical psychology training program or a physician assistant training program. Consistent with the Conference Agreement language in the Conference Report accompanying the Balanced Budget Act of 1997 (Public Law 105-33), these clinical training costs would be paid separately on a reasonable cost basis pursuant to sections 1861(v) and 1886(a)(4) of the Social Security Act.

**Timetable:**

Action	Date	FR Cite
NPRM	01/12/01	66 FR 3377
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Tzvi Hefter, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1304

**RIN:** 0938-AK15

## HHS—HCFA

## Long-Term Actions

**999. PROVISIONS OF THE BALANCED BUDGET AND REFINEMENT ACT OF 1999; HOSPITAL INPATIENT PAYMENTS AND RATES AND COSTS OF GRADUATE MEDICAL EDUCATION (HCFA-1131-IFC)**

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

**Legal Authority:** 42 USC 1302; 12 USC 1395hh; PL 106-113

**CFR Citation:** 42 CFR 410.152; 42 CFR 412.90; 42 CFR 412.102; 42 CFR 412.103; 42 CFR 412.105; 42 CFR 412.108; 42 CFR 413.40; 42 CFR 413.70; 42 CFR 413.86; ...

**Legal Deadline:** None

**Abstract:** This interim final rule with comment period implements, or regulations to, certain statutory provisions conforming the relating to Medicare payments to hospitals for inpatient services that are contained in the Medicare, Medicaid, and (SCHIP) State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (Pub. L. 106-113). These provisions relate to reclassification of hospitals from urban to rural status, reclassification of certain hospitals for purposes of payment during Federal fiscal year 2000, critical access hospitals, payments to hospitals excluded under the hospital inpatient prospective payment system, and payments for indirect and direct graduate medical education costs.

Many of the provisions of Public Law 106-113 modify changes to the Social Security Act made by the Balanced Budget Act of 1997 (Pub. L. 105-33). These provisions are already in effect in accordance with Public Law 106-113.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	08/01/00	65 FR 47026
Interim Final Rule Effective	08/01/00	
Interim Final Rule Comment Period End	08/31/00	

Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Stephen Phillips, Center for Health Plans and Providers, Department of Health and Human

Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

**RIN:** 0938-AK20

**1000. CONDITIONS OF PARTICIPATION OF INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (HCFA-3046-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1302; 42 USC 1396d

**CFR Citation:** 42 CFR 400; 42 CFR 435; 42 CFR 440; 42 CFR 441; 42 CFR 483

**Legal Deadline:** None

**Abstract:** This rule would revise the Conditions of Participation for Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR). It would set forth new requirements that an ICF/MR must meet to participate in the Medicaid program, as well as adhere to current trends in the field of developmental disabilities. It would also increase our focus on client-directed choices, while maintaining essential client protections that reinforce our mandate to protect the health, safety, and welfare of the clients we serve.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Nancy Archer, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, S3-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 401 786-0596

**RIN:** 0938-AK23

**1001. CLINICAL LAB REQUIREMENTS-REVISIONS TO REGULATIONS IMPLEMENTING CLIA (HCFA-2226-F)**

**Priority:** Other Significant

**Legal Authority:** PL 100-578

**CFR Citation:** 42 CFR 493

**Legal Deadline:** None

**Abstract:** This rule revises regulations applicable to clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. The regulations apply to laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. This rule concludes the phase-in for certain quality control and personnel requirements, and addresses comments received on previously promulgated CLIA rules. In addition, this rule consolidates and reorganizes the requirements for patient test management, quality control and quality assurance in a manner that parallels the path of a specimen through the testing process. While this regulation pertains to complex technical requirements, plain language is used whenever possible, as mandated by the Regulatory Reform Initiative.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Cecelia Hinkel, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration

Phone: 410 786-3347

**RIN:** 0938-AK24

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

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

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

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

**CFR Citation:** 42 CFR 410

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

**Abstract:** The Balanced Budget Act (BBA) of 1997 requires that the Secretary establish a fee schedule for ambulance services through negotiated rulemaking. The fee schedule is to be effective beginning with services furnished on or after January 1, 2000.

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## Long-Term Actions

However, other statutory obligations and the scope of systems changes required to implement the ambulance fee schedule were so numerous as to make it impossible for us to accomplish this concurrent with the critical work that we and our contractors had to perform to assure that our respective systems were compliant with the year 2000 requirements. Therefore, since we were unable to implement the ambulance fee schedule on January 1, 2000, we have delayed implementation of the fee schedule for ambulance services until January 1, 2001. This action is in keeping with our objective to have the ambulance fee schedule become effective as soon as possible after the January 1, 2000 statutory date, given our year 2000 activities and our other statutory obligations to implement various revised payment systems in calendar year 2000. In addition to setting the payment rates, the Secretary is to ensure that the aggregate amount of payment made for ambulance services in 2001 may not exceed the amount of payment that would have been made absent the fee schedule. This is a cap on payment, not a budget neutrality adjustment. Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). We used the services of an impartial conveyer to help identify interests that would be significantly affected by the proposed rule (including residents of rural areas) and the names of persons who were willing and qualified to represent those interests. The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule consisted of national representatives of interests that were likely to be significantly affected by the fee schedule. To the extent that this proposed rule accurately reflected the Committee Statement as signed on February 14, 2000, each member to the Committee agreed not to comment on those issues on which consensus was reached.

**Timetable:**

Action	Date	FR Cite
NPRM	09/12/00	65 FR 55076
Final Action	To Be	Determined

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

Undetermined

**Federalism:** Undetermined

**Agency Contact:** Glenn McGuire, Department of Health and Human Services, Health Care Financing Administration, S3-05-27, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-0596

**RIN:** 0938-AK30**1003. FIRE SAFETY REQUIREMENTS FOR RNHCI, ASC, HOSPICES, PACE, HOSPITALS, AND LONG-TERM CARE FACILITIES (HCFA-3047-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 403; 42 CFR 416; 42 CFR 418; 42 CFR 460; 42 CFR 482; 42 CFR 483**Legal Deadline:** None

**Abstract:** This rule would update current fire safety requirements to generally conform to the 2000 edition of the Life Safety Code, published by the National Fire Protection Association.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** None

**Agency Contact:** Tamara Syrek, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration  
Phone: 410 786-3529

**RIN:** 0938-AK35**1004. • MEDICARE PROVIDER AND SUPPLIER HEARING PROCEDURES (HCFA-2093-P)**

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

**Unfunded Mandates:** Undetermined**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 498.40; 42 CFR 498.70; 42 CFR 498.83; 42 CFR 498.88**Legal Deadline:** None

**Abstract:** This rule would revise current hearing regulations applicable to enforcement actions taken by HCFA against Medicare providers and suppliers (and, in some cases, certain

Medicaid providers) based on a lack of compliance with Federal certification requirements. Specifically, this rule would revise existing requirements governing the level of specificity that petitioners must include when seeking review of agency actions governed by these hearing regulations. Additionally, this rule would clarify the meaning of "good cause" as that term is used in the hearing regulations to judge whether petitioners may file requests for review after filing deadlines have passed. The rule would also require dismissal of petitions for review when a petitioner has failed to file a sufficiently detailed hearing request within the time allotted by the regulations.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Organizations**Government Levels Affected:** None

**Agency Contact:** Sandy Haydock, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-3822

**RIN:** 0938-AK39**1005. • HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (HCFA-3050-F)****Priority:** Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 482.21**Legal Deadline:** None

**Abstract:** This rule requires hospitals to develop and maintain a quality assessment and performance improvement (QAPI) program. The QAPI focuses the providers' efforts on the actual care delivered to patients, the performance of the hospital as an organization, and the impact of treatment furnished by the hospital on the health status of its patients. In addition, QAPI entails all activities required for measuring quality of care and maintaining it at acceptable levels. Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework,

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## Long-Term Actions

hospitals will continuously study and improve the processes of healthcare and delivery of service.

**Timetable:**

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66725
NPRM Comment Period End	02/17/98	
Next Action Undetermined		

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

**Agency Contact:** Stephanie Dyson, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9226

RIN: 0938-AK40

**1006. • REQUIREMENTS FOR THE RECREDENTIALING OF MEDICARE+CHOICE ORGANIZATIONS PROVIDERS (HCFA-1160-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1871**CFR Citation:** 42 CFR 422.204**Legal Deadline:** None

**Abstract:** This rule would change the requirements of recredentialing providers for Medicare+Choice Organizations from at least every 2 years to at least every 3 years.

