



# Federal Register

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Monday,  
May 13, 2002

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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; Subtitle B, Chs. II, III, and XIII**

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

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

**ACTION:** Semiannual agenda.

**SUMMARY:** The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the semiannual publication of an inventory of all rulemakings that will be under development or review during the ensuing 12-month period. The purpose of this effort is to encourage more effective public participation in the regulatory process by publicly providing, at an early stage, information about regulatory actions that the Department is working on. All interested members of the public are thus invited to communicate to the Department their views on the rulemakings prospectively outlined below.

**FOR FURTHER INFORMATION CONTACT:** Ann Stallion, Department of Health and Human Services, Washington, DC 20201, (202) 690-7449, or the contact person for a specific component of the Department as listed below.

**SUPPLEMENTARY INFORMATION:** The regulatory actions capsulized below

reflect an effort to present for public scrutiny a realistic forecast of the rulemaking activities that the Department will engage in over the next 12 months. Comments on the policy directions that these rulemakings will take should be sent to the agency representatives listed below, depending on the HHS component and the specific agenda entry that is of interest. Comments may be directed to the Office of the Secretary, if the responsible component of the Department is not apparent, or if a comment covers subjects crossing program lines.

Administration on Aging: Harry Posman, Executive Secretariat, Room 4741, 330 Independence Avenue SW., Washington, DC 20201; Phone (202) 260-0669.

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.

Agency for Health Care Policy and Research: Phyllis Zucker, 2101 East Jefferson Street, Suite 603, Rockville, MD; 20852; Phone (301) 594-1455.

Centers for Disease Control and Prevention: Verla Neslund, Director, Executive Secretariat, 1600 Clifton Road, Building 16, Atlanta, GA 30333; Phone (404) 639-7120.

Centers for Medicare & Medicaid Services: Michelle Shorrt, Director, Division of Regulations and Issuances, 7500 Security Boulevard, C4-26-05, Baltimore, MD 21244; Phone (410) 786-4675.

Food and Drug Administration: Ed Dutra, Director, Regulatory Policy and Management Staff, 5600 Fishers Lane, Rockville, MD 20857; Phone (301) 827-3480.

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

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

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

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; Phone (202) 690-7699.

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

We have indicated as "withdrawn" numerous rulemakings mentioned in previous agendas because we do not plan any developmental work on them during the period covered by this agenda. Should work on these rulemakings begin again, appropriate new entries about them will appear in future agendas.

**Dated:** April 25, 2002.

**Ann C. Agnew,**  
*Executive Secretary to the Department.*

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

Sequence Number	Title	Regulation Identification Number
712	Safe Harbor for Arrangements Involving Federally Qualified Health Centers .....	0991-AB06
713	Implementing the Bioterrorism Prevention and Response Act of 2001 .....	0991-AB15

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

Sequence Number	Title	Regulation Identification Number
714	Shared Risk Exception to the Safe Harbor Provisions .....	0991-AA91
715	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

## HHS

## Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
716	Revisions to 42 CFR Part 1003 .....	0991-AB03
717	Civil Money Penalty Safe Harbor To Protect Payment of Medicare and Medigap Premiums for ESRD Beneficiaries .....	0991-AB04
718	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants) .....	0991-AB12
719	Modifications to Standards for Privacy of Individually Identifiable Health Information .....	0991-AB14

## Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
720	Safe Harbor for Ambulance Restocking .....	0991-AB05
721	Revisions and Technical Corrections to 42 CFR Chapter V .....	0991-AB09

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

Sequence Number	Title	Regulation Identification Number
722	Seclusion and Restraint for Non-Medical Residential Facilities .....	0930-AA10

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

Sequence Number	Title	Regulation Identification Number
723	Community Mental Health Services Block Grant .....	0930-AA08
724	Substance Abuse and Mental Health Services Administration Mental Health and Substance Abuse Emergency Response Criteria .....	0930-AA09

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

Sequence Number	Title	Regulation Identification Number
725	Control of Communicable Diseases .....	0920-AA03
726	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices .....	0920-AA04

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

Sequence Number	Title	Regulation Identification Number
727	Methods for Estimating Radiation Dose and Guidelines for Assessing Probability of Cancer for Energy Employees Occupational Illness Compensation Program .....	0920-AA05

HHS

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
728	DHHS Statement of Policy—Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employee Occupational Illness Compensation Act of 2000 .....	0920-AA07

Centers for Disease Control and Prevention—Completed Actions

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

Departmental Management—Proposed Rule Stage

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

Departmental Management—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
731	Administrative Wage Garnishment .....	0990-AA05

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
732	Requirements for Submission of In Vivo Bioequivalence Data .....	0910-AC23

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
733	Over-the-Counter (OTC) Drug Review .....	0910-AA01
734	Establishment Registration and Product Listing for Drugs and Biologics .....	0910-AA49
735	Investigational New Drugs: Export Requirements for Unapproved New Drug Products .....	0910-AA61
736	Safety Reporting Requirements for Human Drug and Biological Products .....	0910-AA97
737	Blood Initiative .....	0910-AB26
738	Applications for FDA Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications .....	0910-AB34
739	Current Good Manufacturing Practice for Medicated Feeds .....	0910-AB70
740	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements .....	0910-AB88
741	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format .....	0910-AB91
742	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food .....	0910-AB96
743	Status Reports of Distribution and Use Information for Antimicrobial Animal Drug Products Used in Food-Producing Animals .....	0910-AC04
744	Control of Salmonella Enteritidis in Shell Eggs During Production and Retail .....	0910-AC14
745	Institutional Review Boards: Registration Requirements .....	0910-AC17
746	Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition .....	0910-AC18
747	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products .....	0910-AC19

## HHS

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

Sequence Number	Title	Regulation Identification Number
748	Postmarketing Reports of Substandard or Ineffective Bulk Ingredients and Bulk Ingredients From Unapproved Sources .....	0910-AC20
749	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations ....	0910-AC21
750	Exception From General Requirements for Informed Consent; Request for Comments and Information .....	0910-AC25
751	Bar Code Label Requirements for Human Drug Products .....	0910-AC26
752	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen .....	0910-AC30
753	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration .....	0910-AC32
754	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components .....	0910-AC34

## Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
755	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients .....	0910-AA89
756	Labeling for Human Prescription Drugs; Revised Format .....	0910-AA94
757	Use of Ozone-Depleting Substances .....	0910-AA99
758	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
759	Revisions to the General Safety Requirements for Biological Products; Final Rule .....	0910-AB51
760	Supplements and Other Changes to an Approved Application .....	0910-AB61
761	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims .....	0910-AB66
762	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
763	Antibiotic Resistance Labeling .....	0910-AB78
764	Food Additives: Food Contact Substances Notification System .....	0910-AB94
765	Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission into the United States .....	0910-AB95
766	Efficacy Evidence Needed for Products To Be Used Against Toxic Substances When Human Studies Are Unethical .....	0910-AC05
767	Additional Safeguards for Children in Clinical Investigations of FDA Regulated Products .....	0910-AC07
768	Revocation of Conditions for Marketing Digoxin Products for Oral Use .....	0910-AC12
769	Postmarket Surveillance .....	0910-AC31
770	Redacting 510(k) Submissions .....	0910-AC33
771	Section 17 Best Pharmaceuticals for Children Act .....	0910-AC35

## Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
772	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports .....	0910-AA04
773	Investigational Use New Animal Drug Regulations ( <b>Section 610 Review</b> ) .....	0910-AB02
774	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) ...	0910-AB27
775	Current Good Tissue Practice for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) .....	0910-AB28
776	Premarket Notice Concerning Bioengineered Foods .....	0910-AC15

## Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
777	Exports; Notification and Recordkeeping Requirements .....	0910-AB16

## HHS

## Food and Drug Administration—Completed Actions (Continued)

Sequence Number	Title	Regulation Identification Number
778	Foreign Establishment Registration and Listing .....	0910-AB21
779	Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs .....	0910-AB39
780	State Certification of Mammography Facilities .....	0910-AB98
781	Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded .....	0910-AC22

## Food and Drug Administration—Discontinued Entries

Regulation Identification Number	Title	Date With-drawn	Comments
0910-AA02	New Animal Drug Approval Process; Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	03/20/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA19	Food Labeling Review	03/05/2002	Withdrawn
0910-AA20	Medical Foods	03/05/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA45	Current Good Manufacturing Practice; Amendment of Certain Requirements for Finished Pharmaceuticals	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA51	Bioavailability and Bioequivalence Requirements	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA86	Safety Reporting and Recordkeeping Requirements for Marketed OTC Drugs	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA90	Direct-to-Consumer Promotion Regulations	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AA98	Current Good Manufacturing Practice; Revision of Certain Labeling Controls	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB00	Radioactive Drugs for Basic Research	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB14	Administrative Practices and Procedures; Advisory Opinions and Guidelines	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB33	Antibiotic Drug Approval and Exclusivity	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB37	Expanded Access to Investigational Therapies	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB42	Electronic Submission of Postmarketing Safety Reports	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB43	Distinguishing Marks for Drug Products Containing Insulin	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB44	Pregnancy Labeling	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB49	Supplements and Other Changes to Approved New Animal Drug Applications	03/05/2002	Withdrawn
0910-AB50	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	03/05/2002	Withdrawn

## HHS

## Food and Drug Administration—Discontinued Entries (Continued)

Regulation Identification Number	Title	Date With-drawn	Comments
0910-AB56	Natural Rubber-Containing Drugs; User Labeling	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB57	Bulk Drug Substances for Use in Pharmacy Compounding	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB58	Pharmacy and Physician Compounding of Drug Products	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB59	Drug Products That Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB60	Discontinuation of a Lifesaving Product	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB63	Positron Emission Tomography Drugs; Current Good Manufacturing Practice	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB68	Presubmission Conferences	03/05/2002	Withdrawn
0910-AB71	Implementation of the Import Tolerance Provisions of the Animal Drug Availability Act of 1996	03/05/2002	Withdrawn
0910-AB72	Mandatory HACCP Regulations for Manufacturers of Rendered Products	03/05/2002	Withdrawn
0910-AB73	Citizen Petitions; Actions That Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action	03/05/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB74	Surgeon's and Patient Examination Gloves; Reclassification	03/13/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB79	Fixed-Combination Prescription and Over-the-Counter Drugs for Human Use	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB80	180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications	03/06/2002	Withdrawn
0910-AB81	Repackaging Approval Requirements	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB82	Stability Testing of Drugs	03/06/2002	Withdrawn
0910-AB90	Substances Prohibited From Use in Animal Food or Feed	03/05/2002	Withdrawn
0910-AB92	Fees Relating to Drugs; Waiver and Reduction of Fees	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB93	Periodic Testing for Certain Human Drug, Veterinary Drug, and Biological Product Final Specifications	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AB99	Medical Devices, Medical Device Establishment Registration and Listing Requirements; Amendment	03/13/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC00	Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Gene Therapy or Xenotransplantation	03/05/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC01	Addition to the List of Drug Products That Have Been Withdrawn From the Market for Reasons of Safety or Effectiveness	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC02	Reporting Information Regarding Falsification of Data	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC03	Examination of Administrative Record and Other Advisory Committee Records	03/06/2002	Withdrawn - Publication is not projected in the next 12 months

HHS

Food and Drug Administration—Discontinued Entries (Continued)

Regulation Identification Number	Title	Date With-drawn	Comments
0910-AC08	Addition to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC09	Labeling Dietary Supplements for Women Who Are or May Become Pregnant	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC10	Overwrap for Inhalation Products Packaged in Low Density Polyethylene (LDPE) Containers	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC11	Implementing Court Decisions, ANDA Approvals, and 180-Day Exclusivity	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC13	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of "No Residue"	03/20/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC16	Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures	03/05/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC24	Requirements for Medical Gas Containers and Closure Systems	03/06/2002	Withdrawn - Publication is not projected in the next 12 months
0910-AC27	Promotion and Charging For Investigational Drugs	03/06/2002	Withdrawn - Publication is not projected in the next 12 months

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
782	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements .....	0906-AA41
783	Designation of Medically Underserved Populations and Health Professional Shortage Areas .....	0906-AA44
784	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions .....	0906-AA57

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
785	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table .....	0906-AA55

Health Resources and Services Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
786	National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table .....	0906-AA58
787	Adoption of the Interim Final Rule as a Final Rule With Amendments for Ricky Ray Hemophilia .....	0906-AA59

**HHS**

## Indian Health Service—Proposed Rule Stage

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

## Indian Health Service—Final Rule Stage

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

## National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
790	Undergraduate Scholarship Program Regarding Professions Needed by the NIH .....	0925-AA10
791	National Institutes of Health Loan Repayment Program for Research .....	0925-AA18
792	NIH Center Grants .....	0925-AA24
793	NIH Training Grants .....	0925-AA28

## National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
794	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects .....	0925-AA20

## National Institutes of Health—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
795	Standards for a National Chimpanzee Sanctuary System .....	0925-AA31

## National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identification Number
796	National Institutes of Health AIDS Research Loan Repayment Program .....	0925-AA02
797	National Cancer Institute Clinical Cancer Education Program .....	0925-AA17
798	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program .....	0925-AA19
799	National Institutes of Health Clinics Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds .....	0925-AA25
800	NIH Loan Repayment Program for Minority Health Disparities Research .....	0925-AA26
801	Pediatric Research Loan Repayment Program .....	0925-AA27
802	National Institutes of Health Loan Repayment Program for Clinical Researchers .....	0925-AA30

## HHS

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

Sequence Number	Title	Regulation Identification Number
803	Public Health Services Policies on Research Misconduct .....	0940-AA04

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

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

## Office of Public Health and Science—Completed Actions

Sequence Number	Title	Regulation Identification Number
805	Federal Policy (Common Rule) for the Protection of Human Subjects .....	0940-AA03
806	Protection of Human Research Subjects .....	0940-AA05

## Centers for Medicare &amp; Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
807	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-P) .....	0938-AH73
808	National Standard for Identifiers of Health Plans (CMS-1212-P) .....	0938-AH87
809	Medicare Hospice Care Amendments (CMS-1022-P) .....	0938-AJ36
810	End-Stage Renal Disease Bad Debt Payment (CMS-1126-P) .....	0938-AK02
811	Conditions of Participation of Intermediate Care Facilities for Persons With Mental Retardation (CMS-3046-P) .....	0938-AK23
812	Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-P) .....	0938-AK60
813	Revised Process for Making Medicare Coverage Determinations (NCDs) (CMS-3062-N) .....	0938-AK61
814	Health Insurance Reform: Claims Attachments Standards (CMS-0050-P) .....	0938-AK62
815	Health Insurance Reform: Modifications to Standards for Electronic Transactions (CMS-0003-P) .....	0938-AK64
816	Rate of Reimbursement of Photocopy Expenses for Prospective Payment System Providers (CMS-3055-P) .....	0938-AK68
817	Modifications to Medicare Managed Care Rules (CMS-4041-P) .....	0938-AK71
818	Revisions to Transaction and Code Set Standards for Electronic Transactions (CMS-0005-P) .....	0938-AK76
819	Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS-1185-P) .....	0938-AK79
820	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates (CMS-1206-P) .....	0938-AL19
821	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2003 (CMS-1202-P) .....	0938-AL20
822	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 (CMS-1204-P) .....	0938-AL21
823	Hospital Inpatient Rehabilitation Prospective Payment System for FY 2003 (CMS-1205-N) .....	0938-AL22
824	Hospital Inpatient Prospective Payment System for FY 2003 (CMS-1203-P) .....	0938-AL23
825	Payment for Respiratory Assist Devices with Bi-Level Capability and a Back-Up Rate (CMS-1167-P) .....	0938-AL27
826	Self-Declaration of Citizenship (CMS-2085-P) .....	0938-AL33
827	Hospice Wage Index for FY 2003 (CMS-1211-N) .....	0938-AL41
828	Electronic Submission of Cost Reports (CMS-1199-P) .....	0938-AL51
829	Health Insurance Reform: National Standard for Identifiers of Health Plans (CMS-1212-F) .....	0938-AL52
830	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P) .....	0938-AL53
831	Effect of Change of Ownership on Provider and Supplier Penalties (CMS-2215-P) .....	0938-AL72
832	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P) .....	0938-AL88
833	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS-1471-P) .....	0938-AL91

## HHS

## Centers for Medicare &amp; Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
834	Security Standards (CMS-0049-F) .....	0938-AI57
835	National Standard Employer Identifier (CMS-0047-F) .....	0938-AI59
836	External Quality Review of Medicaid Managed Care Organizations (CMS-2015-F) .....	0938-AJ06
837	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions, and Establishment of a Quality Assessment and Improvement Program (CMS-1910-F) .....	0938-AJ17
838	Hospital Conditions of Participation: Laboratory Services (CMS-3014-F) .....	0938-AJ29
839	Non-Federal Governmental Plans Exempt From Health Insurance Portability Requirements (CMS-2033-IFC) .....	0938-AK00
840	Fire Safety Requirements for RNHCI, ASC, Hospices, PACE, Hospitals, and Long-Term Care Facilities and ICFs for the Mentally Retarded (CMS-3047-P) .....	0938-AK35
841	Hospital Conditions of Participation: Quality Assessment and Performance Improvements (CMS-3050-F) .....	0938-AK40
842	Supplementary Medical Insurance Premium Surcharge Agreements (CMS-4007-F) .....	0938-AK42
843	Payment for Upgraded Durable Medical Equipment; Withdrawal of Proposed Rule (CMS-1084-WN) .....	0938-AK50
844	Prospective Payment System for Long-Term Care Hospitals for FY 2003 (CMS-1177-P) .....	0938-AK69
845	Medicare Inpatient Disproportionate Share Hospital (DSH) Adjustment Formula (CMS-1171-IFC) .....	0938-AK77
846	State Allotments for Payment of Medicare Part B Premiums for Qualified Individuals; Federal Fiscal Year 2001 (CMS-2087-PN) .....	0938-AK91
847	Medicaid Managed Care; New Provisions (CMS-2104-F) .....	0938-AK96
848	Modifications to the State Children's Health Insurance Program (CMS-2006-F) .....	0938-AL00
849	Home Health Prospective Payment System Rate Update for FY 2003 (CMS-1198-NC) .....	0938-AL16
850	Medicare Program; Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative (CMS-4027-P) .....	0938-AL28
851	Peer Review Organizations: Name and Other Changes—Technical Amendments (CMS-3088-FC) .....	0938-AL38
852	End-Stage Renal Disease—Rescission of Waiver of Conditions for Coverage Under a State of Emergency in Houston, Texas Area (CMS-3074-F2) .....	0938-AL39
853	Prospective Payment System for Inpatient Rehabilitation Hospital; Correcting Amendment (CMS-1069-F2) .....	0938-AL40
854	Physician Fee Schedule for CY 2002: Correction Notice (CMS-1169-CN) .....	0938-AL48
855	Notice of Modification of Beneficiary Assessment Requirements for Skilled Nursing Facilities (CMS-1209-N) .....	0938-AL55
856	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2003 (CMS-8013-N) .....	0938-AL56
857	Revision of the Procedures for Requesting Exceptions to Cost Limits for Skilled Nursing Facilities and Elimination of Reclassifications; Correction (CMS-1883-F3) .....	0938-AL61
858	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2003 (CMS-8014-N) .....	0938-AL63
859	Request for Information on Benefit-Specific Waiting Periods (CMS-2150-N) .....	0938-AL64
860	Part A Premiums for 2003 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8015-N) .....	0938-AL69
861	Medicaid Managed Care: Withdrawal (CMS-2001-F4) .....	0938-AL83
862	FY 1999 SCHIP Reallocation Notice (CMS-2137-N) .....	0938-AL86