**Timetable:**

Action	Date	FR Cite
NPRM	12/27/00	65 FR 81813
Next Action Undetermined		

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

**Agency Contact:** Siera Gollan, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-6664

RIN: 0938-AK41

**1007. • SUPPLEMENTARY MEDICAL INSURANCE PREMIUM SURCHARGE AGREEMENTS (HCFA-4007-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** Social Security Act, sec 1839(e)**CFR Citation:** 42 CFR 408.200; 42 CFR 408.201; 42 CFR 408.202; 42 CFR 408.205; 42 CFR 408.207; 42 CFR 408.210; ...**Legal Deadline:** None

**Abstract:** This rule would implement section 1839(e) of the SSA, as amended by section 144 of the SAA Amendments of 1994 and the Balanced Budget Act of 1997 to allow State and local government agencies to pay a lump sum for the Supplementary Medical Insurance (SMI) late enrollment fee due for a designated group of eligible individuals.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** State, Local

**Agency Contact:** Marty Abeln, Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1032

Sandy Clarke, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd, Baltimore, MD 21244  
Phone: 410 786-7451

RIN: 0938-AK42

**1008. • MEDICAL DEVICES COVERAGE DECISIONS RELATED TO HEALTH CARE TECHNOLOGY (HCFA-3059-P)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** 42 USC 1302; 42 USC 1395y; 42 USC 1395hh; 42 USC 410; 42 USC 411**CFR Citation:** 42 CFR 405.207**Legal Deadline:** None

**Abstract:** This rule exemption would permit coverage for, and payment, of routine patient care costs associated

with certain approved clinical trials of delays subject to the investigational devices. This would also include costs due to medical complications associated with participating in approved clinical trials.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None

**Agency Contact:** Marty Abeln, Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1032

Sharon Hippler, Office of Clinical Standards and Quality, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4633

RIN: 0938-AK43

**1009. • MEDICAID MANAGEMENT INFORMATION SYSTEM REVISED DEFINITION OF "MECHANIZED CLAIMS PROCESSING AND INFORMATION RETRIEVAL SYSTEM" (HCFA-2123-IFC)****Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 433.111; 42 CFR 433.112; 42 CFR 433.119**Legal Deadline:** None

**Abstract:** This rule revises the definition of mechanized claims processing and information retrieval systems to include the eligibility determination function. This change allows States to request enhanced FFP at the 90 and 75 percent levels to perform the function by either the Medicaid Management Information Systems or the integrated eligibility determination systems.

**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Governmental Jurisdictions**Government Levels Affected:** State, Federal

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## Long-Term Actions

**Agency Contact:** Harvey Heyman, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21044  
Phone: 410 786-0712

**RIN:** 0938-AK44

**1010. • MEDICARE PROGRAM; REPORTING AND REPAYMENT OF OVERPAYMENTS (HCFA-6011-P)**

**Priority:** Other Significant

**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1871

**CFR Citation:** 42 CFR 401.310

**Legal Deadline:** None

**Abstract:** This proposed rule would modify a notice of proposed rulemaking published on March 25, 1998. That notice proposed to amend regulations governing liability for overpayments to providers, suppliers, and individuals.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Barbara Wright, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C3-14-00, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4292

**RIN:** 0938-AK45

**1011. • IMPROVEMENTS TO THE MEDICARE+CHOICE APPEALS AND GRIEVANCE PROCEDURES (HCFA-4024-F)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** BBA, sec 4001; PL 105-33; Social Security Act, sec 1851 to 1859

**CFR Citation:** 42 CFR 422; 42 CFR 489

**Legal Deadline:** NPRM, Judicial, January 19, 2001.

**Abstract:** This rule sets forth several improvements to the Medicare+Choice (M+C) appeal and grievance procedures. Most notably, this rule will: 1) ensure that M+C enrollees

receive written notice, including information about appeal rights, at least 4 days before the proposed termination date of provider services; and 2) establishes a new fast-track independent review process for appealing decisions to terminate services.

This rule also clarifies hospitals' responsibility for issuing discharge notices, amends the Medicare provider agreement regulations with regard to beneficiary notification requirements, and sets forth beneficiary grievance procedures.

**Timetable:**

Action	Date	FR Cite
NPRM	01/24/01	66 FR 7593
Final Action	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Organizations

**Government Levels Affected:** None

**Additional Information:** The Settlement Agreement in *Grijalua v. Shalala* contemplates that a final rule will be published by the end of 2002.

**Agency Contact:** Tony Culotta, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4661

**RIN:** 0938-AK48

**1012. • CIVIL MONEY PENALTIES, ASSESSMENTS, AND REVISED SANCTION AUTHORITIES (HCFA-6145-FC)**

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

**Legal Authority:** PL 105-33, sec 4541(a)(2); PL 105-33, sec 4311(b); PL 105-33, sec 4317; PL 105-33, sec 4031(a)(2); PL 105-33, sec 4531(b)(2); PL 104-191, sec 231(c); ...

**CFR Citation:** 42 CFR 402.1; 42 CFR 402.105; 42 CFR 402.107; 42 CFR 405.520

**Legal Deadline:** None

**Abstract:** This rule with comment period is a technical rule that amends our civil money penalty (CMP) authorities. It adds CMP authorities that were enacted as part of the Balanced Budget Act of 1997 (BBA) and delegated to us. The rule delineates our authority to assess penalties for: failure to bill outpatient therapy services or

comprehensive outpatient rehabilitation services (CORS) on an assignment-related basis, failure to bill ambulance services on an assignment-related basis, failure to provide an itemized statement for Medicare items and services to a Medicare beneficiary upon his/her request, and failure of physicians or nonphysician practitioners to provide diagnostic codes for items or services they furnish or failure to provide this information to the entity furnishing the item or service ordered by the practitioner. As a result of the BBA's redesignation of a statutory paragraph, the rule also includes a technical change to an existing delegated authority. Additionally, the rule includes a technical change that corrects the amount of the CMP in section 405.520(c) and also serves as a cross-reference to the requirements in other sections of the regulations.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Joel Cohen, Office of Financial Management, Department of Health and Human Services, Health Care Financing Administration, C3-04-06, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-3349

**RIN:** 0938-AK49

**1013. • PAYMENT FOR UPGRADED DURABLE MEDICAL EQUIPMENT (HCFA-1084-F)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 414

**Legal Deadline:** None

**Abstract:** This rule amends the Medicare regulations to permit Medicare suppliers to furnish certain upgraded durable medical on an assignment basis. Medicare payment will be made to suppliers as if the DME were without the upgraded features.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

## HHS—HCFA

## Long-Term Actions

**Government Levels Affected:** None

**Agency Contact:** William J. Long, Department of Health and Human Services, Health Care Financing Administration, C4-12-18, Center for Health Plans and Providers, 7500 Security Boulevard, Baltimore, MD 21228  
Phone: 410 786-5655  
Email: wlong@hcfa.gov

**RIN:** 0938-AK50

**1014. • UPDATE TO THE PROSPECTIVE PAYMENT SYSTEM FOR HOME HEALTH AGENCIES FOR FY 2002 (HCFA-1147-NC)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395hh; Social Security Act, sec 1102; Social Security Act, sec 1871

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Other, Statutory, October 1, 2001, Rate updates required by BBA of 97.

Rates for instructing Medicare contractors about system changes must be published in the Federal Register by 07/01/01.

**Abstract:** This notice with comment sets forth an update to the 60-day national home health episode rates and the national per visits amounts used in the calculation of the low utilization payment adjustment (LUPA) under the Medicare prospective payment system for home health agencies. These rates replace the 60-day episode rates and the national per visits amounts used in calculation of the LUPA (published in the July 3, 200 FR (65 FR 41128).

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Susan Levy, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-9364

**RIN:** 0938-AK51

**1015. • RECOGNITION OF THE AMERICAN OSTEOPATHIC ASSOCIATION FOR AMBULATORY SURGICAL CENTER PROGRAMS (HCFA-2079-FN)**

**Priority:** Routine and Frequent

**Legal Authority:** Social Security Act, sec 1865(b)(1); Social Security Act, sec 1832(a)(F)(i)

**CFR Citation:** Not Yet Determined

**Legal Deadline:** NPRM, Statutory, January 12, 2001, Must be published 60 days after receipt of the November 14, 2000 application.

**Abstract:** In this notice we announce the receipt of an application from the American Osteopathic Association (AOA), for recognition as a national accreditation program for ambulatory surgical centers that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a 30-day public comment period.

**Timetable:**

Action	Date	FR Cite
Proposed Notice	03/14/01	66 FR 14906
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Joan Benny, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-7233

**RIN:** 0938-AK53

**1016. • PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES (HCFA-1159-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395; BBA '97; BBRA '99; BIPA '00

**CFR Citation:** 42 CFR 419

**Legal Deadline:** Final, Statutory, November 1, 2001.

**Abstract:** This rule would include the payment system recalibration, implementation of relevant provisions

of the Benefits Improvement and Protection Act (BIPA) of 2000, and other related policies.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	11/13/00	65 FR 67798
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

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

Phone: 410 786-4510

**RIN:** 0938-AK54

**1017. • MEDICARE AS SECONDARY PAYER-RECOVERY OF CONDITIONAL PAYMENTS (HCFA-6009-P)**

**Priority:** Other Significant

**Legal Authority:** None

**CFR Citation:** 42 CFR 411.20; 42 CFR 411.24

**Legal Deadline:** None

**Abstract:** This rule clarifies provider and supplier responsibilities in recovery of conditional payments.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** William Zavoina, Department of Health and Human Services, Health Care Financing Administration, Bureau of Program Operations, 1445 Meadows East Building, Baltimore, MD 21207  
Phone: 410 966-7461

**RIN:** 0938-AK55

## HHS—HCFA

## Long-Term Actions

**1018. • FIVE YEAR REVIEW OF WORK RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE PROPOSED NOTICE (HCFA-1170-PN)**

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

**Legal Authority:** 42 USC 1395w-4(c)

**CFR Citation:** Not Yet Determined

**Legal Deadline:** NPRM, Statutory, May 1, 2001.

**Abstract:** This notice discusses changes to work relative value units (RVUs) affecting payment for physician services.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Federal

**Agency Contact:** Terrence Kay, Center for Health Plans and Providers, Division of Practitioner and Ambulatory C, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, C4-10-26, Baltimore, MD 21244  
Phone: 410 786-4497

James Menas, Department of Health and Human Services, Health Care Financing Administration, C4-05-04, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4507

**RIN:** 0938-AK56

**1019. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2002 (HCFA-1169-P)**

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

**Legal Authority:** 42 CFR 1395w-4

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, November 1, 2001.

**Abstract:** This rule with comment period makes several changes affecting Medicare part B payments, and implements several provisions of the BIPA.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** Federal

**Agency Contact:** Diane Milstead, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3355

Terrence Kay, Center for Health Plans and Providers, Division of Practitioner and Ambulatory C, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, C4-10-26, Baltimore, MD 21244  
Phone: 410 786-4497

**RIN:** 0938-AK57

**1020. • CHANGES TO NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (HCFA-4019-FC)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 405

**Legal Deadline:** None

**Abstract:** This regulation would clarify when and under what circumstances Medicare coverage policy could be challenged.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** James Bossenmeyer, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-16-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9317  
Email: jbossenmeyer@hcfa.gov

**RIN:** 0938-AK58

**1021. • REVISIONS TO THE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES MANDATED BY BIPA (HCFA-1179-IFC)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395l; BBA 1997; BBRA 1999; BIPA 2000

**CFR Citation:** 42 CFR 419

**Legal Deadline:** None

**Abstract:** This rule implements the requirement of the BIPA to establish criteria for new categories of medical devices for transitional pass-through payment under the outpatient prospective payment system. The criteria would become effective on July 1, 2001.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Janet Wellham, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4510

**RIN:** 0938-AK59

**1022. • CHALLENGES TO NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (HCFA-3063-P)**

**Priority:** Other Significant

**Legal Authority:** Sec 522 of the BIPA 2000

**CFR Citation:** 42 CFR 405

**Legal Deadline:** NPRM, Statutory, October 1, 2001.

The effective date for regulation changes is 10/01/01.

**Abstract:** This rule proposes changes to the appeals process for national and local coverage determinations.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** James Bossenmeyer, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-16-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9317  
Email: jbossenmeyer@hcfa.gov

**RIN:** 0938-AK60

## HHS—HCFA

## Long-Term Actions

**1023. • REVISED PROCESS FOR MAKING MEDICARE COVERAGE DECISIONS (HCFA-3062-N)****Priority:** Other Significant**Legal Authority:** Sec 522 of the BIPA 2000**CFR Citation:** Not Yet Determined**Legal Deadline:** Other, Statutory, October 1, 2001, Revision notice.**Abstract:** This notice revises the process for making Medicare coverage decisions.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Vadim Lubarsky, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0840

**RIN:** 0938-AK61**1024. • CLAIMS ATTACHMENT STANDARD (HCFA-0050-P)****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** This action may affect State, local or tribal governments.**Legal Authority:** 42 USC 1320d-2(a)(2)(B)**CFR Citation:** 45 CFR 162**Legal Deadline:** Final, Statutory, August 21, 1998.**Abstract:** This rule proposes an electronic standard transmissions for claims attachments. The standard is required by HIPAA. It would be used to transmit clinical data, beyond those data contained in the claims standard, to help establish medical necessity or coverage.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** State, Local, Federal, Tribal**Federalism:** Undetermined**Procurement:** This is a procurement-related action for which there is a

statutory requirement. There is a paperwork burden associated with this action.

**Agency Contact:** James Krall, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244  
Phone: 410 786-6999**RIN:** 0938-AK62**1025. • STANDARDS FOR ELECTRONIC SIGNATURES (HCFA-0051-F)****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** This action may affect State, local or tribal governments.**Legal Authority:** PL 104-91; SSA, Sec. 1171 to 1179**CFR Citation:** Not Yet Determined**Legal Deadline:** None**Abstract:** This final rule is being jointly developed by HCFA and the Department of Commerce. The final rule implements administrative simplification initiatives that have a national scope beyond the Medicare and Medicaid programs. This rule establishes standards for electronic signature for health care claims processing.**Timetable:**

Action	Date	FR Cite
NPRM	08/12/98	63 FR 43242
NPRM Comment Period End	10/13/98	
Next Action Undetermined		

**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** No**Government Levels Affected:** State, Local, Federal**Federalism:** Undetermined**Additional Information:** Previously reported under 0938-AI57.**Agency Contact:** Barbara Clark, Office of Information Services, Department of Health and Human Services, Health Care Financing Administration, N2-14-10, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3017**RIN:** 0938-AK63**1026. • HEALTH INSURANCE REFORM: MODIFICATIONS TO STANDARDS FOR ELECTRONIC TRANSACTION (HCFA-0003-IFC)****Priority:** Other Significant**Unfunded Mandates:** Undetermined**Legal Authority:** Social Security Act, sec 1871**CFR Citation:** 45 CFR 162**Legal Deadline:** None**Abstract:** This rule adopts a revised national council for prescription drug programs (NCPDP) standards for batched retail pharmacy transactions under 45 CFR 162.**Timetable:** Next Action Undetermined**Regulatory Flexibility Analysis****Required:** Undetermined**Government Levels Affected:** Undetermined**Agency Contact:** Marilyn Abramovitz, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5939

**RIN:** 0938-AK64**1027. • REPLACEMENT OF REASONABLE CHARGE METHODOLOGY BY FEE SCHEDULE (HCFA-1010-F)****Priority:** Other Significant**Unfunded Mandates:** Undetermined**Legal Authority:** Social Security Act, sec 1833; Social Security Act, sec 1842**CFR Citation:** 42 CFR 414**Legal Deadline:** None**Abstract:** This final rule implements fee schedules for payment of items and services, excluding ambulance services, still subject to the reasonable charge payment methodology. The authority for establishing these fee schedules is provided by the Balanced Budget Act of 1997, which amended the Social Security Act. A fee schedule for ambulance services is mandated by a different statutory provision. The Social Security Act specifies that statewide or other areawide fee schedules may be implemented for the following items and services: medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and

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## Long-Term Actions

enteral nutrients, equipment, and supplies; electromyogram devices; salivation devices; blood products; and transfusion medicine. This final rule describes changes made to the proposed fee schedule payment methodology for these items and services and provides that the fee schedules are effective for all specified covered items and services furnished on or after January 1, 2002. Fee schedules will not be implemented for electromyogram devices and salivation devices at this time since these items are not covered by Medicare.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Organizations

**Government Levels Affected:** None

**Agency Contact:** Joel Kaiser, Center for Health Plan and Providers, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4499

**RIN:** 0938-AK66

**1028. • PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-PHASE II (HCFA-1810-FC)**

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

**Unfunded Mandates:** Undetermined

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

**CFR Citation:** 42 CFR 411

**Legal Deadline:** None

**Abstract:** On January 4, 2001, we issued a final rule with comment period (phase I) to incorporate into regulations paragraphs (a), (b), and (h) of section 1877 of the Social Security Act. This final rule with comment period (phase II) will address comments from the January 9, 1998 proposed rule concerning the remainder of section 1877, including the ownership and investment exceptions and the compensation exceptions. In addition, this final rule will address comments from the January 4, 2001 final rule with comment period.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** State, Local

**Federalism:** Undetermined

**Agency Contact:** Joanne Sinsheimer, Technical Assistant, CHPP, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4620

**RIN:** 0938-AK67

**1029. • INCREASE IN THE RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR PROSPECTIVE PAYMENT SYSTEM PROVIDERS (HCFA-3055-P)**

**Priority:** Economically Significant

**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1154; Social Security Act, sec 1159; Social Security Act, sec 1866; Social Security Act, sec 1871

**CFR Citation:** 42 CFR 476.78

**Legal Deadline:** None

**Abstract:** This rule would increase the rate of reimbursement for photocopy expenses of Medicare Prospective Payment System (PPS) providers of medical records requested by Utilization and Quality Control Peer Review Organizations. We would increase the rate from 7 cents to 11 cents per page, which includes labor and supply costs, to reflect inflationary adjustments for these two cost components only.

This rule is necessary due to increases in the inflation factor, and increases in salaries and cost of living. We would specify a provision for periodic review and adjustment of the per-page reimbursement cost to account for inflation and changes in technology. The methodology for calculating the per-page reimbursement rate would remain unchanged.