## Centers for Medicare &amp; Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identification Number
863	"Without Fault" and Beneficiary Waiver of Recovery As It Applies to Medicare Overpayment Liability (CMS-6007-F) .....	0938-AD95
864	Revision of Medicare/Medicaid Hospital Conditions of Participation (CMS-3745-F) .....	0938-AG79
865	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-FC) .....	0938-AG81
866	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) ( <b>Section 610 Review</b> ) .....	0938-AG82
867	Criteria for Approval of Facilities to Perform Covered Heart, Liver, Lung, Pancreas, and Intestinal Transplants (CMS-3835-P) .....	0938-AH17
868	Hospice Care—Conditions of Participation (CMS-3844-P) .....	0938-AH27
869	Medicare and Medicaid Programs; Terms, Definitions, and Addresses: Technical Amendments (CMS-9877-F) .....	0938-AH53
870	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F) .....	0938-AH99
871	Medical Child Support and Health Insurance Coverage of Dependent Children (CMS-2081-P) .....	0938-AI21
872	Appeals of Carrier Determination That a Supplier Fails To Meet the Requirements for Medicare Billing Privileges (CMS-6003-F) .....	0938-AI49
873	Coverage of Religious Non-Medical Health Care Institutions (CMS-1909-F) .....	0938-AI93

## HHS

## Centers for Medicare &amp; Medicaid Services—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identification Number
874	Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (CMS-3006-F) .....	0938-AJ10
875	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F) .....	0938-AJ96
876	Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services) (CMS-1908-F) .....	0938-AJ97
877	Supplier Standards for Home Oxygen, Therapeutic Shoes, Home Nutrition Therapy, and Consignment Closets (CMS-6010-P) .....	0938-AJ98
878	Clinical Lab Requirements—Revisions to Regulations Implementing CLIA (CMS-2226-F) .....	0938-AK24
879	Improvements to the Medicare+Choice Appeals and Grievance Procedures (CMS-4024-F) .....	0938-AK48
880	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-FC) .....	0938-AK67
881	Organ Procurement Organization Condition for Coverage (CMS-3064-IFC) .....	0938-AK81
882	Modifications to Managed Care Rules Based on Payment Provisions in BIPA and Technical Corrections (CMS-4040-F) .....	0938-AK90
883	Extending Medicare Entitlement When Disability Benefit Entitlement Ends Because of Substantial Gainful Activity (CMS-4018-P) .....	0938-AK94
884	Medicare Limits on the Valuation of a Depreciable Asset Recognized as an Allowance for Depreciation and Interest on Capital Indebtedness After a Change of Ownership (CMS-1004-F) .....	0938-AL12
885	Update Interest Assessment on Medicare Overpayment and Underpayment (CMS-6014-P) .....	0938-AL14
886	Requirements for Paid Feeding Assistants in Long-Term Care Facilities (CMS-2131-P) .....	0938-AL18
887	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities that Provide Inpatient or Residential Care (CMS-2130-P) .....	0938-AL26
888	Medicare-Endorsed Prescription Drug Discount Card Assistance Initiative for State Sponsors (CMS-4032-P) .....	0938-AL30
889	State Children's Health Insurance Program; Eligibility for Unborn Children (CMS-2127-F) .....	0938-AL37
890	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F) .....	0938-AL43
891	Interim Final Amendment for Mental Health Parity (CMS-2152-IFC) .....	0938-AL44
892	Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS-1208-P) .....	0938-AL49
893	Prospective Payment System for Psychiatric Hospitals (CMS-1213-P) .....	0938-AL50
894	Provider Reimbursement Determinations and Appeals (CMS-1727-P) .....	0938-AL54
895	Definition of Severe Medically Determinable Impairment (CMS-2143-P) .....	0938-AL57
896	Program for All-Inclusive Care for the Elderly (PACE): Program Revisions (CMS-1201-IFC) .....	0938-AL59
897	SCHIP; Purchase of Family Coverage—Benefit Flexibility in Parent Coverage (CMS-2148-P) .....	0938-AL62
898	Revisions to Medicaid Cost-Sharing Regulations (CMS-2144-P) .....	0938-AL66
899	Revisions to the Medicare Appeals Process (CMS-4004-P) .....	0938-AL67
900	Notice of Intent to Conduct Negotiated Rulemaking for Special Payment Provisions and Standards for Suppliers of Custom-Fabricated Orthotics and Prosthetics (CMS-6012-N) .....	0938-AL68
901	DMERC Service Areas and Related Matters (CMS-1219-P) .....	0938-AL76
902	State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals; Federal Fiscal Year 2002 (CMS-2136-PN) .....	0938-AL79
903	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P) .....	0938-AL80
904	Flexibility in Payment Methods for Services of Hospitals, Nursing Facilities, and Intermediate Care Facilities for the Mentally Retarded (CMS-2004-F) .....	0938-AL81
905	Continue to Allow States an Option Under the Medicaid Spousal Impoverishment Provisions to Increase the Community Spouse's Income When Adjusting the Protected Resource Allowance (CMS-2128-F) .....	0938-AL84
906	Medicaid Coverage Rules for Inmates of Public Institutions (CMS-2077-P) .....	0938-AL85
907	Targeted Case Management (CMS-2061-P) .....	0938-AL87
908	Changes to the Hospital Inpatient Prospective Payment System and FY 2004 Rates (CMS-1470-P) .....	0938-AL89
909	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2004 (CMS-1469-P) .....	0938-AL90
910	Prospective Payment System for Long-Term Care Hospitals: FY 2004 (CMS-1472-P) .....	0938-AL92
911	Prospective Payment System for Psychiatric Hospitals (CMS-1477-P) .....	0938-AL93
912	Home Health Prospective Payment System Rate Update for FY 2004 (CMS-1473-NC) .....	0938-AL94
913	Prospective Payment System for Inpatient Rehabilitation Hospitals (CMS-1474-P) .....	0938-AL95
914	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2004 (CMS-1476-P) .....	0938-AL96

## HHS

## Centers for Medicare &amp; Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identification Number
915	Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests (CMS-3250-F) ...	0938-AI92
916	Fee Schedule for Payment of Ambulance Services and Revisions to the Physician's Certification Requirements for Coverage of Nonemergency Ambulance Services (CMS-1002-FC) .....	0938-AK30
917	Medicare Program; Reporting and Repayment of Overpayments (CMS-6011-P) .....	0938-AK45
918	Prospective Payment System for Hospital Outpatient Services: Criteria for Establishing New Pass-Through Categories for Medical Devices (CMS-1179-IFC) .....	0938-AK59
919	Qualification Requirements for Directors of Laboratories Performing High Complexity Testing (CMS-2094-P) .....	0938-AK83
920	Medicaid Upper Payment Limit for Non-State Government-Owned or -Operated Hospitals (CMS-2134-F) .....	0938-AL05
921	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Delay of Effective Date of the "Set in Advance" Provision (CMS-1809-IFC) .....	0938-AL29
922	Deductible Amount for Medigap High Deductible Options for Calendar Year 2002 (CMS-2135-N) .....	0938-AL34
923	Prospective Payment System for Hospital Outpatient Services; Delay in Effective Date of Calendar Year 2002 Payment Rates and the Pro Rata Reduction on Transitional Pass-Through Payment (CMS-1159-F3) .....	0938-AL35
924	Disapproval of Alcon Laboratories Request for an Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers (CMS-3061-FN) .....	0938-AL36
925	Correction of Certain Calendar Year 2003 Payment Rates Under the Hospital Outpatient Prospective Payment System and the Pro Rata Reduction on Transitional Pass-Through Payment (CMS-1159-F4) .....	0938-AL42
926	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Correction Notice (CMS-1163-CN) .....	0938-AL47

## Centers for Medicare &amp; Medicaid Services—Discontinued Entries

Regulation Identification Number	Title	Date Withdrawn	Comments
0938-AH81	Update of Ratesetting Methodology, Payment Rates and the List of Covered Surgical Procedures for Ambulatory Surgical Centers (CMS-1885-FC)	03/03/2002	Withdrawn
0938-AI48	Surety Bond Requirements for Comprehensive Outpatient Rehabilitation Facilities, Rehabilitation Agencies (CMS-6005-P)	03/06/2002	Withdrawn
0938-AI75	Advance Refunding of Debt and Methodology for Repayment of Loan (CMS-1777-P)	03/20/2002	Withdrawn
0938-AI89	Medicare Coverage of, and Payment for, Bone Mass Measurements (CMS-3004-F)	03/06/2002	Withdrawn
0938-AJ39	Emergency Medical Treatment and Labor Act (EMTALA) (CMS-1063-P)	03/03/2002	Withdrawn
0938-AJ44	Protection for Women Who Elect Reconstruction After a Mastectomy (CMS-2040-IFC)	03/04/2002	Withdrawn
0938-AJ64	Surety Bonds Requirements for Suppliers of Durable Medical Equipment (CMS-6006-P)	03/14/2002	Withdrawn
0938-AJ81	Surety Bond Requirements for Home Health Agencies (HHAS) (CMS-6001-P)	03/14/2002	Withdrawn
0938-AK15	Payment for Clinical Psychology Training Programs (CMS-1089-F)	03/03/2002	Withdrawn
0938-AK39	Medicare Provider and Supplier Hearing Procedures (CMS-2093-P)	03/06/2002	Withdrawn
0938-AK43	Medical Devices Coverage Decisions Related to Health Care Technology (CMS-3059-P)	03/20/2002	Withdrawn
0938-AK53	Recognition of the American Osteopathic Association for Ambulatory Surgical Center Programs (CMS-2079-FN)	03/04/2002	Withdrawn
0938-AK63	Health Insurance Reform: Standards for Electronic Signatures (CMS-0051-F)	03/03/2002	Withdrawn
0938-AK87	Hospital Reference Laboratory and Medicare Secondary Payer (CMS-1187-P)	03/03/2002	Withdrawn
0938-AK88	Portability in the Group Health Insurance Market—Shared HHS Provisions (CMS-2048-F)	03/20/2002	Withdrawn
0938-AK92	Extended Medicaid for Certain Families Who Lose Medicaid Eligibility Because of Earned Income and the Residency of Minor Parents and Pregnancy (CMS 2026-F)	03/04/2002	Withdrawn
0938-AK93	Home Health Prospective Payment System Refinements (CMS-1161-P)	03/20/2002	Withdrawn
0938-AK99	Relief From Medicare Part A Late Enrollment Penalty for Group Buy-In for State and Local Retirees (CMS-4022-P)	03/20/2002	Withdrawn

HHS

Centers for Medicare & Medicaid Services—Discontinued Entries (Continued)

Regulation Identification Number	Title	Date With-drawn	Comments
0938-AL06	Continue To Allow States an Option Under the Medicaid Spousal Impoverishment Provisions To Increase the Community Spouse's Income When Adjusting the Protected Resource Allowance (CMS-2128-P)	03/06/2002	Withdrawn
0938-AL45	Requirements for Long-term Care Facilities (CMS-3096-P)	03/06/2002	Withdrawn

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
927	Program Performance Standards for the Operation of Head Start Programs .....	0970-AB99
928	Safeguarding Child Support and Expanded FPLS Information .....	0970-AC01
929	Developmental Disabilities and Bill of Rights Act .....	0970-AC07

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
930	Construction and Major Renovation of Head Start and Early Head Start Facilities .....	0970-AB54
931	Child Support Enforcement for Indian Tribes .....	0970-AB73
932	Child Support Enforcement Program Omnibus Conforming Regulation .....	0970-AB81
933	Family Child Care Program Option for Head Start Programs .....	0970-AB90
934	Technical Revision of Head Start Regulations To Make Them Conform to Recent Statutory Revisions .....	0970-AC00

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identification Number
935	High Performance Bonus Awards Under the TANF Program .....	0970-AC06

Administration on Aging—Proposed Rule Stage

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

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

Proposed Rule Stage

**712. 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:**

Action	Date	FR Cite
NPRM	10/00/02	
NPRM Comment Period End	12/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

## HHS—OS

## Proposed Rule Stage

**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**Related RIN:** Related To 0991-AA91**RIN:** 0991-AB06**713. IMPLEMENTING THE BIOTERRORISM PREVENTION AND RESPONSE ACT OF 2001****Priority:** Other Significant**Legal Authority:** Not Yet Determined**CFR Citation:** None**Legal Deadline:** None**Abstract:** A variety of regulations will be required once the Bioterrorism Prevention and Response Act has been signed into law. These regulations would implement provisions that address, among other things, biological agents that have the potential to pose a national security threat, provisions relating to foods including recordkeeping regarding foods, food-shipment importation procedures and related matters.**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** State, Tribal, Federal**Agency Contact:** Alex Azar, General Counsel, Department of Health and Human Services, Office of the Secretary Phone: 202 690-7741**RIN:** 0991-AB15**Department of Health and Human Services (HHS)  
Office of the Secretary (OS)**

## Final Rule Stage

**714. 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	10/00/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Additional Information:** Interim final regulations were published on November 19, 1999 (64 FR 63504) and are currently in effect. See 42 CFR 1001.952(t) and (u).**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**Related RIN:** Related To 0991-AB06**RIN:** 0991-AA91**715. 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	12/06/00	65 FR 76460
NPRM Comment Period End	01/05/01	
Final Action	08/00/02	
Final Action Effective	09/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations**Government Levels Affected:** State, Local, Federal, Tribal**Agency Contact:** Robinsue Frohboese, Acting Director, Office for Civil Rights, Department of Health and Human Services, Office of the Secretary Phone: 202 619-0403**RIN:** 0991-AB10

**Department of Health and Human Services (HHS)  
Office of the Secretary (OS)**
**Long-Term Actions****716. REVISIONS TO 42 CFR PART 1003****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 revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments, by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; modify the current definition for the term "claim;" update various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems or names through Internet and e-mail communications.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

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

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

**RIN:** 0991-AB03**717. 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:** The proposed final rule would set forth in the OIG's civil money penalty provisions in 42 CFR

part 1003 a new safe harbor for unlawful inducements to beneficiaries to provide protection for independent dialysis facilities that pay, in whole or in part, premiums for Supplementary Medical Insurance (Medicare part B) or Medicare Supplemental Health Insurance policies (Medigap) for financially needy Medicare beneficiaries with end-stage renal disease (ESRD). The safe harbor would specifically establish 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
Final Rule	To Be	Determined

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

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

**RIN:** 0991-AB04**718. 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 12689; EO 12549**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	01/23/02	67 FR 3315
NPRM Comment Period End	03/25/02	
Next Action	Undetermined	

**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: 202 690-5729 Fax: 202 690-6901 Email: diane.osterhus@hhs.gov

**RIN:** 0991-AB12**719. MODIFICATIONS TO STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION****Priority:** Other Significant. Major under 5 USC 801.**Unfunded Mandates:** This action may affect State, local or tribal governments.**Legal Authority:** 42 USC 1320d-2; 42 USC 1320d-3; PL 104-191, sec 262; PL 104-191, sec 264**CFR Citation:** 45 CFR 160; 45 CFR 164**Legal Deadline:** None

**Abstract:** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Department of Health and Human Services (the Department) to issue standards for health plans, health care clearinghouses, and certain health care providers to protect the privacy of individually identifiable health information. The Department published these standards, entitled "Standards for Privacy of Individually Identifiable Health Information" (the Privacy Rule), as a final rule on December 28, 2000. The final rule was effective on April 14, 2001. The proposed rule would amend the Privacy Rule to, among other things, support the delivery of the highest quality of health care to patients and address concerns regarding the workability of the rule for entities subject to its requirements.

## HHS—OS

## Long-Term Actions

## Timetable:

Action	Date	FR Cite
NPRM	03/27/02	67 FR 14775
NPRM Comment Period End	04/26/02	

Next Action Undetermined

## Regulatory Flexibility Analysis

Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal, State, Local, Tribal

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

Agency Contact: Susan McAndrew, Senior Health Information, Policy

Specialist, Department of Health and Human Services, Office of the Secretary, Office for Civil Rights, 200 Independence Avenue SW., Washington, DC 20201  
Phone: 202 205-8725

RIN: 0991-AB14

## Department of Health and Human Services (HHS)

## Office of the Secretary (OS)

## Completed Actions

## 720. SAFE HARBOR FOR AMBULANCE RESTOCKING

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 1001

## Completed:

Reason	Date	FR Cite
Final Action	12/04/01	66 FR 62679

## Regulatory Flexibility Analysis

Required: No

Government Levels Affected: None

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

RIN: 0991-AB05

## 721. REVISIONS AND TECHNICAL CORRECTIONS TO 42 CFR CHAPTER V

Priority: Substantive, Nonsignificant

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

## Completed:

Reason	Date	FR Cite
Final Action	03/18/02	67 FR 11928

## Regulatory Flexibility Analysis

Required: No

Government Levels Affected: Federal

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

RIN: 0991-AB09

## Department of Health and Human Services (HHS)

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

## Long-Term Actions

## 722. SECLUSION AND RESTRAINT FOR NON-MEDICAL RESIDENTIAL FACILITIES

Priority: Substantive, Nonsignificant

Legal Authority: PL 106-310

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, April 2001.