We also propose to expand the scope of the regulation to encompass other providers subject to the Medicare PPS (for example, skilled nursing facilities and home health agencies), as well as hospitals.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Valerie Mattison-Brown, Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5958

**RIN:** 0938-AK68

**1030. • LONG TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2003 (HCFA-1177-P)**

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

**Legal Authority:** BBA, sec 4422(a)(1); BBRA, sec 123; BIPA, sec 307

**CFR Citation:** 42 CFR 412

**Legal Deadline:** NPRM, Statutory, November 1, 2001, 60 Days before the final rule.

**Abstract:** This regulation will implement a prospective payment system for long-term care hospitals.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, Federal

**Federalism:** Undetermined

**Agency Contact:** Judith H. Richter, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-2590

**RIN:** 0938-AK69

**1031. • MODIFICATIONS TO MANAGED CARE RULES BASED ON PROVISIONS OF BIPA AND TECHNICAL CORRECTIONS (HCFA-1180-P)**

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

**Legal Authority:** BIPA, sec 601 to 608; BIPA, sec 611 to 621; BIPA, sec 623; BIPA, sec 634

**CFR Citation:** Not Yet Determined

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**Legal Deadline:** None

**Abstract:** Implements certain technical and minor provisions of sections 601 to 634 of the Medical Payment Provisions of the Medicare, Medicaid and SCHIP Benefit and Improvement Act of 2000.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** A. G. D'Alberty, Office of Managed Care, Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1100

**RIN:** 0938-AK71

**1032. • CHANGES TO THE HOSPITAL INPATIENTS PROSPECTIVE PAYMENT SYSTEM FOR FISCAL YEAR 2002 RATES (HCFA-1158-P)**

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

**Legal Authority:** Social Security Act, sec 1886(d)

**CFR Citation:** 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 486

**Legal Deadline:** Final, Statutory, August 1, 2001.

**Abstract:** We are revising the Medicare hospital inpatient prospective payment for operating costs to implement changes arising from our continuing experience with the system. In addition, in the Addendum to this final rule, we described changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capita-related costs. These changes apply to discharges occurring on or after October 1, 2001. We also set forth rate-of-increase limits and made changes to our policy for hospitals and hospital units excluded from the prospective payment systems.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Stephen Phillips, Center for Health Plans and Providers,

Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

**RIN:** 0938-AK73

**1033. • CHANGES TO INPATIENT BIPA FOR FISCAL YEAR 2001 (HCFA-1178-IFC)**

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

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

**Legal Authority:** PL 106-554

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Other, Statutory, April 1, 2001, Enacted by the BIPA 2000 on December 21, 2000.

**Abstract:** The BIPA 2000, enacted on December 21, 2000, contained numerous provisions affecting inpatient hospital payment policies. These provisions have varying effective dates. In accordance with the statute, the changes in this regulation are effective either retroactively to October 1, 2000, upon enactment of BIPA 2000 (Dec. 21, 2000), or will be effective on April 1, 2001.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Stephen Phillips, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

**RIN:** 0938-AK74

**1034. • MEDICARE+CHOICE ESRD RATES (HCFA-1182-PN)**

**Priority:** Other Significant

**Legal Authority:** BIPA 2000, sec 605

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This notice announces HCFA's new payment methodology for beneficiaries with ESRD who are enrolled in Medicare+Choice plans.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Anne Hornsby, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1181

**RIN:** 0938-AK75

**1035. • REVISIONS TO TRANSACTION AND CODE SET STANDARDS FOR ELECTRONIC TRANSACTIONS (HCFA-0005-IFC)**

**Priority:** Other Significant

**Legal Authority:** Social Security Act, sec 1871

**CFR Citation:** 45 CFR 162

**Legal Deadline:** None

**Abstract:** This rule adopts revisions to the standards for electronic health care transactions adopted by the Secretary in regulations published August 2000. These revisions enable covered entities to comply with the standards.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis Required:** Undetermined

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

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

**Agency Contact:** Stanley B. Nachimson, Senior Technical Advisor, Department of Health and Human Services, Health Care Financing Administration, N2-16-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6153

**RIN:** 0938-AK76

**1036. • MEDICARE INPATIENT DISPROPORTIONATE SHARE HOSPITAL ADJUSTMENT CALCULATION (HCFA-1171-IFC)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 412106

**Legal Deadline:** None

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## Long-Term Actions

**Abstract:** This rule defines “Medicaid patient days” in the Medicare DSH adjustment calculations.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Stephen Phillips, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

**RIN:** 0938-AK77

**1037. • STATEMENT OF INTENT (HCFA-1185-P)**

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

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 424

**Legal Deadline:** NPRM, Statutory, November 1, 2001.

**Abstract:** This regulation is a review of Medicare statement of intent provisions.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** David Walczak, Center for Health Plans and Providers, Plan and Provider Purchasing Policy Group, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4475

**RIN:** 0938-AK79

**1038. • PROCEDURES FOR PUBLIC CONSULTATIONS FOR CODING AND PAYMENT DETERMINATIONS FOR NEW LABORATORY TESTS (HCFA-1186-N)**

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

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

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** The Benefits Improvement and Protection Act (BIPA) of 2000, section 531 has a statutory deadline of December 20, 2001 to establish procedures for coding and payment determinations for new clinical laboratory tests in a manner consistent with procedures of International Classification of Diseases 9-CM. The procedures will require a minimum of one public meeting per year to allow laboratory and durable medical equipment industries to participate in coding and payment decisions.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Local, Federal

**Agency Contact:** Tzvi Hefter, Center for Health Plans and Providers, Department of Health and Human Services, Health Care Financing Administration, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-1304

**RIN:** 0938-AK80

**1039. • ORGAN PROCUREMENT ORGANIZATION CONDITION FOR COVERAGE (HCFA-3064-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1320b-8(b)(1)(A)(i); 42 USC 273(b)(2)

**CFR Citation:** 42 CFR 486.301

**Legal Deadline:** Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

**Abstract:** This rule will establish conditions for coverage for organ procurement organizations (OPOs) to be certified by the Secretary to receive payment from Medicare and Medicaid for organ procurement costs and to be designated by the Secretary for a specific geographic service area.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Jacqueline Morgan, Health Insurance Specialist,

Department of Health and Human Services, Health Care Financing Administration, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4282

**RIN:** 0938-AK81

**1040. • QUALIFICATION REQUIREMENTS FOR DIRECTORS OF LABORATORIES PERFORMING HIGH COMPLEXITY TESTING (HCFA-2094-NPRM)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** USPHSA, sec 353

**CFR Citation:** 42 CFR 493.1443

**Legal Deadline:** None

**Abstract:** This rule revises the qualification requirements by which an individual with a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Cecelia Hinkel, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration

Phone: 410 786-3347

**RIN:** 0938-AK83

**1041. • PROTECTION AND PROMOTION OF RESIDENT RIGHTS (HCFA-3065-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 290aa, Public Health Service Act

**CFR Citation:** Not Yet Determined

**Legal Deadline:** NPRM, Statutory, October 7, 2001, Rule must be promulgated per part H, sec 593, title V of the Public Health Service Act.

**Abstract:** This rule will impose regulations to ensure protection and promotion of residents' rights to be free from physical or mental abuse, corporal punishment, and any restraints or

## HHS—HCFA

## Long-Term Actions

involuntary seclusion imposed for purpose of discipline or convenience.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Local

**Federalism:** Undetermined

**Agency Contact:** Julie Moyers, Health Insurance Specialist, Health Standards and Quality Bureau, Department of Health and Human Services, Health Care Financing Administration, S1-09-07, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-6772

**RIN:** 0938-AK85

**1042. • STANDARDS FOR ELECTRONIC TRANSACTIONS-ELIMINATION OF NDC CODING STANDARDS (HCFA-0006-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1171-79

**CFR Citation:** 42 CFR 162.1002

**Legal Deadline:** None

**Abstract:** This regulation will change the standard codes for drugs and biologics. It withdraws the designation of the NDC code set as the standard for institutional and professional providers.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

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

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

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

**Agency Contact:** Stanley B. Nachimson, Senior Technical Advisor, Department of Health and Human Services, Health Care Financing Administration, N2-16-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6153

**RIN:** 0938-AK86

**1043. • HOSPITAL REFERENCE LABORATORY AND MEDICARE SECONDARY PAYER (HCFA-1187-P)**

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

**Legal Authority:** Not Yet Determined

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This regulation will address current procedures with respect to independent laboratories' administrative requirements in gathering and verifying Medicare Secondary Payer information in reference lab situations involving "nonpatient" claims.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**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 21244-1850

Phone: 410 786-4472

**RIN:** 0938-AK87

**1044. • PORTABILITY IN THE GROUP HEALTH INSURANCE MARKET (HCFA-2048-F)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 300gg

**CFR Citation:** 42 CFR 144.103; 42 CFR 146.101; 42 CFR 143.111; 42 CFR 146.113; 42 CFR 146.115; 42 CFR 146.117; 42 CFR 146.119; ...

**Legal Deadline:** None

**Abstract:** This regulation will specify the limitations on only preexisting conditions exclusion periods imposed by group health insurance issues and non-Federal government plans, and the requirements on such issues and plans to offer special enrollment to certain individuals who lose eligibility for other coverage when a new dependent becomes eligible through marriage, birth or adoption.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16893
Interim Final Rule Comment Period End	07/07/97	
Interim Final Rule Effective	07/07/97	
Next Action Undetermined		

**Regulatory Flexibility Analysis**

**Required:** Yes

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

**Government Levels Affected:** State, Local

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

**Agency Contact:** Tim Hrynick, Health Insurance Specialist, Department of Health and Human Services, Health Care Financing Administration, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4478

**RIN:** 0938-AK88

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Health Care Financing Administration (HCFA)**
**Completed Actions**
**1045. CHANGES TO PEER REVIEW ORGANIZATION REGULATIONS (HCFA-3135-F)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 400.200; 42 CFR 466.1; 42 CFR 466.71; 42 CFR 466.76; 42 CFR 466.78; 42 CFR 466.83; 42 CFR 411.15; 42 CFR 431.630; 42 CFR 433.15; 42 CFR 462.1; 42 CFR 462.101; 42 CFR 462.102; 42 CFR 462.106; 42 CFR 462.107

**Completed:**

Reason	Date	FR Cite
Withdrawn	02/13/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** William Roskey  
Phone: 410 786-0433

**RIN:** 0938-AD38

**1046. PROTECTION OF INCOME AND RESOURCES FOR COMMUNITY SPOUSES OF INSTITUTIONALIZED INDIVIDUALS (HCFA-2023-P)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 435.650 to 674; 42 CFR 435.750 to 754