Abstract: The Secretary is required by statute to publish regulations governing States that license non-medical, community-based residential facilities for children and youth. The regulation requires States to develop licensing

rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff and that the States provide training for professional staff.

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

Phone: 301 443-7017

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Email: jfaha@samhsa.gov

RIN: 0930-AA10

## Department of Health and Human Services (HHS)

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

## Completed Actions

## 723. COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 96

## Completed:

Reason	Date	FR Cite
Withdrawn	03/13/02	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Agency Contact: Joseph Denis Faha  
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Fax: 301 443-1450

Email: jfaha@samhsa.gov

RIN: 0930-AA08

## 724. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION MENTAL HEALTH AND SUBSTANCE ABUSE EMERGENCY RESPONSE CRITERIA

Priority: Other Significant

CFR Citation: 42 CFR 51d

**HHS—SAMHSA**

**Completed Actions**

**Completed:**

Reason	Date	FR Cite
Interim Final Rule	10/11/01	66 FR 51873

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Joseph Denis Faha

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 Fax: 301 443-1450  
 Email: jfaha@samhsa.gov  
**RIN:** 0930-AA09

**Department of Health and Human Services (HHS)  
 Centers for Disease Control and Prevention (CDC)**

**Proposed Rule Stage**

**725. CONTROL OF COMMUNICABLE DISEASES**

**Priority:** Other Significant. 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

**Abstract:** This proposal updates existing regulations related to prevention of the introduction, transmission, or spread of communicable diseases from foreign countries to the U.S. and from State to State. The regulation addresses the process by which persons infected with, or who have been exposed to, modern communicable diseases should be quarantined; surveillance of quarantined persons and requirements for carriers (e.g., airlines, etc.) to maintain passenger manifests for a determined period of time.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** State

**Federalism:** Undetermined

**Agency Contact:** John Moore, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Atlanta, GA 30333  
 Phone: 404 639-7070

**RIN:** 0920-AA03

**726. 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 modify 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	12/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**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-AA04

**Department of Health and Human Services (HHS)  
 Centers for Disease Control and Prevention (CDC)**

**Final Rule Stage**

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

**Priority:** Other Significant

**Legal Authority:** 42 USC 73847; EO 13179

**CFR Citation:** 42 CFR 81; 42 CFR 82

**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

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
Final Rule	04/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Larry Elliott, 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-AA05

**Department of Health and Human Services (HHS)**  
**Centers for Disease Control and Prevention (CDC)**
**Long-Term Actions**
**728. • DHHS STATEMENT OF POLICY—PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEE OCCUPATIONAL ILLNESS COMPENSATION ACT OF 2000**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 7384g; EO 13129

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** Pursuant to the Energy Employees Occupational Illness Compensation Program Act, HHS plans to propose procedures to petition the Secretary to be added to the Special Exposure Cohort.

**Timetable:**

Action	Date	FR Cite
Statement of Proposed Procedures	To Be Determined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Larry Elliott, 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-AA07

**Department of Health and Human Services (HHS)**  
**Centers for Disease Control and Prevention (CDC)**
**Completed Actions**
**729. PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 72.6 (Renumbered); 42 CFR 72.7 (Renumbered); 42 CFR 72.1-5 (Revision)

**Completed:**

Reason	Date	FR Cite
Withdrawn	03/21/02	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Jonathan Y. Richmond  
Phone: 404 639-2453

**RIN:** 0920-AA02

**Department of Health and Human Services (HHS)**  
**Departmental Management (HHSDM)**
**Proposed Rule Stage**
**730. IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS**

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 45 CFR 13

**Legal Deadline:** None

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

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

**Timetable:**

Action	Date	FR Cite
NPRM	06/19/87	52 FR 23311
NPRM Comment Period End	08/17/87	
Second NPRM	06/00/02	

**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)**  
**Departmental Management (HHSDM)**
**Final Rule Stage**
**731. ADMINISTRATIVE WAGE GARNISHMENT**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 31 USC 3720D; 28 CFR 285.11

**CFR Citation:** 42 CFR 32

**Legal Deadline:** None

**Abstract:** The Department will add a new part 32 to title 42 of the Code of Federal Regulations (CFR) to implement the Administrative Wage Garnishment provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, codified at 31 U.S.C. 3720D, and implemented by the Department of Treasury at 31 C.F.R. 285.11. The

proposed rule will be another tool for the Department to collect its debts by allowing the Department to garnish the wages of non-Federal employees administratively (i.e., without the need for a court order). The wage withholding order will be required to withhold amounts from an employee's wages and pay those amounts to the

## HHS—HHSDM

## Final Rule Stage

Department in satisfaction of the indebtedness.

**Timetable:**

Action	Date	FR Cite
NPRM	03/13/02	67 FR 11264
NPRM Comment Period End	05/13/02	
Final Rule	06/00/02	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** 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-AA05

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

## Prerule Stage

**732. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA****Priority:** Substantive, Nonsignificant**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a; 21 USC 356b; 21 USC 356c; 21 USC 371; 21 USC 374; 21 USC 379**CFR Citation:** 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1)**Legal Deadline:** None**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application

(ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. FDA is proposing to require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

**Timetable:**

Action	Date	FR Cite
ANPRM	11/00/02	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** Aida L. Sanchez, Special Assistant to the Director, Department of Health and Human Services, Food and Drug Administration, HFD-650, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-5847**RIN:** 0910-AC23

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

## Proposed Rule Stage

**733. OVER-THE-COUNTER (OTC) DRUG REVIEW****Priority:** Routine and Frequent**Legal Authority:** 21 USC 321p; 21 USC 351 to 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 to 345; 21 CFR 330; 21 CFR 333 to 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.

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:****Antidiarrheal Products**

NPRM (Amendment)(Trav. Diar.) 09/00/02  
Final Action 09/00/02

**Antiemetic Products**

Final Action (Amendment) (Warning)  
08/00/02

**Antifungal (Topical) Products**

Final Action Clotrimazole 02/08/02 (67 FR  
5942)

**Antiperspirant Products**

Final Action 04/00/03

**Cough/Cold (Antihistamine) Products**

Final Action (Amendment)(Warning)  
08/00/02

**Cough/Cold (Antitussive) Products**

Final Action (Amendment)(Warning)  
08/00/02

**Cough/Cold (Combination) Products**

Final Action 04/00/03

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

NPRM (Phenylpropanolamine) 10/00/02

**Eligibility Criteria for Additional Conditions**

Final Action 01/23/02 (67 FR 3060)

**External Analgesic Products**

Final Action (Amendment)(Warning)  
08/00/02

**Ingrown Toenail Relief Products**

NPRM 12/00/02

**Internal Analgesic Products**

NPRM (Amendment)(Ibuprofen) 09/00/02  
NPRM (Amendment) (Pediatric) 04/00/03

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

Final Action (Ca/Mg/K/Na) 06/00/02  
Final Action (Sodium Labeling) 06/00/02  
NPRM (Sodium Labeling) 06/00/02  
NPRM (Convenience Sizes) 12/00/02

**Nighttime Sleep Aid Products**

Final Action (Amendment)(Warning)  
08/00/02

**Ophthalmic Products**

NPRM (Emergency First Aid Eyewashes)  
04/00/03

**Oral Health Care Products**

ANPRM (Plaque/Gingivitis) 04/00/03

**Pediculicide Products**

NPRM (Labeling Amendment) 06/00/02

**Salicylate (Reye Syndrome)**

Final Action (Warning) 09/00/02

## HHS—FDA

## Proposed Rule Stage

**Skin Protectant Products**

Final Action 08/00/02  
Final Action (Astringent) 11/00/02  
NPRM (Astringent) 11/00/02

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

Final Action 04/00/02  
Final Action 06/00/02

**Sunscreen Products**

Final Action (Names) 07/00/02  
ANPRM (and Insect Repellent) 10/00/02  
NPRM (UVA/UVB) 04/00/03

**Vaginal Contraceptive Products**

NPRM (Amendment) 12/00/02

**Weight Control Products**

NPRM (Phenylpropanolamine) 10/00/02

**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: 301 827-2241

Fax: 301 827-2315

Email: rachanow@cder.fda.gov

**RIN:** 0910-AA01

**734. ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR DRUGS AND BIOLOGICS**

**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 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262

**CFR Citation:** 21 CFR 201; 21 CFR 207; 21 CFR 314

**Legal Deadline:** None

**Abstract:** The proposed rule would amend FDA regulations on the registration of producers of drugs and the listing of drugs in commercial distribution. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list drug or biological products. The proposal describes when, how, and where to register and list, and what information must be submitted for registration and listing. The proposed regulations would also require the electronic submission of most registration and listing information.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/03	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:** Undetermined

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

Phone: 301 594-2041

Fax: 301 827-5562

**RIN:** 0910-AA49

**735. 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 to 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 changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**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: 301 827-0587

Fax: 301 827-4774

Email: pchao@oc.fda.gov

**RIN:** 0910-AA61

**736. 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 320; 21 CFR 600; 21 CFR 601; 21 CFR 606

**Legal Deadline:** None

**Abstract:** This regulation is one component of the Secretary's initiative to reduce medical errors. The proposed

## HHS—FDA

## Proposed Rule Stage

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 Harmonisation and to define new terms; to possibly add to or revise current reporting requirements; to consider revising certain reporting time frames; and to suggest other revisions to these regulations to enhance the quality of safety reports received by FDA.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

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

**Agency Contact:** Audrey Thomas, Regulatory Policy Analyst, Office of Regulatory Policy, 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-AA97

**737. BLOOD INITIATIVE**

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

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 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 end users of plasma-derivative products of product safety information; and 3) requirements for donor suitability and testing. These actions are intended to help ensure the continued safety of the Nation's blood supply.

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

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

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

NPRM 08/19/99 (64 FR 45355)  
Final Action 06/11/01 (66 FR 31165)

**Plasma Derivatives and Similar Recombinant-Based Products; Reqs. for Notification of Recalls and Withdrawals**

ANPRM 08/19/99 (64 FR 45383)  
NPRM 04/00/03

**Regulations for Human Blood and Blood Components Intended for Transfusion or For Further Manufacturing Use**

NPRM 04/00/03

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

NPRM 08/19/99 (64 FR 45340)  
Final Action 06/11/01 (66 FR 31146)

**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)  
DFR: Confirmation in Part and Tech. Amendment 01/10/01 (66 FR 1834)  
Final Action 08/06/01 (66 FR 40886)

**Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma**

NPRM 04/00/03

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

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

Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448  
Phone: 301 827-6210  
Fax: 301 594-1944

**Related RIN:** Related To 0910-AB76

**RIN:** 0910-AB26

**738. 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 to 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

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

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/03	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Brian L. Pendleton, Regulatory Counsel, Office of Regulatory Policy, 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@cder.fda.gov

**RIN:** 0910-AB34

## HHS—FDA

## Proposed Rule Stage

**739. 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	01/00/03	

**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

**740. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND 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	09/00/02	

**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  
Fax: 202 205-5295

Email: kstrauss@cfsan.fda.gov

**RIN:** 0910-AB88

**741. REQUIREMENTS FOR SUBMISSION OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS IN ELECTRONIC FORMAT**

**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 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e; ...

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

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format in which certain labeling in new drug applications, abbreviated new drug applications, certain biological license applications, supplements, and annual reports is required to be submitted. The proposal would require that certain labeling content described under section 201.160(d)(3) be submitted to FDA in electronic format.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

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

**RIN:** 0910-AB91

**742. 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

## HHS—FDA

## Proposed Rule Stage

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	10/00/02	

**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  
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**RIN:** 0910-AB96

#### 743. STATUS REPORTS OF DISTRIBUTION AND USE INFORMATION FOR ANTIMICROBIAL 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(e); 21 USC 371(a)

**CFR Citation:** 21 CFR 510.300

**Legal Deadline:** None

**Abstract:** After approving a new animal drug application, the Food and Drug Administration (FDA) requires the sponsor to submit adverse experience and use information on the product. 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 assist in 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 to help assess the correlation between resistance in human pathogens and the use of antimicrobial drugs in food-producing animals.

**Timetable:**

Action	Date	FR Cite
NPRM	01/00/03	

**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

#### 744. 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 243; 42 USC 264; 42 USC 271; ...

**CFR Citation:** 21 CFR 16; 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, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (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 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), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), 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 certain retail establishments. In addition, the agency plans to propose specific requirements for certain retail establishments that serve populations

## HHS—FDA

## Proposed Rule Stage

most at-risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/02	

**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, 3B-033/HFS-306, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740  
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**RIN:** 0910-AC14

#### 745. 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 to 353; 21 USC 360c to 360f; 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 name of the institution operating the IRB, and names, addresses, phone numbers, facsimile (fax) numbers, and electronic mail (e-mail) addresses of the senior officer of the 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 IRBs and to convey information to IRBs.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/02	

**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  
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**RIN:** 0910-AC17

#### 746. ALUMINUM IN LARGE- AND SMALL-VOLUME PARENTERALS USED IN TOTAL PARENTERAL NUTRITION

**Priority:** Other Significant

**Legal Authority:** 21 USC 321(n); 21 USC 352; 21 USC 355; 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 no more than 25 ug/L of aluminum to state "contains no more than 25ug/L" rather than the exact amount of aluminum.

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/02	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** None

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

Phone: 301 594-2041

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**RIN:** 0910-AC18

#### 747. USE OF MATERIALS DERIVED FROM BOVINE AND OVINE 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 most materials derived from bovine and ovine 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	03/00/03	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Rebecca Buckner, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, 3B-033/HFS-306, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740  
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**RIN:** 0910-AC19

#### 748. 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 to 353; 21 USC 355; 21 USC 371; 21 USC 374; 21 USC 379e

## HHS—FDA

## Proposed Rule Stage

**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	12/00/02	

**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  
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**RIN:** 0910-AC20

**749. 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 of cervids (deer, elk) for food, including dietary supplements, and cosmetics if the cervids 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 validated 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.

**Timetable:**

Action	Date	FR Cite
NPRM	03/00/03	

**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, 3B-033/HFS-306, Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740  
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**RIN:** 0910-AC21

**750. EXCEPTION FROM GENERAL REQUIREMENTS FOR INFORMED CONSENT; REQUEST FOR COMMENTS AND INFORMATION**

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360bbb; 21 USC 360c; 21 USC 360d; 21 USC 360e; 21 USC 360f; 21 USC 360h; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 379e; 21

USC 381; 42 USC 241; 42 USC 262; 42 USC 263b-263n

**CFR Citation:** 21 CFR 50.23

**Legal Deadline:** None

**Abstract:** FDA is proposing to clarify its regulations about the exception from the general requirement for informed consent in life-threatening situations necessitating the use of a test article. This clarification will explain how the regulations would apply during emergencies, including a response to chemical or biological terrorism, requiring the use of investigational products regulated by FDA.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Bonnie M. Lee, Associate Director for Human Subject Protection Policy, Department of Health and Human Services, Food and Drug Administration, Room 9C24 (HF-34), Office of Good Clinical Practice, Office of Science Coordination & Communication, 5600 Fishers Lane, Rockville, MD 20857  
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**RIN:** 0910-AC25

**751. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS**

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

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

**CFR Citation:** 21 CFR 201.25; 21 CFR 601.67

**Legal Deadline:** None

**Abstract:** This regulation is one component of the Secretary's initiative to reduce medical errors. The proposal would require human drug products and biological products and possibly other products to have a bar code. The bar code would contain certain information about the product and,

## HHS—FDA

## Proposed Rule Stage

when used in conjunction with bar code scanners and computer equipment, would help reduce the number of medication errors.

**Timetable:**

Action	Date	FR Cite
NPRM	11/00/02	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
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**RIN:** 0910–AC26

**752. • MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 351; 21 USC 360c(e)(1); 21 USC 371

**CFR Citation:** 21 CFR 868.2700; 21 CFR 868.5905

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration is proposing to reclassify pressure regulators for use with medical oxygen from class I to class II and to establish a special control for oxygen pressure regulators to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the special control will be exempt from the premarket notification requirements of the act. The agency believes it is taking a least burdensome approach for industry. This rule will enable all manufacturers to most easily comply by implementing a phase-in compliance approach that will minimize the cost. FDA seeks to

reclassify these devices under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1)).

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/02	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Government Levels Affected:** Undetermined

**Federalism:** 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

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**RIN:** 0910–AC30

**753. • MEDICAL DEVICES; PATIENT EXAMINATION AND SURGEONS' GLOVES; ADULTERATION**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 371; 21 USC 374

**CFR Citation:** 21 CFR 800.20

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is proposing to amend the sampling plans, test method, and acceptable quality levels in 21 CFR 800.20. As prescribed by this regulation, FDA samples patient examination and surgeons' gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet specified quality levels. This proposal would clarify sampling plans and the scoring of defects, lower acceptance rates for leaking gloves, raise rejection rates for leaking gloves, and add tightened inspection schemes for reexamined glove lots. The rule is intended to facilitate industry compliance and enhance the safety and effectiveness of gloves.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**Government Levels Affected:** Undetermined

**Federalism:** 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

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**RIN:** 0910–AC32

**754. • AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 301 et seq; 21 USC 360kk et seq

**CFR Citation:** 21 CFR 1020.30; 21 CFR 1020.31; 21 CFR 1020.32

**Legal Deadline:** None

**Abstract:** This rule amends the performance standard for diagnostic x-ray systems and their components in 21 CFR 1020.30, 1020.31, and 1020.32 to address the changes in technology and practice and to fully utilize the currently accepted metric system.

**Timetable:**

Action	Date	FR Cite
NPRM	12/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**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

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**RIN:** 0910–AC34

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

**Final Rule Stage**

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

**Priority:** Other Significant

**Legal Authority:** 21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 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

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

**Legal Deadline:** None

**Abstract:** The final rule would establish 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. Under Federal law, 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, contrary to the best interests of recipients, or contrary to national security interests.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	10/05/99	64 FR 54180
Final Action	07/00/02	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** Federal

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
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**RIN:** 0910-AA89

**756. 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 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371;

21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

**CFR Citation:** 21 CFR 201

**Legal Deadline:** None

**Abstract:** This regulation is one component of the Secretary's initiative to reduce medical errors. The 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 regulation 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 regulation 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
NPRM Comment Period End	03/22/01	
NPRM Comment Period Reopened	03/30/01	
NPRM Comment Period Reopening End	06/22/01	
Final Action	09/00/02	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Lee D. Korb, Regulatory Counsel, Office of Regulatory Policy, 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-AA94

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

**Priority:** Other Significant

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

**CFR Citation:** 21 CFR 2

**Legal Deadline:** None

**Abstract:** FDA is 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	10/00/02	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

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**RIN:** 0910-AA99

## HHS—FDA

## Final Rule Stage

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

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 21 CFR 1.84

**Legal Deadline:** None

**Abstract:** The 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	11/00/02	

**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  
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**RIN:** 0910-AB24

**759. REVISIONS TO THE GENERAL SAFETY REQUIREMENTS FOR BIOLOGICAL PRODUCTS; 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 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

Action	Date	FR Cite
Direct Final Rule Withdrawn in Part	08/05/98	63 FR 41718
Final Action	03/00/03	

**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

**760. 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	01/00/03	

**Regulatory Flexibility Analysis Required:** No

HHS—FDA

Final Rule Stage

**Government Levels Affected:** None

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

**RIN:** 0910—AB61

### 761. 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 (NLEA), requires that the label or labeling of food products bear nutrition information. Among other things, section 403(q) of the Act 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 NLEA 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

Action	Date	FR Cite
NPRM Comment	12/05/00	65 FR 75887
Period Reopened		
NPRM Comment	01/19/01	
Period End		
Final Rule	09/00/02	

**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  
Fax: 202 205-5532  
Email: sthompson1@cfsan.fda.gov

**RIN:** 0910—AB66

### 762. 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; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa-25

**CFR Citation:** 21 CFR 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 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 reactive for evidence of HCV. The HIV lookback regulations will be amended for consistency.

**Timetable:**

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69377
NPRM Comment	02/14/01	
Period End		
Final Action	09/00/02	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448  
Phone: 301 827-6210  
Fax: 301 594-1944

**Related RIN:** Related To 0910-AB26

**RIN:** 0910—AB76

### 763. ANTIBIOTIC RESISTANCE LABELING

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

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

**CFR Citation:** 21 CFR 201.24

**Legal Deadline:** None

**Abstract:** The final rule would require the inclusion of certain statements about the use of antibiotics in the prescription drug labeling of these products. These statements will emphasize the proper use of these products in an effort to reduce the development of drug-resistant bacterial strains.

**Timetable:**

Action	Date	FR Cite
NPRM	09/19/00	65 FR 56511
Final Rule	12/00/02	

**Regulatory Flexibility Analysis Required:** No

## HHS—FDA

## Final Rule Stage

**Government Levels Affected:** None

**Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852  
Phone: 301 594-2041  
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**RIN:** 0910-AB78

#### 764. FOOD ADDITIVES: FOOD CONTACT SUBSTANCES NOTIFICATION SYSTEM

**Priority:** Substantive, Nonsignificant

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

**CFR Citation:** 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 maintains 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. Three comments were received on the proposed rule.

#### Timetable:

Action	Date	FR Cite
NPRM	07/13/00	65 FR 43269
Final Rule	05/00/02	

#### Regulatory Flexibility Analysis

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Mitchell Alan Cheeseman, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-205, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20704  
Phone: 202 418-3083  
Fax: 202 418-3131  
Email: mcheesem@cfsan.fda.gov

**RIN:** 0910-AB94

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

**Priority:** Other Significant

**Legal Authority:** 15 USC 145; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 343; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 362; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 243; 42 USC 262; 42 USC 264

**CFR Citation:** 21 CFR 1.98

**Legal Deadline:** None

**Abstract:** The rule would require food products that have been 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	06/00/02	

#### Regulatory Flexibility Analysis

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Room 15-61 (HF-23), Office of Policy, Planning and Legislation, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 827-0587  
Fax: 301 827-4774  
Email: pchao@oc.fda.gov

**RIN:** 0910-AB95

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

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

**Legal Authority:** 15 USC 1451 to 1561; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; PL 105-115, sec 122, 111 stat 2322 (21 USC 355 note); 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

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

**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 effectiveness of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances when adequate and well-controlled efficacy studies in humans cannot be ethically conducted. Efficacy studies in humans cannot be conducted

HHS—FDA

Final Rule Stage

ethically if: 1) the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers; and 2) field trials (assessment of use of the product after accidental or hostile exposure to the substance) are not feasible. FDA is taking this action because it 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	05/00/02	

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

**Agency Contact:** Wayne H. Mitchell, Regulatory Counsel, Office of Regulatory Policy, 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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Email: mitchellw@cdcr.fda.gov

**RIN:** 0910-AC05**767. 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 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 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 that, within six months of the date of its enactment on 10/17/2000, FDA adopt existing HHS regulations providing additional protections for children involved as

subjects in research. FDA published an interim rule in April 2001.

**Abstract:** The final rule will finalize the interim rule that published in April 2001 and 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	04/24/01	66 FR 20589
Final Rule	09/00/02	

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

**Agency Contact:** Carol Drew, Regulatory Counsel, Office of Regulatory Policy, 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-AC07**768. REVOCATION OF CONDITIONS FOR MARKETING DIGOXIN PRODUCTS FOR ORAL USE****Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 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	10/00/02	

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

**Agency Contact:** Mary E. Catchings, Regulatory Counsel, Office of

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

**RIN:** 0910-AC12**769. • POSTMARKET SURVEILLANCE****Priority:** Substantive, Nonsignificant

**Legal Authority:** 21 USC 331; 21 USC 352; 21 USC 360i; 21 USC 360l; 21 USC 371; 21 USC 374; ...

**CFR Citation:** 21 CFR 822**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is implementing a final rule for the postmarket surveillance provisions of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The purpose of this rule is to provide for the collection of useful data about devices that can reveal unforeseen adverse events or other information necessary to protect the public health.

**Timetable:**

Action	Date	FR Cite
NPRM	08/29/00	65 FR 52376
NPRM Comment Period End	11/27/00	
Final Action	06/00/02	

**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses**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

Fax: 301 594-4795

Email: jms@cdrh.fda.gov

**RIN:** 0910-AC31**770. • REDACTING 510(K) SUBMISSIONS****Priority:** Substantive, Nonsignificant

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

## HHS—FDA

## Final Rule Stage

USC 360j; 21 USC 371; 21 USC 374;

...

**CFR Citation:** 21 CFR 807

**Legal Deadline:** None

**Abstract:** The Food and Drug Administration (FDA) is issuing a final rule that amends the premarket notification provisions of our regulations at 21 CFR part 807 to require a 510(k) holder to submit a redacted version of a medical device premarket notification submission once we find the device to be substantially equivalent to another legally marketed device. The purpose of this requirement is to facilitate the release and dissemination of useful information to the health care community, the medical device industry, and the public, while providing the applicant a more timely opportunity to protect trade secret and confidential commercial information contained in the premarket notification. FDA will provide the redacted version to the public through the internet. The information to be released is information to which the public is entitled under the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, and FDA's Public Information regulation. The regulation does not require submission of a

redacted version of any premarket notification received by FDA prior to the effective date of the regulation.

**Timetable:**

Action	Date	FR Cite
Final Action	12/00/02	

**Regulatory Flexibility Analysis Required:** No

**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

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Email: jms@cdrh.fda.gov

**RIN:** 0910-AC33

**771. • SECTION 17 BEST PHARMACEUTICALS FOR CHILDREN ACT**

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

**Legal Authority:** 21 USC 355a

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Final, Statutory, January 4, 2003.

**Abstract:** To require drug product labeling to include a toll-free number for reports of adverse events regarding drug products, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	12/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Ann L. Simoneau, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037, HFD-7, 1451 Rockville Pike, Rockville, MD 20852

Phone: 301 594-2041

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**RIN:** 0910-AC35

## Department of Health and Human Services (HHS)

## Long-Term Actions

## Food and Drug Administration (FDA)

**772. INFANT FORMULA: REQUIREMENTS PERTAINING TO 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.

**Timetable:**

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

NPRM 07/09/96 (61 FR 36154)

NPRM Comment Period End 12/06/96

Final Action To Be Determined

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

NPRM 01/26/89 (54 FR 3783)

NPRM Comment Period End 03/27/89

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

**Infant Formula Quality Factors**

NPRM 07/09/96 (61 FR 36154)

NPRM Comment Period End 12/06/96

Final Action 09/00/03

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Darla Danford, Supervisory Nutritionist, Department of Health and Human Services, Food and Drug Administration, (HFS-800), Center for Food Safety and Applied Nutrition,

5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436-2373

**RIN:** 0910-AA04

**773. 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.

## HHS—FDA

## Long-Term Actions

The investigational use new animal drug regulations are expected to include regulations to implement provisions of the Animal Drug Availability Act of 1996, specifically presubmission conferences, and implement parts of the President's National Performance Report, "Reinventing the Regulation of Animal Drugs," May 1996. In the reinventing regulations report, FDA proposed to revise its regulations to reflect numerous new process changes and programs that will enable a more streamlined animal drug application review and approval process, and 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 solicit and consider 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	
End Review	12/00/03	

**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

#### 774. ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)

**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:** The Food and Drug Administration is requiring certain manufacturers of human cells, tissues, and cellular and tissue-based products to take actions to screen 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 cells, tissues, and cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor suitability requirements into existing good manufacturing practice regulations for those products.

**Timetable:**

Action	Date	FR Cite
NPRM	09/30/99	64 FR 52696
NPRM Comment Period End	12/29/99	
NPRM Comment Period Reopened	04/18/00	65 FR 20774
NPRM Comment Period Reopened End	07/17/00	
Final Action	To Be Determined	

**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:** 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  
Fax: 301 594-1944

**RIN:** 0910-AB27

#### 775. CURRENT GOOD TISSUE PRACTICE FOR MANUFACTURERS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)

**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:** The Food and Drug Administration (FDA) is proposing to require certain 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, the maintenance of a quality program, labeling, reporting, inspections, and enforcement.

**Timetable:**

Action	Date	FR Cite
NPRM	01/08/01	66 FR 1508
NPRM Comment Period End	05/08/01	
Final Action	To Be Determined	

**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:** 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  
Fax: 301 594-1944

**RIN:** 0910-AB28

#### 776. 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

## HHS—FDA

## Long-Term Actions

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 bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act.

**Timetable:**

Action	Date	FR Cite
NPRM Final Rule	01/18/01 To Be Determined	66 FR 4706

**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

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**RIN:** 0910-AC15

## Department of Health and Human Services (HHS)

## Completed Actions

## Food and Drug Administration (FDA)

**777. EXPORTS; NOTIFICATION AND RECORDKEEPING REQUIREMENTS**

**Priority:** Routine and Frequent

**CFR Citation:** 21 CFR 1.101

**Completed:**

Reason	Date	FR Cite
Final Action	12/19/01	66 FR 65429

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao

Phone: 301 827-0587

Fax: 301 827-4774

Email: pchao@oc.fda.gov

**RIN:** 0910-AB16

**Government Levels Affected:** None

**Agency Contact:** Philip L. Chao

Phone: 301 827-0587

Fax: 301 827-4774

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**RIN:** 0910-AB21

**Completed:**

Reason	Date	FR Cite
Final Rule	02/06/02	67 FR 5446

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State

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

**Agency Contact:** Ruth Fischer

Phone: 301 827-2960

**RIN:** 0910-AB98

**778. FOREIGN ESTABLISHMENT REGISTRATION AND LISTING**

**Priority:** Other Significant

**CFR Citation:** 21 CFR 207.3; 21 CFR 207.7; 21 CFR 207.10; 21 CFR 207.20; 21 CFR 207.21; 21 CFR 207.25; 21 CFR 207.37; 21 CFR 207.40; 21 CFR 607.3; 21 CFR 607.7; 21 CFR 607.20; 21 CFR 607.22; 21 CFR 607.25; 21 CFR 607.26; 21 CFR 607.31; 21 CFR 607.35; 21 CFR 607.37; 21 CFR 607.40; 21 CFR 607.65; 21 CFR 807.3; 21 CFR 807.20; 21 CFR 807.25; 21 CFR 807.40

**Completed:**

Reason	Date	FR Cite
Final Action	11/27/01	66 FR 59138

**Regulatory Flexibility Analysis Required:** No

**779. AMENDMENT OF REGULATIONS REGARDING CERTAIN LABEL STATEMENTS ON PRESCRIPTION DRUGS**

**Priority:** Substantive, Nonsignificant

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

**Completed:**

Reason	Date	FR Cite
Final Action	02/01/02	67 FR 4904

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Christine F. Rogers

Phone: 301 594-2041

Fax: 301 827-5562

**RIN:** 0910-AB39

**780. STATE CERTIFICATION OF MAMMOGRAPHY FACILITIES**

**Priority:** Other Significant

**CFR Citation:** 21 CFR 900.2; 21 CFR 900.20 to 900.25

**781. ADDITIONAL CRITERIA AND PROCEDURES FOR CLASSIFYING OVER-THE-COUNTER DRUGS AS GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED**

**Priority:** Economically Significant

**CFR Citation:** 21 CFR 330

**Completed:**

Reason	Date	FR Cite
Final Action	01/23/02	67 FR 3060

**Regulatory Flexibility Analysis Required:** Yes

**Government Levels Affected:** None

**Agency Contact:** Gerald M. Rachanow

Phone: 301 827-2241

Fax: 301 827-2315

Email: rachanow@cder.fda.gov

**RIN:** 0910-AC22

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

**Proposed Rule Stage**

**782. 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, 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	
Second NPRM	10/00/02	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and

Human Services, Public Health Service, Suite 300, 7519 Standish Place, Rockville, MD 20957  
 Phone: 301 443-2300  
 Fax: 301 443-6725

**RIN:** 0906-AA41

**783. 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	11/00/02	

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** Jerilyn A. Thornburg RN., MPH., Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, Room 91C4, National Center for Health Workforce Analysis, Bureau of Health Professions, 4350 East-West Highway, Bethesda, MD 20814  
 Phone: 301 594-0197  
 Email: dsd@hrsa.gov

**RIN:** 0906-AA44

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

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1396r-2

**CFR Citation:** 45 CFR 60

**Legal Deadline:** None

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

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Public Health Service, Suite 300, 7519 Standish Place, Rockville, MD 20957  
 Phone: 301 443-2300  
 Fax: 301 443-6725

**RIN:** 0906-AA57

## Department of Health and Human Services (HHS)

Final Rule Stage

## Health Resources and Services Administration (HRSA)

**785. 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	07/05/01	66 FR 36735
Final Rule	06/00/02	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, BHPR, Department of Health and Human Services, Health Resources and Services Administration, Room 8A-45, 5600 Fishers Lane, Rockville, MD 20857  
Phone: 301 443-4998  
Fax: 301 443-8196  
Email: gevens@hrsa.gov**Related RIN:** Duplicate of 0906-AA58**RIN:** 0906-AA55

## Department of Health and Human Services (HHS)

Completed Actions

## Health Resources and Services Administration (HRSA)

**786. NATIONAL VACCINE INJURY COMPENSATION PROGRAM: REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE****Timetable:**

Action	Date	FR Cite
Duplicate of 0906-AA55	05/01/02	

**RIN:** 0906-AA58**787. ADOPTION OF THE INTERIM FINAL RULE AS A FINAL RULE WITH AMENDMENTS FOR RICKY RAY HEMOPHILIA****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 130**Completed:**

Reason	Date	FR Cite
Final Rule	11/23/01	66 FR 58667

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Thomas C. Croft  
Phone: 301 443-2300**RIN:** 0906-AA59

## Department of Health and Human Services (HHS)

Proposed Rule Stage

## Indian Health Service (IHS)

**788. TRIBAL SELF-GOVERNANCE AMENDMENTS****Priority:** Other Significant**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, Expiration of authority to promulgate final rule: May 18, 2002.**Abstract:** Title V of the Tribal Self-Governance Amendments of 2000 (Pub. L. 106-260) made permanent the

demonstration program which allowed tribes full control over the operation and redesign of various activities historically managed by IHS. The proposal includes provisions that govern how IHS and Tribes will carry out their responsibilities under the Act.

**Timetable:**

Action	Date	FR Cite
NPRM	02/14/02	67 FR 6998
NPRM Comment Period End	04/15/02	
Final Rule	05/00/02	

**Regulatory Flexibility Analysis Required:** No**Small Entities Affected:** No**Government Levels Affected:** Federal, Tribal**Agency Contact:** Paula K. Williams, Director of Tribal Self-Governance, Department of Health and Human Services, Indian Health Service, Suite 240, Thompson Building, 801 Thompson Avenue, Rockville, MD 20852  
Phone: 301 443-7821**RIN:** 0917-AA05

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

Final Rule Stage

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

Priority: Info./Admin./Other

Legal Authority: 25 USC 3201 et seq

CFR Citation: 42 CFR 36

Legal Deadline: None

**Abstract:** The Indian Health Service (IHS) is proposing to establish regulations as mandated by the Indian Child Protection and Family Violence

Protection Act, Public Law 101-630, 25 U.S.C. 3201 to 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	07/00/02	

**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, 12300 Twinbrook Parkway, Rockville, MD 20852  
Phone: 301 443-1589

RIN: 0917-AA02

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

Proposed Rule Stage

**790. 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	06/00/02	

**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

**791. 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	05/00/02	

**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

**792. NIH CENTER GRANTS**

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; PL 106-310; PL 106-505; PL 106-525

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 485F 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	04/00/02	

**Regulatory Flexibility Analysis Required: No**

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

## HHS—NIH

## Proposed Rule Stage

**793. 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 National Institute of Child Health and Human Development (NICHD) in consultation with the Administrator of Health Resources and Services Administration (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	06/00/02	

**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)

## Final Rule Stage

## National Institutes of Health (NIH)

**794. 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 of Government 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	06/00/02	

**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)

## Long-Term Actions

## National Institutes of Health (NIH)

**795. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 287a-3a**CFR Citation:** 42 CFR 8**Legal Deadline:** NPRM, Statutory, June 18, 2001.**Abstract:** The National Institutes of Health proposes to establish standards

for operating a national chimpanzee sanctuary system to provide for the permanent retirement of federally-owned or supported chimpanzees no longer needed for research.