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** State, Local

**Federalism:** Undetermined

**Agency Contact:** Roy Trudel  
Phone: 410 786-3417

**RIN:** 0938-AE12

**1047. EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT) SERVICES (HCFA-2028-F)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 441.50; 42 CFR 440.40

**Completed:**

Reason	Date	FR Cite
Withdrawn	04/23/01	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** State, Local

**Agency Contact:** Cindy Ruff  
Phone: 410 786-5916

**RIN:** 0938-AE72

**1048. PAYMENT FOR NURSING AND ALLIED HEALTH SCIENCE EDUCATION (HCFA-1685-F)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 413

**Completed:**

Reason	Date	FR Cite
Final Rule	01/12/01	66 FR 3358
Final Rule Effective	01/12/01	
60-Day Delay of Effective Date	03/12/01	66 FR 14342

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Rebecca Hirshorn  
Phone: 410 786-3411

**RIN:** 0938-AE79

**1049. COVERAGE OF SCREENING PAP SMEARS (HCFA-3705-F)**

**Priority:** Other Significant

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

**Completed:**

Reason	Date	FR Cite
Withdrawn	02/06/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Joyce Eng  
Phone: 410 786-4619

Sharon Lappalainen  
Phone: 410 786-9262

**RIN:** 0938-AE98

**1050. REFERRAL TO CHILD SUPPORT ENFORCEMENT AGENCIES OF MEDICAID FAMILIES (HCFA-2051-F)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.151; 42 CFR 433.160

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** Robert Nakielny  
Phone: 410 786-4466

**RIN:** 0938-AF68

**1051. DISCLOSURE OF CONFIDENTIAL PRO AND ESRD NETWORK ORGANIZATION INFORMATION FOR RESEARCH PURPOSES (HCFA-3208-P)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 405.2115; 42 CFR 476.144

**Completed:**

Reason	Date	FR Cite
Withdrawn	02/13/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Alfreda Staton  
Phone: 410 786-6940

**RIN:** 0938-AG33

**1052. EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES, SANCTIONS, UNDERPAYMENTS AND OVERPAYMENTS (HCFA-2215-P)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 405.1801; 42 CFR 405.1803; 42 CFR 405.1811; 42 CFR 405.1835; 42 CFR 405.1843; 42 CFR 405.1805; 42 CFR 489.2; 42 CFR 489.13; 42 CFR 489.18

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Mike Goldman  
Phone: 410 786-6813

**RIN:** 0938-AG59

**1053. OPTIONAL COVERAGE OF CERTAIN TUBERCULOSIS TO TB-RELATED SERVICES, TB-INFECTED INDIVIDUALS (HCFA-2082-P)**

**Priority:** Economically Significant

**CFR Citation:** 42 CFR 435.219; 42 CFR 435.201; 42 CFR 440.250; 42 CFR

## HHS—HCFA

## Completed Actions

436.201; 42 CFR 436.219; 42 CFR 440.164

**Completed:**

Reason	Date	FR Cite
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Withdrawn-Under review	02/22/01	
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**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Local**Federalism:** Undetermined**Agency Contact:** Ingrid Osborne  
Phone: 410 786-4461**RIN:** 0938-AG72**1054. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-EXPANDED TO DESIGNATED HEALTH SERVICES (HCFA-1809-FC)****Priority:** Other Significant**CFR Citation:** 42 CFR 411.1; 42 CFR 411.350 to 411.361; 42 CFR 424.22; 42 CFR 435.1002; 42 CFR 435.1012; 42 CFR 455.100 to 455.103; 42 CFR 455.108; 42 CFR 455.109**Completed:**

Reason	Date	FR Cite
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Final Rule	01/04/01	66 FR 856
60-Day Delay of Effective Date To 04/06/2001	02/02/01	66 FR 8771
60-Day Extension of Comment Period	04/04/01	66 FR 17813

**Regulatory Flexibility Analysis Required:** Yes**Government Levels Affected:** State**Agency Contact:** Joanne Sinsheimer  
Phone: 410 786-4620**RIN:** 0938-AG80**1055. DISTINCT PART REQUIREMENTS FOR NURSING HOMES AND PROHIBITION ON FINANCIAL SCREENING OF APPLICANTS FOR NURSING HOME ADMISSION (HCFA-3815-P)****Priority:** Other Significant**CFR Citation:** 42 CFR 409; 42 CFR 483**Completed:**

Reason	Date	FR Cite
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Withdrawn	02/13/01	
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**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** None**Agency Contact:** Nancy Archer  
Phone: 401 786-0596**RIN:** 0938-AG84**1056. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HCFA-2225-FC)****Priority:** Other Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 493.2; 42 CFR 493.39; 42 CFR 493.45; 42 CFR 493.47; 42 CFR 493.49; 42 CFR 493.53; 42 CFR 493.1775; 42 CFR 493.7; 42 CFR 493.8; 42 CFR 493.9; 42 CFR 493.15; 42 CFR 493.20; 42 CFR 493.25; 42 CFR 493.35; 42 CFR 493.37**Completed:**

Reason	Date	FR Cite
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Withdrawn-Under review	02/22/01	
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**Regulatory Flexibility Analysis Required:** Yes**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Judy Yost  
Phone: 410 786-3531**RIN:** 0938-AG99**1057. ADDITIONAL SUPPLIER STANDARDS (HCFA-6004-FC)****Priority:** Other Significant**CFR Citation:** 42 CFR 424.57**Completed:**

Reason	Date	FR Cite
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Final Action	10/11/00	65 FR 60366
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**Regulatory Flexibility Analysis Required:** Yes**Government Levels Affected:** None**Agency Contact:** Charles Waldhauser  
Phone: 410 786-6140Ralph Goldberg  
Phone: 410 786-4870  
Email: rgoldberg@hcfa.gov**RIN:** 0938-AH19**1058. STATE PLAN AMENDMENT (SPA) RECONSIDERATION PROCESS (HCFA-2096-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 430.18; 42 CFR 430.60**Completed:**

Reason	Date	FR Cite
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Withdrawn	04/23/01	
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**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Robert Tomlinson  
Phone: 410 786-4463**RIN:** 0938-AH24**1059. MEDICARE COVERAGE OF SERVICES OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS (HCFA-1843-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 484; 42 CFR 485**Completed:**

Reason	Date	FR Cite
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Withdrawn-Under review	03/06/01	
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**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Jacqueline Gordon  
Phone: 410 786-4517**RIN:** 0938-AH37**1060. MEDICAID; ESTATE RECOVERIES (HCFA-2083-P)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 433**Completed:**

Reason	Date	FR Cite
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Withdrawn-Under review	02/22/01	
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**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** State**Federalism:** Undetermined**Agency Contact:** Ingrid Osborne  
Phone: 410 786-4461**RIN:** 0938-AH63

## HHS—HCFA

## Completed Actions

**1061. INDIVIDUAL MARKET HEALTH INSURANCE REFORM: PORTABILITY FROM GROUP TO INDIVIDUAL COVERAGE; FEDERAL RULES FOR ACCESS IN THE INDIVIDUAL MARKET; STATE ALTERNATIVE MECHANISMS TO FEDERAL RULES (HCFA-2882-F)**

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

**CFR Citation:** 45 CFR 148

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** Undetermined

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

**Federalism:** Undetermined

**Agency Contact:** Gertrude Saunders  
Phone: 410 786-5888  
Email: gsaunders@hcfa.gov

**RIN:** 0938-AH75

**1062. DISCLOSURE OF PEER REVIEW ORGANIZATION INFORMATION IN RESPONSE TO BENEFICIARY COMPLAINTS (HCFA-3241-P)**

**Priority:** Other Significant

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

**Completed:**

Reason	Date	FR Cite
Withdrawn	02/13/01	

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Alfreda Staton  
Phone: 410 786-1910

**RIN:** 0938-AH85

**1063. MEDICAID PROGRAM; AMENDMENT TO THE PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW PROGRAM (HCFA-2107-P)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 405; 42 CFR 431; 42 CFR 433; 42 CFR 441; 42 CFR 483

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** Jan Earle  
Phone: 410 786-9004

**RIN:** 0938-AH89

**1064. MEDICALLY NEEDY DETERMINATIONS UNDER WELFARE REFORM (HCFA-2109-IFC)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 435; 42 CFR 436

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** Jackie Wilder  
Phone: 410 786-4579  
Email: jwilder@hcfa.gov

**RIN:** 0938-AH92

**1065. MEDICAID PROGRAM; COVERAGE AND PAYMENT FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES (HCFA-2043-P)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 431; 42 CFR 440; 42 CFR 441; 42 CFR 447

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** State, Tribal

**Federalism:** Undetermined

**Agency Contact:** David Worgo  
Phone: 410 786-5919

**RIN:** 0938-AH95

**1066. NONDISCRIMINATION IN HEALTH COVERAGE IN THE GROUP MARKET (HCFA-2022-F)**

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

**CFR Citation:** 45 CFR 146

**Completed:**

Reason	Date	FR Cite
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
60-Day Delay of Effective Date To 05/08/2001	03/09/01	66 FR 14076
Withdrawn-Under review	05/02/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Dave Holstein  
Phone: 410 786-1564

**RIN:** 0938-AI08

**1067. MEDICARE PROGRAM; IMPROVEMENTS TO THE APPEALS PROCESS FOR MEDICARE BENEFICIARIES ENROLLED IN HMOS, CMPS, AND HCPPS (HCFA-4024-P)**

**Timetable:**

Action	Date	FR Cite
Duplicate of RIN 0938-AK48	01/18/01	

**RIN:** 0938-AI11

**1068. MEDICARE PROGRAM; ADJUSTMENTS TO COST LIMITS FOR SKILLED NURSING FACILITY INPATIENT ROUTINE SERVICE COSTS (HCFA-1896-FN)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 1001

**Completed:**

Reason	Date	FR Cite
Withdrawn	02/08/01	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Richard Strauss  
Phone: 410 786-2019  
Email: rstrauss@hcfa.gov

**RIN:** 0938-AI14

**1069. MEDICARE/MEDICAID PROGRAM; USER FEES FOR INFORMATION, PRODUCTS, AND SERVICES (HCFA-6021-P)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 401

**Completed:**

Reason	Date	FR Cite
Withdrawn	11/02/99	

## HHS—HCFA

## Completed Actions

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** David Escobedo  
Phone: 410 786-5401

RIN: 0938-AI46

**1070. PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES (HCFA-1005-F)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 409.10; 42 CFR 413; 42 CFR 413.124; 42 CFR 413.130; 42 CFR 489.20; 42 CFR 103.105; 42 CFR 410.2; 42 CFR 410.27; 42 CFR 410.28; 42 CFR 410.30; 42 CFR 411.15; 42 CFR 412.50; 42 CFR 413.118; 42 CFR 413.122; 42 CFR 103.101; 42 CFR 103.102**Completed:**

Reason	Date	FR Cite
Final Action	04/07/00	65 FR 18434

**Regulatory Flexibility Analysis**

Required: Yes

**Government Levels Affected:** None**Agency Contact:** Chuck Braver  
Phone: 410 786-6719

RIN: 0938-AI56

**1071. STATE PLAN REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT PROVIDERS (HCFA-2007-P)****Priority:** Other Significant**CFR Citation:** 42 CFR 441**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis**

Required: Undetermined

**Government Levels Affected:** State, Local, Tribal**Agency Contact:** Mary Linda Morgan  
Phone: 410 786-2011  
Email: mmorgan@hcfa.gov

RIN: 0938-AI63

**1072. MEDICAID PROGRAM; HOME AND COMMUNITY-BASED SERVICES (HCFA-2010-FC)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 440; 42 CFR 441**Completed:**

Reason	Date	FR Cite
Final Action	10/10/00	65 FR 60105

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** State**Agency Contact:** Bill Coons  
Phone: 410 786-5921

RIN: 0938-AI67

**1073. MEDICAID MANAGED CARE; REGULATORY PROGRAM TO IMPLEMENT CERTAIN MEDICAID PROVISIONS OF THE BALANCED BUDGET ACT OF 1997 (HCFA-2001-F)****Priority:** Other Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 438; 42 CFR 430; 42 CFR 431; 42 CFR 434; 42 CFR 435; 42 CFR 438; 42 CFR 440; 42 CFR 447**Completed:**

Reason	Date	FR Cite
Final Action	01/19/01	66 FR 6227
Final Action Effective	04/19/01	
60-Day Delay of Effective Date To	02/26/01	66 FR 11546
	06/18/2001	

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** State, Local, Tribal, Federal**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Michael Fiore  
Phone: 410 786-0623

RIN: 0938-AI70

**1074. PROSPECTIVE FEE SCHEDULE FOR AMBULANCE SERVICES (HCFA-1002-P)****Timetable:**

Action	Date	FR Cite
Duplicate of RIN 0938-AK30	02/01/01	

RIN: 0938-AI72

**1075. REVISION OF PROCEDURES FOR REQUESTING EXCEPTIONS TO COST LIMITS FOR SNFS AND ELIMINATION OF RECLASSIFICATIONS (HCFA-1883-F)****Priority:** Other Significant**CFR Citation:** 42 CFR 413.30**Completed:**

Reason	Date	FR Cite
Final Action	10/10/00	65 FR 60104

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Steve Raitzyk  
Phone: 410 786-4599

RIN: 0938-AI80

**1076. EXPANDED COVERAGE FOR DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES (HCFA-3002-F)****Priority:** Economically Significant**CFR Citation:** 42 CFR 410; 42 CFR 414; 42 CFR 424; 42 CFR 476; 42 CFR 498**Completed:**

Reason	Date	FR Cite
Final Action	12/29/00	65 FR 83130

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Mary Stojak  
Phone: 410 786-6939

RIN: 0938-AI96

**1077. MEDICARE PROGRAM; CRITERIA AND STANDARDS FOR EVALUATING INTERMEDIARY AND CARRIER PERFORMANCE: MILLENNIUM COMPLIANCE (HCFA-4002-GNC)****Priority:** Info./Admin./Other**CFR Citation:** 42 CFR ch IV**Completed:**

Reason	Date	FR Cite
Notice	12/11/98	63 FR 68464

**Regulatory Flexibility Analysis**

Required: No

**Government Levels Affected:** None**Agency Contact:** Sue Lathroum  
Phone: 410 786-7409

RIN: 0938-AJ15

**1078. MEDICARE/MEDICAID AND CLIA PROGRAMS: CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 EXEMPTION OF LABORATORIES IN THE STATE OF CALIFORNIA (HCFA-2245-N)****Priority:** Other Significant**CFR Citation:** 42 CFR 493

## HHS—HCFA

## Completed Actions

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Federal**Agency Contact:** Jim Cometa  
Phone: 410 786-6720**RIN:** 0938-AJ47**1079. MEDICARE PROGRAM: CRITERIA FOR MAKING NATIONAL COVERAGE DECISION (HCFA-3432-P)****Priority:** Other Significant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	03/06/01	

**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined**Agency Contact:** Patricia Brocato-Simons

Phone: 410 786-0261

**RIN:** 0938-AJ54**1080. MEDICARE PROGRAM; SUSTAINABLE GROWTH RATE FOR FISCAL YEAR 2000 (HCFA-1110-N)****Priority:** Substantive, Nonsignificant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Final Action	04/10/00	65 FR 19000

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Marc Hartstein  
Phone: 410 786-4539**RIN:** 0938-AJ60**1081. MEDICARE AND MEDICAID PROGRAMS; PROGRAMS FOR ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) (HCFA-1903-P)****Priority:** Other Significant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	03/06/01	

**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** Undetermined**Federalism:** Undetermined**Agency Contact:** Janet Samen  
Phone: 410 786-9161**RIN:** 0938-AJ63**1082. CLINICAL SOCIAL WORKER SERVICES (HCFA-1088-F)****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 410**Completed:**

Reason	Date	FR Cite
NPRM	10/19/00	65 FR 62681
Merged With RIN 0938-AK57	02/13/01	

**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Paul Kim  
Phone: 410 786-7410**RIN:** 0938-AJ71**1083. MEDICAID DISPROPORTIONATE SHARE HOSPITAL PAYMENTS-INSTITUTIONS FOR MENTAL DISEASE (HCFA-2062-N)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Withdrawn	05/01/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Agency Contact:** Christine Hinds  
Phone: 410 786-4578**RIN:** 0938-AJ74**1084. THE CHILDREN'S HEALTH INSURANCE PROGRAM: IMPLEMENTING THE BALANCED BUDGET ACT OF 1997 (HCFA-2006-F)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 457**Completed:**

Reason	Date	FR Cite
Final Action	01/11/01	66 FR 2490

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Local**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Cheryl Austein-Casnoff

Phone: 410 786-4196

Cynthia Shirk  
Phone: 410 786-6614**RIN:** 0938-AJ75**1085. MEDICARE PROGRAM UPDATE OF AMBULATORY SURGICAL CENTER PAYMENT RATES EFFECTIVE FOR SERVICES ON OR AFTER OCTOBER 1, 1999 (HCFA-1085-N)****Priority:** Other Significant**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Notice	02/09/00	65 FR 6380

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Bob Cereghino  
Phone: 410 786-4645**RIN:** 0938-AJ86**1086. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES-UPDATE (HCFA-1112-F)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 411; 42 CFR 489**Completed:**

Reason	Date	FR Cite
Final Action	07/31/00	65 FR 46770

**Regulatory Flexibility Analysis Required:** No

## HHS—HCFA

## Completed Actions

**Government Levels Affected:** None**Agency Contact:** Susan Burris

Phone: 410 786-6655

Email: sburris@hcfa.gov

**RIN:** 0938-AJ93**1087. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (HCFA-2065-F)****Priority:** Economically Significant**CFR Citation:** 42 CFR 441; 42 CFR 483**Completed:**

Reason	Date	FR Cite
Final Rule	01/11/01	66 FR 2316
Final Rule Effective	03/12/01	
60-Day Delay of Effective Date To	03/12/01	66 FR 14343
	05/11/2001	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Mary Kay Mullen

Phone: 410 786-5480

**RIN:** 0938-AJ96**1088. CONDITIONS OF PARTICIPATION FOR INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED****Timetable:**

Action	Date	FR Cite
Duplicate of RIN 0938-AK23	02/01/01	

**RIN:** 0938-AJ99**1089. FLEXIBILITY IN PAYMENT METHODS FOR SERVICES OF HOSPITALS, NURSING FACILITIES, AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED (HCFA-2004-F)****Priority:** Other Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 447.205; 42 CFR 447.250 to 447.257; 42 CFR 447.271; 42 CFR 447.272; 42 CFR 447.280**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis****Required:** Undetermined**Government Levels Affected:** State**Federalism:** Undetermined**Agency Contact:** Marge Lee