**Timetable:** Next Action Undetermined**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-AA31

## Department of Health and Human Services (HHS)

## Completed Actions

## National Institutes of Health (NIH)

**796. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68**Completed:**

Reason	Date	FR Cite
Withdrawn	04/30/02	

**Regulatory Flexibility Analysis Required:** Undetermined**Government Levels Affected:** Undetermined**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA02

## HHS—NIH

## Completed Actions

**797. NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM****Priority:** Info./Admin./Other**CFR Citation:** 42 CFR 52d**Completed:**

Reason	Date	FR Cite
Withdrawn	03/20/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA17**798. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68c**Completed:**

Reason	Date	FR Cite
Final Rule	04/11/02	67 FR 17650

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA19**799. NATIONAL INSTITUTES OF HEALTH CLINICS RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68a**Completed:**

Reason	Date	FR Cite
Withdrawn	04/30/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA25**800. NIH LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68f**Completed:**

Reason	Date	FR Cite
Withdrawn	04/30/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA26**801. PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68f**Completed:**

Reason	Date	FR Cite
Withdrawn	04/30/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA27**802. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS****Priority:** Substantive, Nonsignificant**CFR Citation:** 42 CFR 68f**Completed:**

Reason	Date	FR Cite
Withdrawn	04/30/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** None**Agency Contact:** Jerry Moore  
Phone: 301 496-4606  
Email: jm40z@nih.gov**RIN:** 0925-AA30**Department of Health and Human Services (HHS)  
Office of Public Health and Science (OPHS)****Proposed Rule Stage****803. PUBLIC HEALTH SERVICES POLICIES ON RESEARCH MISCONDUCT****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 216; 42 USC 241; 42 USC 289b**CFR Citation:** 42 CFR 93**Legal Deadline:** None**Abstract:** This notice of proposed rulemaking proposes substantial revisions to the existing regulations at 42 CFR part 50, subpart A, "Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," 54 FR 32449, August 8, 1989.

The National Institutes of Health Revitalization Act of 1993 (NIH Act), Public Law 103-43, contains provisions that affect the current rule. For example, section 161 of the NIH Act established the Office of Research Integrity (ORI) as an independent entity reporting to the Secretary, and recent organizational changes have also affected the ORI's operations. In addition, the Office of Science and Technology Policy (OSTP) published a governmentwide policy that applies to federally-funded research and proposals submitted to the Federal agencies for research funding, 65 FR 76260, December 6, 2000. The proposed

revised regulation will implement this OSTP policy, which contains a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct. The current regulation, which implemented section 493(e) of the Public Health Service Act, would be deleted, and a new part 93, subparts A, B, C, D, and E would be added.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	
NPRM Comment Period End	11/00/02	

## HHS—OPHS

## Proposed Rule Stage

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**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

**Related RIN:** Related To 0940-AA01**RIN:** 0940-AA04**Department of Health and Human Services (HHS)****Final Rule Stage****Office of Public Health and Science (OPHS)****804. 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, Pub. L. 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
NPRM Comment Period End	01/29/01	
Final Action	12/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**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

**Related RIN:** Related To 0940-AA04**RIN:** 0940-AA01**Department of Health and Human Services (HHS)****Completed Actions****Office of Public Health and Science (OPHS)****805. FEDERAL POLICY (COMMON RULE) FOR THE PROTECTION OF HUMAN SUBJECTS****Priority:** Other Significant**CFR Citation:** 45 CFR 46**Completed:**

Reason	Date	FR Cite
Withdrawn	04/26/02	

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

**Agency Contact:** Glen Drew

Phone: 301 402-4994  
Fax: 301 402-2071  
Email: gdrew@osophs.dhhs.gov

**RIN:** 0940-AA03**806. PROTECTION OF HUMAN RESEARCH SUBJECTS****Priority:** Other Significant**CFR Citation:** 45 CFR 46**Completed:**

Reason	Date	FR Cite
Final Rule	11/13/01	66 FR 56775

**Regulatory Flexibility Analysis**

Required: No

Government Levels Affected: None

**Agency Contact:** Irene Stith-Coleman,  
Ph.D  
Phone: 202 260-1587  
Fax: 202 205-0493  
Email: istithco@osophs.dhhs.gov

**RIN:** 0940-AA05**Department of Health and Human Services (HHS)****Proposed Rule Stage****Centers for Medicare & Medicaid Services (CMS)****807. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS-6002-P)****Priority:** Other Significant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 424**Legal Deadline:** None

**Abstract:** This regulation is needed as part of the Administration's anti-fraud and abuse efforts. It would give us the authority to enroll and re-enroll providers with time frames for re-enrollment.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

## HHS—CMS

## Proposed Rule Stage

**Additional Information:** Formerly known as HCFA-1023-P

**Agency Contact:** Michael Collett, OFM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6121

**RIN:** 0938-AH73

### 808. NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (CMS-1212-P)

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

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

**Legal Authority:** 42 USC 1320d to 1320d-8

**CFR Citation:** 45 CFR 160; 45 CFR 162

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

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

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**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:** Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-07-17, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7448

**RIN:** 0938-AH87

### 809. MEDICARE HOSPICE CARE AMENDMENTS (CMS-1022-P)

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 105-33, sec 4441(a); PL 105-33, sec 4442 to 4444; PL 105-33, sec 4448 to 4449

**CFR Citation:** 42 CFR 418

**Legal Deadline:** None

**Abstract:** This proposed rule revises certain regulations governing coverage and payments for hospice care under the Medicare program as required by the BBA of 1997.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Carol Blackford, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5909  
Email: cblackford@hcfa.gov

**Related RIN:** Previously reported as 0938-AH73

**RIN:** 0938-AJ36

### 810. END-STAGE RENAL DISEASE BAD DEBT PAYMENT (CMS-1126-P)

**Priority:** Other Significant

**Legal Authority:** Sec 110 of the Social Security Act; sec 1812(d) of the Social Security Act; sec 1814(b) of the Social Security Act; sec 1815 of the Social Security Act; sec 1833(a) of the Social Security Act; sec 1833(i) of the Social Security Act; sec 1833(n) of the Social Security Act; sec 1861(v) of the Social Security Act; sec 1866 of the Social Security Act; sec 1871 of the Social Security Act; sec 1881 of the Social Security Act; sec 1883 of the Social Security Act; 42 USC 1302; 42 USC 1395f(b); 42 USC 1395g; 42 USC 1395(a); 42 USC 1395(i); 42 USC 1395(n); 42 USC 1395x(v); 42 USC 1395cc; 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt

**CFR Citation:** 42 CFR 413.178

**Legal Deadline:** None

**Abstract:** This proposed rule would implement a court settlement agreement and remove the cap on End-Stage Renal Disease (ESRD) bad debt reimbursement, which limits payment

of allowable bad debts to the facility's unrecovered costs. The final rule following this proposed rule would be effective for cost reporting periods beginning on or after January 1, 2001.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Katie Walker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-03-03, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7278

**RIN:** 0938-AK02

### 811. CONDITIONS OF PARTICIPATION OF INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (CMS-3046-P)

**Priority:** Other Significant

**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 proposed rule would revise the conditions of participation for ICFs/MR. We would set forth these new requirements that ICFs/MR must meet to adhere to current trends in the field of developmental disabilities. It would address recent developments in some facilities in the District of Columbia to further protect the health and safety of this vulnerable population.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**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, Centers for Medicare &

## HHS—CMS

## Proposed Rule Stage

Medicaid Services, S3-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 401 786-0596

RIN: 0938-AK23

### 812. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS-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 proposed rule would announce a new process for beneficiaries to appeal national and local coverage determinations (LCDs).

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**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, Centers for Medicare & Medicaid Services, C5-16-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9317  
Email: jbossenmeyer@hcfa.gov

RIN: 0938-AK60

### 813. REVISED PROCESS FOR MAKING MEDICARE COVERAGE DETERMINATIONS (NCDS) (CMS-3062-N)

**Priority:** Other Significant

**Legal Authority:** Sec 522 of the BIPA

**CFR Citation:** None

**Legal Deadline:** Other, Statutory, October 1, 2001, Revision notice.

**Abstract:** This notice will announce a revised process for making Medicare National Coverage Ddecisions.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**Regulatory Flexibility Analysis Required:** No

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

**Government Levels Affected:** Federal

**Agency Contact:** Vadim Lubarsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0840

RIN: 0938-AK61

### 814. HEALTH INSURANCE REFORM: CLAIMS ATTACHMENTS STANDARDS (CMS-0050-P)

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

**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 proposed rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act. It would be used to transmit clinical data, beyond those data contained in the claims standard, to help establish medical necessity for coverage.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

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

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

**Agency Contact:** James Krall, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6999

RIN: 0938-AK62

### 815. HEALTH INSURANCE REFORM: MODIFICATIONS TO STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0003-P)

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1871

**CFR Citation:** 45 CFR 162

**Legal Deadline:** None

**Abstract:** This proposed rule would adopt a revised National Council for Prescription Drug Programs (NCPDP) standard for batched retail pharmacy transactions. This rule is not significant because the changes are technical with no policy or budget implications.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/02	

**Regulatory Flexibility Analysis Required:** Undetermined

**Government Levels Affected:** Undetermined

**Agency Contact:** Gladys Wheeler, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2-14-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0273

RIN: 0938-AK64

### 816. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR PROSPECTIVE PAYMENT SYSTEM PROVIDERS (CMS-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 proposed rule would increase the rate of reimbursement of photocopy expenses as required by the regulations governing Utilization and Quality Control Peer Review Organizations. Our current regulations identify the photocopying reimbursement methodology for prospective payment system hospitals.

## HHS—CMS

## Proposed Rule Stage

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**Regulatory Flexibility Analysis**

Required: No

**Small Entities Affected:** No**Government Levels Affected:**

Undetermined

**Agency Contact:** Valerie Mattison-Brown, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5958

RIN: 0938-AK68

**817. MODIFICATIONS TO MEDICARE MANAGED CARE RULES (CMS-4041-P)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Legal Authority:** BIPA, sec 605; BIPA, sec 606; BIPA, sec 612; BIPA, sec 615 to 617; BIPA, sec 620; BIPA, sec 621; BIPA, sec 623**CFR Citation:** 42 CFR 409; 42 CFR 417; 42 CFR 422**Legal Deadline:** None

**Abstract:** This proposed rule would implement certain Medicare payment provisions of the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000. The policy changes include premium reductions for M+C enrollees, uniform coverage for M+C plans in multiple locations, eliminating health disparities, ESRD enrollees, and increased civil money penalties for M+C organizations that terminate contracts mid-year. Moreover, this proposed rule describes authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in the M+C plans offered to employers or labor unions.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis**

Required: Yes

**Small Entities Affected:** Businesses**Government Levels Affected:** Federal**Additional Information:** CMS-4041-P was previously identified as CMS-1180-P.

**Agency Contact:** Alfred G. D'Alberto, Office of Managed Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1100

RIN: 0938-AK71

**818. REVISIONS TO TRANSACTION AND CODE SET STANDARDS FOR ELECTRONIC TRANSACTIONS (CMS-0005-P)****Priority:** Other Significant**Legal Authority:** Social Security Act, sec 1171 to 1179; PL 104-191**CFR Citation:** 45 CFR 162**Legal Deadline:** None

**Abstract:** This proposed rule would adopt revisions to the standards for electronic health care transactions adopted by the Secretary in regulations published August 2000. These revisions would enable covered entities to comply with the standards.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/02	

**Regulatory Flexibility Analysis**

Required: Undetermined

**Small Entities Affected:** Businesses, Governmental Jurisdictions, Organizations**Government Levels Affected:** State, Local, Tribal, Federal

**Agency Contact:** Gladys Wheeler, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2-14-17, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0273

RIN: 0938-AK76

**819. ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS-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:** None

**Abstract:** This proposed rule would revise the requirements concerning the written statement of intent procedures for filing Medicare claims from the current Medicare regulation.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis**

Required: Undetermined

**Small Entities Affected:** No**Government Levels Affected:** State, Federal**Federalism:** Undetermined

**Agency Contact:** David Walczak, Center for Health Plans and Providers, Plan and Provider Purchasing Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4475

RIN: 0938-AK79

**820. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2003 PAYMENT RATES (CMS-1206-P)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Legal Authority:** 42 USC 1395(L); BBA '97; BBRA '99; BIPA '00**CFR Citation:** Not Yet Determined**Legal Deadline:** None

**Abstract:** This proposed rule would revise the Medicare hospital outpatient payment system beginning January 1, 2003.

**Timetable:**

Action	Date	FR Cite
NPRM with Comment Period	06/00/02	

**Regulatory Flexibility Analysis**

Required: Yes

**Small Entities Affected:** Businesses**Government Levels Affected:** Federal

**Agency Contact:** Cindy Read, Division of Medical Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21207

Phone: 410 786-0378

RIN: 0938-AL19

## HHS—CMS

## Proposed Rule Stage

**821. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2003 (CMS-1202-P)**

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

**Legal Authority:** Social Security Act, sec 1888(e)

**CFR Citation:** None

**Legal Deadline:** NPRM, Statutory, April 12, 2002.

Final, Statutory, July 31, 2002.

**Abstract:** This annual proposed rule updates the payment rates used under the SNF PPS beginning October 1, 2002.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** William Ullman, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 401 786-5667

**RIN:** 0938-AL20

**822. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2003 (CMS-1204-P)**

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

**Legal Authority:** 42 USC 1395W-4

**CFR Citation:** 42 CFR 410; 42 CFR 414

**Legal Deadline:** None

**Abstract:** This rule would make several changes affecting Medicare part B payment.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/02	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Latesha Walker, Department of Health and Human

Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1101

**RIN:** 0938-AL21

**823. HOSPITAL INPATIENT REHABILITATION PROSPECTIVE PAYMENT SYSTEM FOR FY 2003 (CMS-1205-N)**

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

**Legal Authority:** PL 105-33, sec 4421; 42 USC 1395ww(j), sec 1886(j) of the Social Security Act

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** A prospective payment system was implemented for inpatient rehabilitation services on 8/7/01, with an effective date of 1/1/02. Since 2002 is the first year of operation under the new system, there is not sufficient data for a proposed and final notice. This notice is limited to updating the marketbasket and wage rates for this category of facilities.

**Timetable:**

Action	Date	FR Cite
Notice	08/00/02	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Laurence Wilson, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4603

**RIN:** 0938-AL22

**824. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR FY 2003 (CMS-1203-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1886(d) of the Social Security Act

**CFR Citation:** 42 CFR 405; 42 CFR 412; 42 CFR 413; 42 CFR 485; 42 CFR 489

**Legal Deadline:** NPRM, Statutory, April 1, 2002.

Final, Statutory, August 1, 2002.

**Abstract:** We are proposing to revise the Medicare acute care hospital inpatient prospective payment systems for operating and capital costs to implement changes arising from our continuing experience with these systems. These changes would be applicable to discharges occurring on or after October 1, 2002. We also are setting forth proposed rate-of-increase limits, as well as proposed policy changes for hospitals and hospital units excluded from the prospective payment systems.

**Timetable:**

Action	Date	FR Cite
NPRM	05/00/02	

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Stephen Phillips, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4548

**RIN:** 0938-AL23

**825. PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI-LEVEL CAPABILITY AND A BACK-UP RATE (CMS-1167-P)**

**Priority:** Other Significant

**Legal Authority:** 42 CFR 1302; 42 CFR 1395hh; 42 CFR 1395rr(b)(1); PL 103-66

**CFR Citation:** 42 CFR 414

**Legal Deadline:** None

**Abstract:** This rule removes respiratory assist devices with bi-level capability and a back-up rate from the category for items requiring frequent and substantial servicing, and places them in the category for other items, or capped rental items. This rule corrects an error that occurred in 1992, where these devices were inappropriately placed in the category for items requiring frequent and substantial servicing.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/02	

## HHS—CMS

## Proposed Rule Stage

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** None**Federalism:** Undetermined**Agency Contact:** Joel Kaiser, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4499

RIN: 0938-AL27

**826. • SELF-DECLARATION OF CITIZENSHIP (CMS-2085-P)****Priority:** Info./Admin./Other**Legal Authority:** Public Law 104-193, Sec 431**CFR Citation:** 42 CFR 435.410; 42 CFR 436.410**Legal Deadline:** None**Abstract:** This proposed rule would require States, on a post-determination basis, to carry out a process for verifying citizenship in a sample of cases to ensure that program integrity is being maintained. This proposed rule would also clearly state that acceptance of the individual's self-declaration is an option.**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis****Required:** No**Government Levels Affected:** State**Agency Contact:** Sarah DeLone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7010

RIN: 0938-AL33

**827. • HOSPICE WAGE INDEX FOR FY 2003 (CMS-1211-N)****Priority:** Routine and Frequent**Legal Authority:** 42 USC 1395f(i)(1)**CFR Citation:** None**Legal Deadline:** None**Abstract:** This notice will announce the annual update to the hospice wage index.**Timetable:**

Action	Date	FR Cite
Notice	08/00/02	

**Regulatory Flexibility Analysis****Required:** Undetermined**Government Levels Affected:** None**Agency Contact:** Lynn Riley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-02/23, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1286

RIN: 0938-AL41

**828. • ELECTRONIC SUBMISSION OF COST REPORTS (CMS-1199-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** Social Security Act, sec 1815(a); Social Security Act, sec 1833(e)**CFR Citation:** 42 CFR 413.24**Legal Deadline:** None**Abstract:** This proposed rule would establish the requirement for ESRD facilities, hospices, rural health clinics, and federally qualified health centers to file cost reports in a standardized electronic format. This rule would also provide a delay or waiver of this requirement where implementation would result in financial hardship. The provisions of this rule would allow for more accurate preparation and more efficient processing of each cost report.**Timetable:**

Action	Date	FR Cite
NPRM	06/00/02	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** Thomas Talbott, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-01-01, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4592

RIN: 0938-AL51

**829. • HEALTH INSURANCE REFORM: NATIONAL STANDARD FOR IDENTIFIERS OF HEALTH PLANS (CMS-1212-F)****Priority:** Other Significant. Major under 5 USC 801.**Unfunded Mandates:** This action may affect State, local or tribal governments and the private sector.**Legal Authority:** 42 USC 1320d to 1320d-8**CFR Citation:** 45 CFR 162**Legal Deadline:** Final, Statutory, February 2, 1998.**Abstract:** This proposed rule implements a standard identifier to identify health plans that process and pay certain electronic health care transactions. It implements one of the requirements for administrative simplification in section 262 of the Health Insurance Portability & Accountability Act of 1996.**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**Regulatory Flexibility Analysis****Required:** Yes**Small Entities Affected:** Businesses, Governmental Jurisdictions**Government Levels Affected:** State, Local, Tribal**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Helen Dietrick, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-07-17, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-7448

RIN: 0938-AL52

**830. • REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS-6146-P)****Priority:** Info./Admin./Other**Legal Authority:** PL 97-35, sec 2105; 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 231c**CFR Citation:** 42 CFR 402 subpart C**Legal Deadline:** None

## HHS—CMS

## Proposed Rule Stage

**Abstract:** This proposed rule revises CMS civil money penalty authorities. These proposed revisions are intended to add the specific exclusion sanction authorities as established in the procedures for imposing civil money penalties, assessments, and exclusions for certain violations of the Medicare program.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**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, Centers for Medicare & Medicaid Services, C3-04-06, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3349

**RIN:** 0938-AL53

**831. • EFFECT OF CHANGE OF OWNERSHIP ON PROVIDER AND SUPPLIER PENALTIES (CMS-2215-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Social Security Act, sec 1866

**CFR Citation:** 42 CFR 405; 42 CFR 489

**Legal Deadline:** None

**Abstract:** This proposed rule would amend regulations on provider and certain supplier agreements by clarifying the effect a change of ownership has on penalties and sanctions incurred by the former provider or supplier.

**Timetable:**

Action	Date	FR Cite
NPRM	09/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Mike Goldman, Division of Integrated Health Systems, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-27, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-6813

**RIN:** 0938-AL72

**832. • HEALTH COVERAGE PORTABILITY: TOLLING CERTAIN TIME PERIODS AND INTERACTIONS WITH FAMILY AND MEDICAL LEAVE ACT (CMS-2158-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 300 gg; PL 104-191

**CFR Citation:** 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145

**Legal Deadline:** None

**Abstract:** This proposed rule would clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. This rule would implement changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

**Timetable:**

Action	Date	FR Cite
NPRM	08/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses, Organizations

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

**Agency Contact:** David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6851

**RIN:** 0938-AL88

**833. • CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS-1471-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 1395L; BBA'97; BBRA'99; BIPA'00

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This rule would revise the Medicare hospital outpatient department prospective payment system for the January 2, 2004 update.

**Timetable:**

Action	Date	FR Cite
NPRM	06/00/02	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Cindy Read, Division of Medical Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21207  
Phone: 410 786-0378

**RIN:** 0938-AL91

**Department of Health and Human Services (HHS)  
Centers for Medicare & Medicaid Services (CMS)**

## Final Rule Stage

**834. SECURITY STANDARDS (CMS-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 final rule is being jointly developed by CMS and the Department of Commerce. This final rule adopts standards for the security of certain electronic identifiable health information of health plans, health care

clearinghouses, and certain health care providers. It implements administrative simplification initiatives that have a national scope beyond the Medicare and Medicaid programs.

## HHS—CMS

## Final Rule Stage

**Timetable:**

Action	Date	FR Cite
NPRM	08/12/98	63 FR 43242
NPRM Comment Period End	10/13/98	
Final Rule	08/00/02	

**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, Centers for Medicare & Medicaid Services, N2-14-10, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-3017

**RIN:** 0938-AI57**835. NATIONAL STANDARD EMPLOYER IDENTIFIER (CMS-0047-F)****Priority:** Economically Significant. Major under 5 USC 801.**Legal Authority:** PL 104-191; 42 USC 1320d to 1320d-8**CFR Citation:** 45 CFR 162**Legal Deadline:** Final, Statutory, February 21, 1998.

**Abstract:** This rule is being jointly developed by CMS, Treasury, Labor, and Defense. The regulation adopts an employer's tax ID number as the standard for electronic transactions, implementing an administrative simplification initiative that has a national scope beyond the Medicare and Medicaid programs.

**Timetable:**

Action	Date	FR Cite
NPRM	06/16/98	63 FR 32784
NPRM Comment Period End	08/17/98	
Final Rule	06/00/02	

**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:** Patricia Peyton, Office of Information Services, Department of Health and Human Services, Centers for Medicare &

Medicaid Services, N3-20-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-1812

**RIN:** 0938-AI59**836. EXTERNAL QUALITY REVIEW OF MEDICAID MANAGED CARE ORGANIZATIONS (CMS-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 final rule will require State agencies to contract with managed care organizations and to monitor and evaluate their performances through annual external, independent reviews conducted by accrediting organizations that are approved by CMS.

**Timetable:**

Action	Date	FR Cite
NPRM	12/01/99	64 FR 67223
Final Rule	07/00/02	

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1177

**RIN:** 0938-AJ06**837. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS, AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS-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 amends the Medicare certification and payment

requirements for rural health clinics (RHCs), as required by section 4205 of the Balanced Budget Act of 1997.

**Timetable:**

Action	Date	FR Cite
NPRM	02/28/00	65 FR 10450
Final Rule	08/00/02	

**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, Centers for Medicare & Medicaid Services, C4-15-18, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5919

**RIN:** 0938-AJ17**838. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS-3014-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1302; 42 USC 1395hh**CFR Citation:** 42 CFR 482.27**Legal Deadline:** None

**Abstract:** This final rule revises requirements for hospitals that transfuse blood and blood products regarding written procedures, quarantine, testing, and counseling for hepatitis C virus (HCV) and records maintenance.

**Timetable:**

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Final Rule	12/00/02	

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3189

**RIN:** 0938-AJ29

## HHS—CMS

## Final Rule Stage

**839. NON-FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HEALTH INSURANCE PORTABILITY REQUIREMENTS (CMS-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 interim final rule revises certain procedural requirements associated with the filing of an election to exempt certain non-Federal governmental group health plans from various Federal requirements of HIPAA that are generally applicable to employment-related group health plans.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	07/00/02	

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1564

**RIN:** 0938-AK00

**840. FIRE SAFETY REQUIREMENTS FOR RNHCI, ASC, HOSPICES, PACE, HOSPITALS, AND LONG-TERM CARE FACILITIES AND ICFS FOR THE MENTALLY RETARDED (CMS-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 adopts the 2000 edition of the National Fire Protection Association's Life Safety Code as the fire standards for Religious Non-Medical Health Care Institutions, Ambulatory Surgery Centers, Hospices that provide in-patient services, Programs of All-Inclusive Care for the

Elderly, Hospitals, Long-Term Care Facilities, and Intermediate Care Facilities for the Mentally Retarded.

**Timetable:**

Action	Date	FR Cite
NPRM	10/26/01	66 FR 54179
Final Rule	09/00/02	

**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, Centers for Medicare & Medicaid Services  
Phone: 410 786-3529

**RIN:** 0938-AK35

**841. HOSPITAL CONDITIONS OF PARTICIPATION: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENTS (CMS-3050-F)**

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 482.21

**Legal Deadline:** None

**Abstract:** This final rule addresses provisions relating to the development and implementation of a QAPI program and its components. It imposes several requirements that are designed to increase patient safety and track the methodologies and/or programs or both used to increase patient safety.

**Timetable:**

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66725
NPRM Comment Period End	02/17/98	
Final Rule	08/00/02	

**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, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-9226

**RIN:** 0938-AK40

**842. SUPPLEMENTARY MEDICAL INSURANCE PREMIUM SURCHARGE AGREEMENTS (CMS-4007-F)**

**Priority:** Other Significant

**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 proposed rule would provide a special payment arrangement with States and local government entities for the payment of part B premium late enrolment surcharges.

**Timetable:**

Action	Date	FR Cite
NPRM	10/26/01	66 FR 54186
Final Rule	08/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State, Local

**Agency Contact:** Marty Abeln, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1032

Sandy Clarke, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-7451

**RIN:** 0938-AK42

**843. PAYMENT FOR UPGRADED DURABLE MEDICAL EQUIPMENT; WITHDRAWAL OF PROPOSED RULE (CMS-1084-WN)**

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

**Legal Authority:** Not Yet Determined

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This notice will withdraw the proposed rule that was published in the Federal Register on April 27, 2000.

**Timetable:**

Action	Date	FR Cite
NPRM	04/27/00	65 FR 24666
Final Rule	04/00/02	

## HHS—CMS

## Final Rule Stage

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

**Agency Contact:** William J. Long, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-08-27, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21228  
Phone: 410 786-5655  
Email: wlong@hcfa.gov

**RIN:** 0938-AK50
**844. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS FOR FY 2003 (CMS-1177-P)**
**Priority:** Other Significant**Unfunded Mandates:** Undetermined

**Legal Authority:** BBRA, sec 123; BIPA, sec 307; PL 105-33, sec 4422; PL 106-113, sec 123; PL 106-544, sec 307(b)

**CFR Citation:** 42 CFR 412

**Legal Deadline:** NPRM, Statutory, October 1, 2002, Effective date.

**Abstract:** This rule would establish a PPS for long-term care facilities effective October 1, 2002.

**Timetable:**

Action	Date	FR Cite
NPRM	03/22/02	67 FR 13416
NPRM Comment Period End	05/21/02	
Final Rule	08/00/02	

**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, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-2590

**RIN:** 0938-AK69
**845. MEDICARE INPATIENT DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FORMULA (CMS-1171-IFC)**
**Priority:** Other Significant**Legal Authority:** Not Yet Determined**CFR Citation:** 42 CFR 412106**Legal Deadline:** None

**Abstract:** This interim final rule clarifies the Medicare DSH adjustment calculation in reference to the inclusion of Medicaid patient days. It describes the criteria to use in calculating the Medicare DSH adjustment for hospitals for purposes of payment under the hospital inpatient prospective payment system.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	09/00/02	

**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, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4548

**RIN:** 0938-AK77
**846. STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFIED INDIVIDUALS; FEDERAL FISCAL YEAR 2001 (CMS-2087-PN)**
**Priority:** Other Significant

**Legal Authority:** 42 USC 1396a(a)(10)(E); 42 USC 1396x

**CFR Citation:** None**Legal Deadline:** None

**Abstract:** This notice announces the Federal fiscal year 2001 allotments that are available for State agencies to pay Medicare part B premiums for two specific eligibility groups of low-income Medicare beneficiaries, referred to as Qualified Individuals.

**Timetable:**

Action	Date	FR Cite
NPRM	01/25/02	67 FR 3713
Final Action	09/00/02	

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

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

Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4466

**RIN:** 0938-AK91
**847. MEDICAID MANAGED CARE; NEW PROVISIONS (CMS-2104-F)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Balanced Budget Act of 1997, sec 4701 to 4710; Social Security Act, sec 1932

**CFR Citation:** 42 CFR 400; 42 CFR 430; 42 CFR 431; 42 CFR 434; 42 CFR 435; 42 CFR 438; 42 CFR 440; 42 CFR 447

**Legal Deadline:** None

**Abstract:** This final rule will revise recently published provisions for the Medicaid Managed Care Program. The provisions involve quality of care and services under Medicaid managed care arrangements. The provisions affect enrollee rights and responsibilities, as well as contracts between State Medicaid agencies and managed care organizations.

**Timetable:**

Action	Date	FR Cite
NPRM	08/20/01	66 FR 43613
NPRM Comment Period End	10/19/01	
Final Rule	05/00/02	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** State, Federal

**Agency Contact:** Bruce Johnson, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD  
Phone: 410 786-0615

Deirdre Duzor, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-13-15, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4626

**RIN:** 0938-AK96

## HHS—CMS

## Final Rule Stage

**848. MODIFICATIONS TO THE STATE CHILDREN'S HEALTH INSURANCE PROGRAM (CMS-2006-F)****Priority:** Substantive, Nonsignificant**Legal Authority:** PL 105-33**CFR Citation:** 42 CFR 435; 42 CFR 436; 42 CFR 457**Legal Deadline:** None**Abstract:** This final rule responds to public comments received and will revise certain provisions to the State Children's Health Insurance Program (CHIP) final rule, published on January 11, 2002.**Timetable:**

Action	Date	FR Cite
Interim Final Rule	06/25/01	66 FR 33810
Interim Final Rule Comment Period End	07/26/01	
Interim Final Rule Effective	08/24/01	
Final Rule	09/00/02	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** State**Federalism:** This action may have federalism implications as defined in EO 13132.**Agency Contact:** Regina Fletcher, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3293

**RIN:** 0938-AL00**849. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR FY 2003 (CMS-1198-NC)****Priority:** Other Significant**Legal Authority:** Balanced Budget Act, PL 105-33, sec 460.3(a); OCSAA, PL 105-277, sec 5101(c); OCSAA, PL 105-277, sec 5101(d); Balanced Budget Act Refinement Act of 1999, PL 100-113, sec 305; Balanced Budget Act Refinement Act of 1999, PL 100-113, sec 306; Medicare, Medicaid & SCHIP Benefits Improve. & Protection Act of 2000, PL 106-544; ...**CFR Citation:** Not Yet Determined**Legal Deadline:** Other, Statutory, October 1, 2002, Publish by 06/28/2002.**Abstract:** This notice with comment period sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies for FY 2003.**Timetable:**

Action	Date	FR Cite
Notice	06/00/02	

**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, Centers for Medicare & Medicaid Services, C5-08-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-9364

**RIN:** 0938-AL16**850. MEDICARE PROGRAM; MEDICARE-ENDORSED PRESCRIPTION DRUG DISCOUNT CARD ASSISTANCE INITIATIVE (CMS-4027-P)****Priority:** Economically Significant**Legal Authority:** 42 USC 1395b-3; 42 USC 1302; 42 USC 1302b-10**CFR Citation:** None**Legal Deadline:** None**Abstract:** This final rule would set forth a Department of Health and Human Services' initiative for a Medicare endorsement to entities currently offering prescription drug discounts to the general public to offer prescription drug discount cards to Medicare beneficiaries.**Timetable:**

Action	Date	FR Cite
NPRM	03/06/02	67 FR 10262
NPRM Comment Period End	05/06/02	
Final Rule	06/00/02	

**Regulatory Flexibility Analysis****Required:** Undetermined**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** Paula Stannard, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Room 707F, 200 Independence Avenue SW., Washington, DC 20201  
Phone: 202 690-7741

Teresa Decaro, Department of Health and Human Services, Centers for Medicare &amp; Medicaid Services, C5-17-14, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6604

Email: tdecaro@cms.hhs.gov

**RIN:** 0938-AL28**851. • PEER REVIEW ORGANIZATIONS: NAME AND OTHER CHANGES—TECHNICAL AMENDMENTS (CMS-3088-FC)****Priority:** Other Significant**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1871**CFR Citation:** 42 CFR 400**Legal Deadline:** None**Abstract:** This final rule with comment period changes the term "peer review organization" to "quality improvement organization" in the CFR.**Timetable:**

Action	Date	FR Cite
Final Rule	05/00/02	

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** None**Agency Contact:** Valerie Mattison-Brown, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5958

**RIN:** 0938-AL38**852. • END-STAGE RENAL DISEASE—RESCISSION OF WAIVER OF CONDITIONS FOR COVERAGE UNDER A STATE OF EMERGENCY IN HOUSTON, TEXAS AREA (CMS-3074-F2)****Priority:** Other Significant**Legal Authority:** Not Yet Determined**CFR Citation:** 42 CFR 405**Legal Deadline:** None**Abstract:** This final rule removes an emergency waiver of the Medicare end-stage renal disease conditions for coverage granted to permit the transplant team of an approved renal transplant center to furnish kidney transplant services in three specific hospitals in the Houston, TX area during a state of emergency.

## HHS—CMS

## Final Rule Stage

**Timetable:**

Action	Date	FR Cite
Final Rule	07/00/02	

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

**Agency Contact:** Lori Davis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0710

**RIN:** 0938–AL39

**853. ● PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITAL; CORRECTING AMENDMENT (CMS-1069-F2)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Social Security Act, sec 1886(j); PL 105-33; PL 106-554; PL 106-113

**CFR Citation:** 42 CFR 412; 42 CFR 413**Legal Deadline:** None

**Abstract:** This notice corrects typographical and data errors identified in the August 7, 2001 rule.

**Timetable:**

Action	Date	FR Cite
Final Rule	06/00/02	

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

**Agency Contact:** Robert Kuhl, Technical Advisor, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4597

**RIN:** 0938–AL40

**854. ● PHYSICIAN FEE SCHEDULE FOR CY 2002: CORRECTION NOTICE (CMS-1169-CN)**

**Priority:** Info./Admin./Other**Legal Authority:** 42 USC 1395W-4

**CFR Citation:** 42 CFR 405; 42 CFR 410; 42 CFR 411; 42 CFR 414; 42 CFR 415

**Legal Deadline:** None

**Abstract:** This notice corrects technical errors that occurred in the final rule with comment period published on November 1, 2001. The final rule sets forth the physician fee schedule for CY 2002.