Phone: 410 786-4361

**RIN:** 0938-AK04**1090. HOSPITAL CONDITIONS OF PARTICIPATION; ANESTHESIA SERVICES (HCFA-3049-F)****Priority:** Other Significant**CFR Citation:** 42 CFR 416.42; 42 CFR 482.52; 42 CFR 485.639**Completed:**

Reason	Date	FR Cite
Final Rule	01/18/01	66 FR 4674
Final Rule Effective	01/18/01	
60-Day Delay of Effective Date	03/19/01	66 FR 15352

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Debbie Hattery

Phone: 410 786-1855

**RIN:** 0938-AK08**1091. CHANGES TO THE APPEALS PROCESS FOR BENEFICIARIES RECEIVING HOME HEALTH SERVICES IN THE FEE FOR SERVICE PROGRAM (HCFA-4006-P)****Priority:** Other Significant**CFR Citation:** 42 CFR 405**Completed:**

Reason	Date	FR Cite
Withdrawn	02/13/01	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Rosalind Little

Phone: 410 786-6972

**RIN:** 0938-AK10**1092. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2001 (HCFA-1120-F)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 414**Completed:**

Reason	Date	FR Cite
Final Action	11/02/00	65 FR 65376

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** None**Agency Contact:** Diane Milstead

Phone: 410 786-3355

**RIN:** 0938-AK11**1093. REVISIONS TO MEDICAID UPPER PAYMENT LIMIT REQUIREMENTS FOR HOSPITAL, NURSING FACILITY, INTERMEDIATE CARE FACILITY SERVICES FOR THE MENTALLY RETARDED AND CLINIC SERVICES (HCFA-2071-F)****Priority:** Economically Significant. Major under 5 USC 801.**CFR Citation:** 42 CFR 447**Completed:**

Reason	Date	FR Cite
NPRM	10/10/00	65 FR 60151
Final Action	01/12/01	66 FR 3148

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** State, Local**Agency Contact:** Robert Weaver

Phone: 410 786-5914

**RIN:** 0938-AK12**1094. HOSPICE WAGE INDEX (HCFA-1135-N)****Priority:** Routine and Frequent**CFR Citation:** None**Completed:**

Reason	Date	FR Cite
Notice	10/06/00	65 FR 60071

**Regulatory Flexibility Analysis****Required:** Yes**Government Levels Affected:** None**Agency Contact:** Carol Blackford

Phone: 410 786-5909

Email: cblackford@hcfa.gov

**RIN:** 0938-AK13**1095. HIPAA PROGRAM; BONA FIDE WELLNESS PROGRAMS (HCFA-2078-F)****Priority:** Substantive, Nonsignificant**CFR Citation:** 45 CFR 146

## HHS—HCFA

## Completed Actions

**Completed:**

Reason	Date	FR Cite
NPRM	01/08/01	66 FR 1420
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Ruth Bradford  
Phone: 410 786-2636

**RIN:** 0938-AK19

**1096. APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2086-F)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 435

**Completed:**

Reason	Date	FR Cite
NPRM	10/31/00	65 FR 64919
Final Action	01/11/01	66 FR 2316

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

**Agency Contact:** Roy Trudel  
Phone: 410 786-3417

**RIN:** 0938-AK22

**1097. PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES: EXCEPTION TO THE PROVIDER-BASED LOCATION CRITERIA FOR PPS-EXEMPT FACILITIES (HCFA-1143-F)**

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

**CFR Citation:** 42 CFR 413

**Completed:**

Reason	Date	FR Cite
Withdrawn	12/12/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** None

**Agency Contact:** Michael Lefkowitz  
Phone: 410 786-5316

**RIN:** 0938-AK25

**1098. CRITERIA AND STANDARDS FOR EVALUATING INTERMEDIARY AND CARRIER PERFORMANCE DURING FY 2001 (HCFA-4010-GNC)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 421.122

**Completed:**

Reason	Date	FR Cite
Notice	10/31/00	65 FR 47706

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Kristy McCarthy  
Phone: 410 786-7139

**RIN:** 0938-AK26

**1099. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2001 (HCFA-8007-N)**

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

**CFR Citation:** None

**Completed:**

Reason	Date	FR Cite
Final Action	10/19/00	65 FR 62725

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Clare McFarland  
Phone: 410 786-6390

**RIN:** 0938-AK27

**1100. MANDATORY TRANSMISSION OF OASIS FOR NON-MEDICARE/MEDICAID PATIENTS IN HOME HEALTH AGENCIES AND CONTINUED DELAY OF REQUIREMENTS FOR PATIENTS RECEIVING PERSONAL CARE SERVICES (HCFA-2070-N)**

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

**CFR Citation:** None

**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	04/27/01	

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Mary Weakland

Phone: 410 786-6835

**RIN:** 0938-AK28

**1101. REMOVAL OF THE REQUIREMENTS FOR THE CARDIAC PACEMAKER REGISTRY (HCFA-3045-F)**

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 42 CFR 409; 42 CFR 410; 42 CFR 489; 42 CFR 498

**Completed:**

Reason	Date	FR Cite
Final Action	10/19/00	65 FR 62645

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Shana Olshan  
Phone: 410 786-5246

**RIN:** 0938-AK29

**1102. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-PHASE II (HCFA-1810-FC)**

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

**CFR Citation:** 42 CFR 411

**Completed:**

Reason	Date	FR Cite
Withdrawn	12/27/00	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** State, Local

**Federalism:** Undetermined

**Agency Contact:** Joanne Sinsheimer  
Phone: 410 786-4620

**RIN:** 0938-AK31

**1103. ELIMINATION OF APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2086-P)**

**Timetable:**

Action	Date	FR Cite
Duplicate of RIN 0938-AK22	02/13/01	

**RIN:** 0938-AK32

## HHS—HCFA

## Completed Actions

**1104. CONFORMING REGULATIONS CHANGES AND STATUTORY REVISIONS FOR APPROVAL AND OVERSIGHT OF ACCREDITATION ORGANIZATIONS (HCFA-2088-P)****Priority:** Other Significant**CFR Citation:** 42 CFR 488.1; 42 CFR 488.5; 42 CFR 488.6; 42 CFR 488.8**Completed:**

Reason	Date	FR Cite
Withdrawn-Under review	02/22/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** Undetermined**Agency Contact:** Joan C. Berry  
Phone: 410 786-7233  
Email: jberry@hcfa.gov**RIN:** 0938-AK36**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)  
Administration for Children and Families (ACF)**

## Proposed Rule Stage

**1105. PROGRAM PERFORMANCE STANDARDS FOR THE OPERATION OF HEAD START PROGRAMS****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1304**Legal Deadline:** None**Abstract:** The education component of the Head Start Performance Standards will be revised to ensure the school readiness of children participating in a Head Start program and to assure that Head Start children have certain understandings in the areas of language and numeracy.**Timetable:**

Action	Date	FR Cite
NPRM	10/00/01	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** Governmental Jurisdictions, Organizations**Government Levels Affected:** None**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447  
Phone: 202 205-8569  
Email: dklafehn@acf.dhhs.gov**RIN:** 0970-AB99**CFR Citation:** 45 CFR 303.21**Legal Deadline:** None**Abstract:** The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 made far-reaching amendments to title IV-D of the Social Security Act, which governs the child support enforcement program. The Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997 and the Child Support Performance and Incentive Act of 1998 further amended title IV-D. A significant result of this legislation is an expansion in the scope of information available to State IV-D child support enforcement agencies. The legislation has rendered obsolete or inconsistent several regulations at 45 CFR chapter III, Office of Child Support Enforcement, including the regulations on the Federal Parent Locator Service, the State Parent Locator Services, offset of Federal payments for purposes of collecting child support, and safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State, Local**Agency Contact:** Eileen C. Brooks, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP,370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401-5369  
Email: ebrooks@acf.dhhs.gov**RIN:** 0970-AC01**1107. • DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT****Priority:** Substantive, Nonsignificant**Legal Authority:** PL 106-402**CFR Citation:** Not Yet Determined**Legal Deadline:** NPRM, Statutory, October 30, 2001, Not later than one year from enactment of the Developmental Disabilities and Bill of Rights Act of 2000.**Abstract:** A notice of proposed rulemaking will be published in the Federal Register by October 30, 2001, to amend current regulations and to implement changes made by the Developmental Disabilities Assistance and Bill of Rights Act of 2000.**Timetable:**

Action	Date	FR Cite
NPRM	10/00/01	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** Undetermined**Agency Contact:** Elsbeth Wyatt, Program Specialist, Department of Health and Human Services, Administration for Children and Families, ADD HHH-300F, 370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 690-5841**RIN:** 0970-AC07**1106. SAFEGUARDING CHILD SUPPORT AND EXPANDED FPLS INFORMATION****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 652 to 654; 42 USC 663; 42 USC 653A; 42 USC 654A

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**  
**Administration for Children and Families (ACF)**

Final Rule Stage

**1108. CONSTRUCTION AND MAJOR RENOVATION OF HEAD START AND EARLY HEAD START FACILITIES**
**Priority:** Other Significant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1309**Legal Deadline:** None

**Abstract:** This rule establishes procedures to be used by Head Start and Early Head Start agencies in requesting to use Head Start grant funds to construct or perform major renovation on a Head Start or Early Head Start Facility.