**Timetable:**

Action	Date	FR Cite
Notice	04/00/02	

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

**Agency Contact:** Diane Milstead, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3355

**RIN:** 0938–AL48

**855. ● NOTICE OF MODIFICATION OF BENEFICIARY ASSESSMENT REQUIREMENTS FOR SKILLED NURSING FACILITIES (CMS-1209-N)**

**Priority:** Info./Admin./Other**Legal Authority:** None**CFR Citation:** None**Legal Deadline:** None

**Abstract:** This notice offers skilled nursing facilities the option of using a modified, shorter version of the minimum data set to satisfy Medicare payment and quality requirements.

**Timetable:**

Action	Date	FR Cite
Notice	06/00/02	

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

**Agency Contact:** Dana Burley, Policy Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-06-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4547

**RIN:** 0938–AL55

**856. ● INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2003 (CMS-8013-N)**

**Priority:** Other Significant. Major under 5 USC 801.**Legal Authority:** 42 USC 1395e-2(g)(2)**CFR Citation:** None**Legal Deadline:** None

**Abstract:** This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2003 under the Medicare hospital insurance program (part A). The Medicare statute specifies the formula used to determine these amounts.

**Timetable:**

Action	Date	FR Cite
Notice	09/00/02	

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

**Agency Contact:** Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6390

**RIN:** 0938–AL56

**857. ● REVISION OF THE PROCEDURES FOR REQUESTING EXCEPTIONS TO COST LIMITS FOR SKILLED NURSING FACILITIES AND ELIMINATION OF RECLASSIFICATIONS; CORRECTION (CMS-1883-F3)**

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

**Legal Authority:** 42 USC 1302; 42 USC 1395d(d); 42 USC 1395F(b); 42 USC 1395(g); 42 USC 13951(a); 42 USC 13951(n); 42 USC 1395hh; 42 USC 1395rr; 42 USC 1395tt; 42 USC 1395ww

**CFR Citation:** 42 CFR 413.30(d)**Legal Deadline:** None

**Abstract:** This technical correction corrects an error in 42 CFR 413.30(d) found in the technical correction dated October 10, 2000.

## HHS—CMS

## Final Rule Stage

**Timetable:**

Action	Date	FR Cite
Final Rule	08/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**Agency Contact:** Julie Stankiuc, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-06-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-5725

RIN: 0938-AL61

### 858. ● MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2003 (CMS-8014-N)

Priority: Economically Significant

Legal Authority: 42 CFR 1395r; Social Security Act, sec 1839

CFR Citation: 42 CFR 407; 42 CFR 408

Legal Deadline: NPRM, Statutory, September 27, 2002.

**Abstract:** This notice announces the monthly actuarial rates for aged and disabled enrollees in the Medicare Supplementary Medical Insurance (SMI) program for 2003. It also announces the monthly SMI premium to be paid by all enrollees during 2003.

**Timetable:**

Action	Date	FR Cite
Final Rule	09/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**Agency Contact:** Carter S. Warfield, Office of Medicare and Medicaid Cost Estimates, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6396

RIN: 0938-AL63

### 859. ● REQUEST FOR INFORMATION ON BENEFIT-SPECIFIC WAITING PERIODS (CMS-2150-N)

Priority: Info./Admin./Other

Legal Authority: None

CFR Citation: None

Legal Deadline: None

**Abstract:** This notice requests information on the use of benefit-specific waiting periods by group health plan and group health insurance issuers.

**Timetable:**

Action	Date	FR Cite
Notice	08/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**Agency Contact:** David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6851

RIN: 0938-AL64

### 860. ● PART A PREMIUMS FOR 2003 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS-8015-N)

Priority: Other Significant

Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2)

CFR Citation: None

Legal Deadline: None

**Abstract:** This notice announces the hospital insurance premium for calendar year 2003 under Medicare's hospital insurance program (part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. (The statute requires that this notice be published September 30, 2002.)

**Timetable:**

Action	Date	FR Cite
Final Rule	09/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**Agency Contact:** Clare McFarland, Deputy Directory, Medicare and Medicaid Cost Estimates Group, Department of Health and Human

Services, Centers for Medicare & Medicaid Services, N3-26-24, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-6390

RIN: 0938-AL69

### 861. ● MEDICAID MANAGED CARE: WITHDRAWAL (CMS-2001-F4)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

**Abstract:** This final rule withdraws the January 2001 Medicaid Managed Care final rule and finalizes the IFC rule published on August 17, 2001. It will be published at the same time as the new final Medicaid Managed Care Final Rule, CMS-2104-F.

**Timetable:**

Action	Date	FR Cite
Final Rule	05/00/02	

**Regulatory Flexibility Analysis**

Required: No

Small Entities Affected: No

Government Levels Affected: None

**Agency Contact:** Bruce Johnson, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD

Phone: 410 786-0615

RIN: 0938-AL83

### 862. ● FY 1999 SCHIP REALLOCATION NOTICE (CMS-2137-N)

Priority: Substantive, Nonsignificant

Legal Authority: PL 106-554, sec 801

CFR Citation: None

Legal Deadline: None

**Abstract:** This notice announces the application of statutory provisions concerning the redistribution and availability of unexpended funds appropriated for fiscal year 1999 for SCHIP. Title XXI of the Social Security Act authorizes payment of Federal matching funds to States, the District of Columbia, and U.S. Territories and Commonwealths to initiate and expand health insurance coverage to uninsured, low-income children under the State

HHS—CMS

Final Rule Stage

Children’s Health Insurance Program (SCHIP).

**Timetable:**

Action	Date	FR Cite
Notice	04/00/02	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Richard Strauss, Deputy Director, Division of Financial Management, Department of Health and

Human Services, Centers for Medicare & Medicaid Services, S3-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-2019

Email: rstrauss@hcfa.gov

**RIN:** 0938–AL86

**Department of Health and Human Services (HHS)  
Centers for Medicare & Medicaid Services (CMS)**

**Long-Term Actions**

**863. “WITHOUT FAULT” AND BENEFICIARY WAIVER OF RECOVERY AS IT APPLIES TO MEDICARE OVERPAYMENT LIABILITY (CMS-6007-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1395gg; Social Security Act, sec 1870

**CFR Citation:** 42 CFR 401; 42 CFR 466.86; 42 CFR 466.94; 42 CFR 473.14; 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 amends the Medicare regulations to clarify the interpretation of “without fault” as it applies to physicians, providers, suppliers and beneficiary liability for overpayments.

**Timetable:**

Action	Date	FR Cite
NPRM	03/25/98	63 FR 14506
Final Action	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Barbara Wright, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3-14-00, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4292

**RIN:** 0938–AD95

**864. REVISION OF MEDICARE/MEDICAID HOSPITAL CONDITIONS OF PARTICIPATION (CMS-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 and unnecessary procedural requirements.

**Timetable:**

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66726
NPRM Comment	03/20/98	
Period End		
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Stephanie Dyson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-9226

**RIN:** 0938–AG79

**865. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS-3819-FC)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

**CFR Citation:** 42 CFR 484

**Legal Deadline:** None

**Abstract:** This final rule revises the existing CoPs that HHAs must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of the Administration’s efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs, while at the same time reducing procedural burdens on providers.

**Timetable:**

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment	06/09/97	
Period End		
Final Rule	To Be	Determined

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4882

## HHS—CMS

## Long-Term Actions

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6775

RIN: 0938-AG81

### 866. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS-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 to 414; 42 CFR 489; 42 CFR 494

**Legal Deadline:** None

**Abstract:** This proposed rule would revise the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

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

**Government Levels Affected:** None

**Agency Contact:** Robert Miller, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-6797

Email: rmiller@cms.hhs.gov

Theresa Casey, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-05-04, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-7215

RIN: 0938-AG82

### 867. CRITERIA FOR APPROVAL OF FACILITIES TO PERFORM COVERED HEART, LIVER, LUNG, PANCREAS, AND INTESTINAL TRANSPLANTS (CMS-3835-P)

**Priority:** Other Significant

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

**CFR Citation:** 42 CFR 482

**Legal Deadline:** None

**Abstract:** This proposed rule would establish conditions of participation for Medicare-covered transplants.

**Timetable:**

Action	Date	FR Cite
NPRM	07/00/03	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Marty Abeln, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-1032

Kathy Linstromberg, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-8279

Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-06-6, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-7539

RIN: 0938-AH17

### 868. HOSPICE CARE—CONDITIONS OF PARTICIPATION (CMS-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 proposed rule would revise existing conditions of participation that hospices must meet to participate in the Medicare program. The proposed requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, allow hospices greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements.

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6051

Rachael Weinstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6775

RIN: 0938-AH27

### 869. MEDICARE AND MEDICAID PROGRAMS; TERMS, DEFINITIONS, AND ADDRESSES: TECHNICAL AMENDMENTS (CMS-9877-F)

**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 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 would initiate the rationalization of our system of definitions, correct outdated addresses and formulas, clarify which steps of the appeals process are binding and which are final, remove content that is duplicative or unnecessary, and make other clarifying editorial changes.

**Timetable:**

Action	Date	FR Cite
NPRM	01/25/02	67 FR 3641
NPRM Comment Period End	03/26/02	
Final Rule	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

## HHS—CMS

## Long-Term Actions

**Agency Contact:** Margaret Teeters, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-14-03, Division of Regulation and Issuances, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4678

**RIN:** 0938-AH53

### 870. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS-0045-F)

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

**Legal Authority:** 42 USC 1320D-2(b)(1)

**CFR Citation:** 42 CFR 160; 42 CFR 162

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

**Abstract:** This rule establishes a standard unique ID for all health care providers under HIPAA. The rule implements administrative simplification initiatives that have a national scope beyond Medicare and Medicaid.

**Timetable:**

Action	Date	FR Cite
NPRM	05/07/98	63 FR 25320
NPRM Comment Period End	07/06/98	
Final Action	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

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

**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, Centers for Medicare & Medicaid Services, N3-20-05, 7500 Security Boulevard, Baltimore, MD 21224-1850

Phone: 410 786-1812

**RIN:** 0938-AH99

### 871. MEDICAL CHILD SUPPORT AND HEALTH INSURANCE COVERAGE OF DEPENDENT CHILDREN (CMS-2081-P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1396(a)(25); 42 USC 1396(a)(45); 42

USC 1396(a)(60); 42 USC 1396(o); 42 USC 1396g-1; 42 USC 1396(k)

**CFR Citation:** 42 CFR 433.135; 42 CFR 433.137; 42 CFR 433.170

**Legal Deadline:** None

**Abstract:** This rule would require States to provide assurances that laws relating to medical child support have satisfactorily been implemented in accordance with the Social Security 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. This requirement would implement section 13623, OBRA of 1993.

**Timetable:**

Action	Date	FR Cite
Final Rule	To Be	Determined

**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, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-0488  
**RIN:** 0938-AI21

### 872. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS-6003-F)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1302; 42 USC 1395u(b)(3)(C); 42 USC 1395ff(b)

**CFR Citation:** 42 CFR 405.874

**Legal Deadline:** None

**Abstract:** This rule would extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under other existing appeals provisions of our regulations.

**Timetable:**

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Final Rule	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Charles Waldhauser, Division of Provider/Supplier Enrollment, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-6140  
Yvonne West, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244

Phone: 410 786-6479  
**RIN:** 0938-AI49

### 873. COVERAGE OF RELIGIOUS NON-MEDICAL HEALTH CARE INSTITUTIONS (CMS-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 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 4454(d).

**Abstract:** This final rule follows an Interim Final with Comment that removed all references in the Medicare regulations to specific religious institutions to include all religious nonmedical institutions.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	11/30/99	64 FR 67028
Final Action	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Jean Marie Moore, Center for Health Plans and Providers,

## HHS—CMS

## Long-Term Actions

Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3508

RIN: 0938-AI93

#### 874. REPORTING OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA AS PART OF THE CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (CMS-3006-F)

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

**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 final rule requires home health agencies to electronically report OASIS data as a condition of participation in the Medicare program.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	01/25/99	64 FR 3748
Final Rule	To Be Determined	

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

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

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

**Agency Contact:** Janice Stevenson, Office of Clinical Standards and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4882

RIN: 0938-AJ10

#### 875. USE OF RESTRAINT AND SECLUSION IN RESIDENTIAL TREATMENT FACILITIES PROVIDING INPATIENT PSYCHIATRIC SERVICES TO INDIVIDUALS UNDER AGE 21 (CMS-2065-F)

**Priority:** Economically Significant

**Legal Authority:** 42 USC 1302; 42 USC 1396d

**CFR Citation:** 42 CFR 441; 42 CFR 483

**Legal Deadline:** None

**Abstract:** This rule addresses standards of practices that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints and seclusion.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	01/22/01	66 FR 7148
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
60-Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	To Be Determined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Larry Cutler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5903

RIN: 0938-AJ96

#### 876. APPLICATION OF INHERENT REASONABLENESS TO ALL MEDICARE PART B SERVICES (OTHER THAN PHYSICIAN SERVICES) (CMS-1908-F)

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

**Legal Authority:** PL 105-33, sec 4316

**CFR Citation:** 42 CFR 405

**Legal Deadline:** None

**Abstract:** This final rule 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.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	01/07/98	63 FR 687
Next Action	Undetermined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** William J. Long, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-08-27, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21228  
Phone: 410 786-5655  
Email: wlong@hcfa.gov

RIN: 0938-AJ97

#### 877. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, HOME NUTRITION THERAPY, AND CONSIGNMENT CLOSETS (CMS-6010-P)

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 424.57

**Legal Deadline:** None

**Abstract:** This rule would establish service standards for suppliers of home oxygen equipment, therapeutic shoes, home infusion therapy, and standards for consignment closets.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Frank Whelan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3-02-16, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-1302

RIN: 0938-AJ98

#### 878. CLINICAL LAB REQUIREMENTS—REVISIONS TO REGULATIONS IMPLEMENTING CLIA (CMS-2226-F)

**Priority:** Other Significant

**Legal Authority:** PL 100-578

**CFR Citation:** 42 CFR 493

**Legal Deadline:** None

## HHS—CMS

## Long-Term Actions

**Abstract:** This final rule finalizes certain laboratory requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

**Timetable:**

Action	Date	FR Cite
Final Action	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Cecelia Hinkel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services  
Phone: 410 786-3347

**RIN:** 0938-AK24

**879. IMPROVEMENTS TO THE MEDICARE+CHOICE APPEALS AND GRIEVANCE PROCEDURES (CMS-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 final rule sets forth several improvements to the Medicare+Choice (M+C) appeal and grievance procedures. This rule addresses the termination date of provider services, independent review process, and discharge notices.

**Timetable:**

Action	Date	FR Cite
NPRM Final Rule	01/24/01 To Be	66 FR 7593 Determined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Organizations

**Government Levels Affected:** None

**Additional Information:** The Settlement Agreement in *Grijalva 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, Centers for Medicare &

Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4661

**RIN:** 0938-AK48

**880. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS-1810-FC)**

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

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

**CFR Citation:** 42 CFR 411

**Legal Deadline:** None

**Abstract:** This final rule addresses the provisions of sections 1877 and 1903(s) of the Social Security Act that preclude payment for services under the Medicare program if a physician makes a referral to a facility in which he/she has a financial interest. This rule with comment period will address comments from the January 9, 1998 proposed rule concerning the ownership and investment exceptions and the compensation exceptions. In addition, this rule will address comments from the January 4, 2001 Phase I final rule with comment period.

**Timetable:**

Action	Date	FR Cite
Final Action	To Be	Determined

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** State, Local

**Agency Contact:** Joanne Sinsheimer, Technical Advisor, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-4620

**RIN:** 0938-AK67

**881. ORGAN PROCUREMENT ORGANIZATION CONDITION FOR COVERAGE (CMS-3064-IFC)**

**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:**

Action	Date	FR Cite
NPRM	To Be	Determined

**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, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4282

**RIN:** 0938-AK81

**882. MODIFICATIONS TO MANAGED CARE RULES BASED ON PAYMENT PROVISIONS IN BIPA AND TECHNICAL CORRECTIONS (CMS-4040-F)**

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

**Legal Authority:** BIPA, sec 601 to 605; BIPA, sec 601 to 603; BIPA, sec 607; BIPA, sec 608; BIPA, sec 613; BIPA, sec 619; BIPA, sec 634; ...

**CFR Citation:** 42 CFR 417; 42 CFR 422

**Legal Deadline:** None

**Abstract:** This final rule will implement certain technical and minor changes of the provisions of sections 601 to 634 of the Medicare payment provisions of the Medicare, Medicaid & SCHIP Benefits Improvement and Protection Act of 2000. It is significant because although the changes mandated by BIPA are minor and technical in nature, they involve updates to payment rates.

**Timetable:**

Action	Date	FR Cite
Final Action	To Be	Determined

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

## HHS—CMS

## Long-Term Actions

**Agency Contact:** Alfred G. D'Alberto, Office of Managed Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-1100

RIN: 0938-AK90

### 883. EXTENDING MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENTITLEMENT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS-4018-P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec. 202 of the TWWIA of 1999; PL 106-170 of the TWWIA of 1999

**CFR Citation:** 42 CFR 406.12

**Legal Deadline:** None

**Abstract:** This rule would provide working disabled individuals with continued Medicare entitlement for an additional 54 months beyond the current limit. It would implement the Ticket to Work and Work Incentives Improvement Act of 1999.

**Timetable:** Next Action Undetermined

#### Regulatory Flexibility Analysis

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Denise Cox, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3195

RIN: 0938-AK94

### 884. MEDICARE LIMITS ON THE VALUATION OF A DEPRECIABLE ASSET RECOGNIZED AS AN ALLOWANCE FOR DEPRECIATION AND INTEREST ON CAPITAL INDEBTEDNESS AFTER A CHANGE OF OWNERSHIP (CMS-1004-F)

**Priority:** Other Significant

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1861(v)(1)(O) of the Social Security Act, as amended

**CFR Citation:** 42 CFR 413.134

**Legal Deadline:** None

**Abstract:** This final rule responds to public comments received and makes technical corrections to the Medicare provider reimbursement regulations that set forth requirements related to allowable costs.