**Timetable:**

Action	Date	FR Cite
NPRM	02/08/99	64 FR 6013
NPRM Comment Period End	04/09/99	
Final Action	06/00/01	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Governmental Jurisdictions, Organizations**Government Levels Affected:** Local, Tribal

**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447  
Phone: 202 205-8569  
Email: dklafehn@acf.dhhs.gov

**RIN:** 0970-AB54
**1109. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES**
**Priority:** Other Significant**Legal Authority:** 42 USC 655(f)**CFR Citation:** 45 CFR 309**Legal Deadline:** None

**Abstract:** This rule specifies how tribes can obtain direct payments from the Department of Health and Human Services for provision of child support enforcement services if they submit a plan meeting the objectives of title IV-D, including establishment of paternity, modification and enforcement of support orders, and location of absent parents.

**Timetable:**

Action	Date	FR Cite
NPRM	08/21/00	65 FR 50800

Action	Date	FR Cite
NPRM Comment Period End	12/19/00	
Final Action	12/00/01	

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

**Agency Contact:** Paige Biava, Division of Policy and Planning, Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401-9386

**RIN:** 0970-AB73
**1110. CHILD SUPPORT ENFORCEMENT PROGRAM OMNIBUS CONFORMING REGULATION**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302**CFR Citation:** 45 CFR 301 to 305**Legal Deadline:** None

**Abstract:** This rule eliminates child support enforcement program regulations rendered obsolete or inconsistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, and its technical amendments, the Balanced Budget Act of 1997, the Adoption and Safe Families Act of 1997, and the Child Support Performance and Incentive Act of 1998.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	02/09/99	64 FR 6237
Final Action	09/00/01	

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

**Agency Contact:** Eileen C. Brooks, Program Specialist, Department of Health and Human Services, Administration for Children and Families, 4th Floor East, OCSE, DPP, 370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401-5369  
Email: ebroads@acf.dhhs.gov

**RIN:** 0970-AB81
**1111. FAMILY CHILD CARE PROGRAM OPTION FOR HEAD START PROGRAMS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1304; 45 CFR 1306**Legal Deadline:** None

**Abstract:** This rule would allow Head Start programs to choose Family Child Care as a Head Start program option.

**Timetable:**

Action	Date	FR Cite
NPRM	08/29/00	65 FR 52394
Final Action	11/00/01	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Governmental Jurisdictions, Organizations**Government Levels Affected:** State, Local, Tribal

**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447  
Phone: 202 205-8569  
Email: dklafehn@acf.dhhs.gov

**RIN:** 0970-AB90
**1112. TECHNICAL REVISION OF HEAD START REGULATIONS TO MAKE THEM CONFORM TO RECENT STATUTORY REVISIONS**
**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 9801 et seq**CFR Citation:** 45 CFR 1301 to 1303; 45 CFR 1308**Legal Deadline:** None

**Abstract:** This rule will correct several Head Start regulations which define Head Start programs as "nonprofit" agencies. Recent statutory changes now allow "for-profit" agencies to receive Head Start grant funds.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	09/00/01	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations**Government Levels Affected:** None

## HHS—ACF

## Final Rule Stage

**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447  
Phone: 202 205-8569  
Email: dklafehn@acf.dhhs.gov

**RIN:** 0970—AC00

### 1113. ● HIGH PERFORMANCE BONUS AWARDS UNDER THE TANF PROGRAM

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 401 et seq

**CFR Citation:** 45 CFR 270

**Legal Deadline:** None

**Abstract:** This interim final regulation specifies how we will compute scores and rank States on the affordability and quality components of the child care measure for awarding high performance bonuses to States in FY 2002 and FY 2003 under the Temporary Assistance for Needy Families (TANF) program.

#### Timetable:

Action	Date	FR Cite
Interim Final Rule	04/00/01	

#### Regulatory Flexibility Analysis

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Stephanie Fanjul, Deputy Associate Commissioner for Child Care, Department of Health and Human Services, Administration for Children and Families, Room 2046, 330 C Street SW., Washington, DC 20201  
Phone: 202 690-6782  
Email: sfanjul@acf.dhhs.gov

**RIN:** 0970—AC06

### 1114. ● INDIVIDUAL DEVELOPMENT ACCOUNTS

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 105-285

**CFR Citation:** 45 CFR 1000

**Legal Deadline:** None

**Abstract:** This final rule implements a statutory requirement in the Assets for

Independence Act under title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, requiring the Secretary of HHS to prescribe regulation that grantees must follow in accounting for amounts grantees deposit in reserve funds established under the Assets for Independence Program.

#### Timetable:

Action	Date	FR Cite
Interim Final Rule	02/25/00	65 FR 10027
Final Action	04/00/01	

#### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Sheldon Shalit, Office of Community Services, Department of Health and Human Services, Administration for Children and Families, OCS, 5th Floor West, 370 L'Enfant Promenade SW., Washington, DC 20447  
Phone: 202 401-4807

**RIN:** 0970—AC08

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Administration for Children and Families (ACF)

## Completed Actions

### 1115. STANDARDS FOR SAFE TRANSPORTATION

**Priority:** Other Significant

**CFR Citation:** 45 CFR 1310

#### Completed:

Reason	Date	FR Cite
Final Action	01/18/01	66 FR 5295

#### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** Local, Tribal

**Agency Contact:** Douglas Klafehn  
Phone: 202 205-8569  
Email: dklafehn@acf.dhhs.gov

**RIN:** 0970—AB24

### 1116. INCENTIVE PAYMENTS AND AUDIT PENALTIES TO STATES AND POLITICAL SUBDIVISIONS

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 45 CFR 305; 45 CFR 302.55; 45 CFR 304.12

#### Completed:

Reason	Date	FR Cite
Final Action	12/27/00	65 FR 82177

#### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** State

**Agency Contact:** Joyce Pitts  
Phone: 202 401-5374  
Email: jpitts@acf.dhhs.gov

**RIN:** 0970—AB85

### 1117. STATE SELF-ASSESSMENTS TO DETERMINE COMPLIANCE WITH FEDERAL REGULATIONS

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 45 CFR 308

#### Completed:

Reason	Date	FR Cite
Final Action	12/12/00	65 FR 77742

#### Regulatory Flexibility Analysis

**Required:** No

**Government Levels Affected:** State

**Agency Contact:** Jan Rothstein

Phone: 202 401-5073  
Email: jrothstein@acf.dhhs.gov

**RIN:** 0970—AB96

### 1118. NATIONAL MEDICAL SUPPORT NOTICE

**Priority:** Substantive, Nonsignificant

**CFR Citation:** 45 CFR 303.32

#### Completed:

Reason	Date	FR Cite
Final Action	12/27/00	65 FR 82154
60-Day Delay of Effective Date To	01/26/01	66 FR 8073
	03/27/2001	

#### Regulatory Flexibility Analysis

**Required:** No

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

**Agency Contact:** Elizabeth Matheson  
Phone: 202 401-9386  
Email: bmatheson@acf.dhhs.gov

John Seneta  
Phone: 202 401-5154

HHS—ACF

Completed Actions

Email: jseneta@acf.dhhs.gov

RIN: 0970—AB97

**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)  
Administration on Aging (AOA)**

Proposed Rule Stage

**1119. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, INTRASTATE FUNDING FORMULAS; TRAINING, RESEARCH AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; AND GRANTS TO INDIANS AND NATIVE HAWAIIANS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 3001 et seq

**CFR Citation:** 45 CFR 1321; 45 CFR 1326 to 1328

**Legal Deadline:** None

**Abstract:** In response to the recent reauthorization of the Older Americans Act, Public Law 106-501, the Administration on Aging (AoA) proposes to promulgate rules implementing the 2000 amendments by the latter part of 2001.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis**

**Required:** Yes

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

**Government Levels Affected:** State, Tribal

**Federalism:** Undetermined

**Agency Contact:** Edwin Walker, Director, Office of Program Operations and Development, Department of Health and Human Services, Administration on Aging, Room 4733, 330 Independence Avenue SW., Cohen Building, Washington, DC 20201  
Phone: 202 619-0011

**RIN:** 0985—AA00

**1120. • GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, FAMILY CAREGIVERS, AMERICAN INDIANS, AND NATIVE HAWAIIANS (SECTION 610 REVIEW)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 106-501

**CFR Citation:** 42 CFR 1321; 42 CFR 1322; 42 CFR 1326; 42 CFR 1328

**Legal Deadline:** NPRM, Statutory, December 31, 2001.

**Abstract:** In response to the recent reauthorization of the Older Americans Act (Pub. L. 106-501), the Assistant Secretary shall consult and coordinate with State agencies, area agencies on aging, and recipients of grants under title VI in the development of Federal regulations under this Act. Those

provisions of the Act that were not changed may need no further regulations after consultation with affected parties, and the extent of regulation development required for the new family caregivers program will, in major part, depend on the Assistant Secretary's consultation with those parties funded to carry out the new program.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/01	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** None

**Agency Contact:** Edwin Walker, Director, Office of Program Operations and Development, Department of Health and Human Services, Administration on Aging, Room 4733, 330 Independence Avenue SW., Cohen Building, Washington, DC 20201  
Phone: 202 619-0011

**RIN:** 0985—AA01

[FR Doc. 01-6922 Filed 05-11-01; 8:45 am]

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