**Timetable:** Next Action Undetermined

#### Regulatory Flexibility Analysis

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Ann Pash, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4516

Email: apash@hcfa.gov

RIN: 0938-AL12

### 885. UPDATE INTEREST ASSESSMENT ON MEDICARE OVERPAYMENT AND UNDERPAYMENT (CMS-6014-P)

**Priority:** Other Significant

**Legal Authority:** Social Security Act, sec 1815(d); Social Security Act, sec 1833(j)

**CFR Citation:** 42 CFR 405.378

**Legal Deadline:** None

**Abstract:** This proposed rule would change the formula used to compute interest on provider, supplier overpayments and underpayments.

#### Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

#### Regulatory Flexibility Analysis

**Required:** Undetermined

**Small Entities Affected:** Businesses, Organizations

**Government Levels Affected:** None

**Agency Contact:** Paul Thomas Reed, Financial Management Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3-15-07, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4001

Email: preed2@cms.hhs.gov

RIN: 0938-AL14

### 886. REQUIREMENTS FOR PAID FEEDING ASSISTANTS IN LONG-TERM CARE FACILITIES (CMS-2131-P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1819(a) to (f) of the Social Security Act; sec 1919(a) to (g) of the Social Security Act; PL 100-203

**CFR Citation:** 42 CFR 483.73; 42 CFR 483.75(c)

**Legal Deadline:** None

**Abstract:** This final rule would allow long-term care facilities to use paid feeding assistants to supplement the services of certified nurse aides. If facilities choose this option, feeding assistants must complete a specified training program.

#### Timetable:

Action	Date	FR Cite
NPRM	03/29/02	67 FR 15149
NPRM Comment Period End	05/28/02	
Final Rule	To Be	Determined

#### Regulatory Flexibility Analysis

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** State, Federal

**Agency Contact:** Nola Petrovich, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-4671

RIN: 0938-AL18

### 887. USE OF RESTRAINT AND SECLUSION IN MEDICARE AND MEDICAID PARTICIPATING FACILITIES THAT PROVIDE INPATIENT OR RESIDENTIAL CARE (CMS-2130-P)

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Children's Health Act of 2000

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This proposed rule would implement provisions of the Children's Health Act related to the use of restraints or seclusion for individuals receiving services in health care

## HHS—CMS

## Long-Term Actions

facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** Undetermined

**Federalism:** Undetermined

**Agency Contact:** Frank Sokolik, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-13-23, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-7089  
**RIN:** 0938-AL26

**888. • MEDICARE-ENDORSED PRESCRIPTION DRUG DISCOUNT CARD ASSISTANCE INITIATIVE FOR STATE SPONSORS (CMS-4032-P)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This proposed rule would outline steps that support State efforts to make affordable prescription drugs available to Medicare beneficiaries.

**Timetable:**

Action	Date	FR Cite
NPRM	03/06/02	67 FR 10293
NPRM Comment Period End	05/06/02	
Next Action	Undetermined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

**Agency Contact:** Teresa Decaro, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-17-14, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6604  
Email: tdecaro@cms.hhs.gov  
**RIN:** 0938-AL30

**889. • STATE CHILDREN'S HEALTH INSURANCE PROGRAM; ELIGIBILITY FOR UNBORN CHILDREN (CMS-2127-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 2110

**CFR Citation:** 42 CFR 457

**Legal Deadline:** None

**Abstract:** This regulation would provide States with the option to consider an unborn child to be a targeted low-income child and therefore eligible for SCHIP if other applicable State eligibility requirements are met. This would mean that regardless of the age of the mother, eligibility for the unborn child may be established thereby making services including prenatal care and delivery available.

**Timetable:**

Action	Date	FR Cite
NPRM	03/05/02	67 FR 9936
NPRM Comment Period End	05/06/02	
Final Action	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Kathleen Muriel Farrell, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-03-18, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3285  
**RIN:** 0938-AL37

**890. • HEALTH COVERAGE PORTABILITY FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS (CMS-2151-F)**

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

**Legal Authority:** 42 USC 300gg; PL 104-191

**CFR Citation:** 45 CFR 144.103; 45 CFR 146.101; 45 CFR 146.111; 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.119; 45 CFR 146.145; ...

**Legal Deadline:** None

**Abstract:** This final rule addresses limitations on preexisting exclusions periods and requests for special enrollments.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/07/97	
Interim Final Rule Effective	07/07/97	
Next Action	Undetermined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

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

**Agency Contact:** David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6851

**RIN:** 0938-AL43

**891. • INTERIM FINAL AMENDMENT FOR MENTAL HEALTH PARITY (CMS-2152-IFC)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 2705; PL 107-116; PL 104-191

**CFR Citation:** 45 CFR 146.136

**Legal Deadline:** None

**Abstract:** This interim final rule changes the sunset date of regulations under the Mental Health Parity Act of 1996.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	11/22/97	62 FR 66932
Interim Final Rule Effective	01/01/98	
Interim Final Rule Comment Period End	03/23/98	
Next Action	Undetermined	

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State, Local

**Agency Contact:** David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-16-26, 7500 Security Boulevard, Baltimore, MD 21244

## HHS—CMS

## Long-Term Actions

Phone: 410 786-6851

RIN: 0938-AL44

**892. • PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS-1208-P)****Priority:** Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** Not Yet Determined**CFR Citation:** 42 CFR 408.ff**Legal Deadline:** Final, Statutory, January 1, 2003.**Abstract:** This proposed rule would implement section 606 of BIPA to allow M+C organizations to elect a reduction in capitation payments so that these organizations could offer Medicare part B premium reductions to enrollees.**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** State, Local, Federal**Agency Contact:** Michele Sanders, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-0808

RIN: 0938-AL49

**893. • PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS (CMS-1213-P)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Unfunded Mandates:** Undetermined**Legal Authority:** PL 106-113, Sec 124**CFR Citation:** Not Yet Determined**Legal Deadline:** NPRM, Statutory, October 1, 2002, per section 124 of Public Law 106-113.**Abstract:** This proposed rule would set forth a prospective payment system for psychiatric hospitals.**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis****Required:** Undetermined**Government Levels Affected:** State, Local, Federal**Federalism:** Undetermined**Agency Contact:** Lana Price, Director, Division of End-Stage Renal Disease, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4533

RIN: 0938-AL50

**894. • PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS-1727-P)****Priority:** Substantive, Nonsignificant**Legal Authority:** Sec 1878 of the Social Security Act**CFR Citation:** Not Yet Determined**Legal Deadline:** None**Abstract:** This proposed rule would redefine, clarify, and update the guidelines and procedures for provider reimbursement review board appeals.**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Businesses**Government Levels Affected:** None**Agency Contact:** Morton Marcus, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-26-22, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4477

RIN: 0938-AL54

**895. • DEFINITION OF SEVERE MEDICALLY DETERMINABLE IMPAIRMENT (CMS-2143-P)****Priority:** Other Significant. Major status under 5 USC 801 is undetermined.**Legal Authority:** PL 106-170, sec 201(a)(2)(D)**CFR Citation:** 42 CFR 430; 42 CFR 435; 42 CFR 436**Legal Deadline:** None**Abstract:** This proposed rule would define "severe medically determinable impairment" for purposes of eligibility to Medicaid buy-in programs for employed individuals with a medically improved disability. States have the option, under the Ticket to Work and Work Incentives Improvement Act, of amending their State plans to include workers with a medically improved disability.**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** No**Government Levels Affected:** State, Local, Federal**Federalism:** Undetermined**Agency Contact:** Carey M. O'Connor, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-2117

RIN: 0938-AL57

**896. • PROGRAM FOR ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE): PROGRAM REVISIONS (CMS-1201-IFC)****Priority:** Other Significant**Legal Authority:** 42 USC 1395, as revised by sec 903 of BIPA; 42 USC 1396, as revised by sec 903 of BIPA**CFR Citation:** 42 CFR 460ff**Legal Deadline:** None**Abstract:** This rule revises the interim final rule with comment period that established requirements for Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll. The revisions in this rule will implement section 903 of BIPA.**Timetable:**

Action	Date	FR Cite
Interim Final Rule	To Be	Determined

**Regulatory Flexibility Analysis****Required:** No**Small Entities Affected:** Organizations

## HHS—CMS

## Long-Term Actions

**Government Levels Affected:** State, Tribal

**Federalism:** Undetermined

**Agency Contact:** Janet Samen, Center for Medicare Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-08-15, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-9161

**RIN:** 0938-AL59

**897. • SCHIP; PURCHASE OF FAMILY COVERAGE—BENEFIT FLEXIBILITY IN PARENT COVERAGE (CMS-2148-P)**

**Priority:** Substantive, Nonsignificant

**Unfunded Mandates:** Undetermined

**Legal Authority:** 42 USC 2110

**CFR Citation:** 42 CFR 457

**Legal Deadline:** None

**Abstract:** This proposed rule would provide flexibility to States in defining their benefit package for adults covered under the State Children's Health Insurance Program (SCHIP) family coverage options.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Terese Klitenic, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-25-02, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 410 786-5942

**RIN:** 0938-AL62

**898. • REVISIONS TO MEDICAID COST-SHARING REGULATIONS (CMS-2144-P)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** 42 CFR 447

**Legal Deadline:** None

**Abstract:** This proposed rule would revise existing regulations related to cost-sharing in Medicaid.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State, Tribal

**Federalism:** Undetermined

**Agency Contact:** Ginni Hain, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-16-27, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-6036

**RIN:** 0938-AL66

**899. • REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS-4004-P)**

**Priority:** Other Significant

**Legal Authority:** Sec 521 of BIPA

**CFR Citation:** 42 CFR 426

**Legal Deadline:** NPRM, Statutory, October 1, 2002, Statutory effective date 10/01/2002.

**Abstract:** This rule will incorporate recommendations from an SSA/HHS workgroup to improve the Administrative Law Judge (ALJ) hearing process. ALJs within the SSA who conduct hearings for Medicare fee-for-service and managed care cases are currently governed by the SSA disability regulations. These regulations apply to disability cases and not to Medicare. In an effort to improve the integrity of the appeals process, CMS has recognized the need to develop regulations that are specific to the adjudication of Medicare cases.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** No

**Government Levels Affected:** Undetermined

**Agency Contact:** Tony Culotta, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4661

**RIN:** 0938-AL67

**900. • NOTICE OF INTENT TO CONDUCT NEGOTIATED RULEMAKING FOR SPECIAL PAYMENT PROVISIONS AND STANDARDS FOR SUPPLIERS OF CUSTOM-FABRICATED ORTHOTICS AND PROSTHETICS (CMS-6012-N)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Section 1834(h)(i); 42 USC 1395m(h)(i)

**CFR Citation:** None

**Legal Deadline:** None

**Abstract:** This notice announces standards for suppliers allowed to bill for prosthetics and certain customized orthotics. The Congress requires this proposed rule to be developed by a negotiated rulemaking advisory committee.

**Timetable:**

Action	Date	FR Cite
Notice	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Kathryn S Cox, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3-02-16, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5954

**RIN:** 0938-AL68

**901. • DMERC SERVICE AREAS AND RELATED MATTERS (CMS-1219-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Social Security Act, sec 1842; Social Security Act, sec 1834(a)(12); Social Security Act, sec 1834(h)(3); Social Security Act, sec 1834(j)(1)(E)

**CFR Citation:** 42 CFR 421.210(c); 42 CFR 421.210(d); 42 CFR 421.210(e)

**Legal Deadline:** None

**Abstract:** This proposed rule would allow flexibility in regulatory changes to the DMERC contractor structure.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

## HHS—CMS

## Long-Term Actions

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** James Holt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1-14-27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1953

Email: jholt@cms.hhs.gov

**RIN:** 0938-AL76

**902. • STATE ALLOTMENTS FOR PAYMENT OF MEDICARE PART B PREMIUMS FOR QUALIFYING INDIVIDUALS; FEDERAL FISCAL YEAR 2002 (CMS-2136-PN)**

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

**Legal Authority:** Social Security Act, sec 1902(a)(10); Social Security Act, sec 1933; 42 USC 139; PL 105-33

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** This proposed notice announces the Federal FY 2002 allotments that are available for State agencies to pay Medicare part B premiums for two distinct categories of low-income Medicare beneficiaries. The eligible groups are called qualified individuals.

**Timetable:**

Action	Date	FR Cite
Notice	To Be Determined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Nakielny, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4466

**RIN:** 0938-AL79

**903. • REVISIONS TO CONDITIONS FOR COVERAGE FOR AMBULATORY SURGICAL CENTERS (CMS-3887-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1102; Social Security Act, sec 1832; Social Security Act, sec 1871

**CFR Citation:** 42 CFR 410; 42 CFR 424; 42 CFR 416; 42 CFR 488; 42 CFR 489

**Legal Deadline:** None

**Abstract:** This proposed rule would revise the ambulatory surgical center conditions for coverage to reflect current innovations in healthcare delivery, quality assessment, and performance improvement.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be Determined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** State

**Agency Contact:** Joan Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-5526

**RIN:** 0938-AL80

**904. • FLEXIBILITY IN PAYMENT METHODS FOR SERVICES OF HOSPITALS, NURSING FACILITIES, AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED (CMS-2004-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 105-33

**CFR Citation:** 42 CFR 435; 42 CFR 436; 42 CFR 457

**Legal Deadline:** None

**Abstract:** This final rule removes all references to the "Boren Amendment" and grants States greater flexibility in setting payment rates for inpatient hospital and long-term care services.

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	06/25/01	66 FR 33810
Interim Final Rule Comment Period End	07/25/01	
Interim Final Rule Effective	08/24/01	
Final Action	To Be Determined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State

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

**Agency Contact:** Regina Fletcher, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3293

**RIN:** 0938-AL81

**905. • CONTINUE TO ALLOW STATES AN OPTION UNDER THE MEDICAID SPOUSAL IMPOVERISHMENT PROVISIONS TO INCREASE THE COMMUNITY SPOUSE'S INCOME WHEN ADJUSTING THE PROTECTED RESOURCE ALLOWANCE (CMS-2128-F)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 1924 of the Social Security Act

**CFR Citation:** 42 CFR 431

**Legal Deadline:** None

**Abstract:** This rule will continue CMS' policy of giving States an option to either require, or not require, that income be contributed to a community spouse before additional resources are made available in making certain calculations related to spousal impoverishment protection.

**Timetable:**

Action	Date	FR Cite
NPRM	09/07/01	66 FR 46763
Next Action	Undetermined	

**Regulatory Flexibility Analysis Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Roy Trudel, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-20-15, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-3417

**Related RIN:** Previously reported as 0938-AL06

**RIN:** 0938-AL84

## HHS—CMS

## Long-Term Actions

**906. • MEDICAID COVERAGE RULES FOR INMATES OF PUBLIC INSTITUTIONS (CMS-2077-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Social Security Act, sec 1905(a)(A)

**CFR Citation:** 42 CFR 435.1008; 42 CFR 435.1009; 42 CFR 435.1012; 42 CFR 436.1004

**Legal Deadline:** None

**Abstract:** This rule would provide a new interpretation of the statute in order to eliminate confusion among the States and to ensure consistent application of the FFP exclusionary rules for services provided to inmates of a public institution.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** State, Local

**Agency Contact:** Tom Shenk, Center for Medicaid and State Operations, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-3295

**RIN:** 0938-AL85

**907. • TARGETED CASE MANAGEMENT (CMS-2061-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Sec 1915(g) of the Social Security Act

**CFR Citation:** 42 CFR 431; 42 CFR 440; 42 CFR 441

**Legal Deadline:** None

**Abstract:** This proposed rule would amend the Medicaid regulations to provide for optional coverage of case management services furnished to specific groups, geographic areas, or political subdivisions within a State. This proposed rule rescinds the proposed rule that was published on 10/15/93.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Kathy Poisal, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-5940

**RIN:** 0938-AL87

**908. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2004 RATES (CMS-1470-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1886(d) of the Social Security Act

**CFR Citation:** 42 CFR 412 to 413; 42 CFR 485; 42 CFR 489

**Legal Deadline:** NPRM, Statutory, April 1, 2003.  
Final, Statutory, August 1, 2003.

**Abstract:** We would revise the Medicare acute hospital inpatient prospective payment systems for operating and capital market costs to implement changes arising from our continuing experience with these systems. These changes apply to discharges occurring on or after October 1, 2003.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**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, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-4548

**RIN:** 0938-AL89

**909. • PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2004 (CMS-1469-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** Sec 1888(e) of the Social Security Act

**CFR Citation:** None

**Legal Deadline:** NPRM, Statutory, April 1, 2003.

Final, Statutory, July 31, 2003, final rule to be published before August 1, 2003.

**Abstract:** This annual proposed rule updates the payment rates used under the SNF PPS beginning October 1, 2003.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** William Ullman, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850  
Phone: 401 786-5667

**RIN:** 0938-AL90

**910. • PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS: FY 2004 (CMS-1472-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** BBRA 1999, sec 123; BIPA 2000, sec 307(b)

**CFR Citation:** 42 CFR 412; 42 CFR 413

**Legal Deadline:** None

**Abstract:** This rule establishes a Prospective Payment System for Medicare payment of inpatient hospital services provided by long-term care hospitals to replace the reasonable cost-based payment system under which they are currently paid. It implements section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

## HHS—CMS

## Long-Term Actions

**Timetable:** 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, Centers for Medicare & Medicaid Services, C4-07-07, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-1304

**RIN:** 0938-AL92

**911. • PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS (CMS-1477-P)**

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

**Unfunded Mandates:** Undetermined

**Legal Authority:** PL 106-113, sec 124

**CFR Citation:** Not Yet Determined

**Legal Deadline:** NPRM, Statutory, October 1, 2002.

**Abstract:** This proposed rule would implement a per diem inpatient psychiatric prospective payment system as required by section 124 of Public Law 106-113.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Undetermined

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

**Government Levels Affected:** None

**Federalism:** Undetermined

**Agency Contact:** Lana Price, Director, Division of End-Stage Renal Disease, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4533

**RIN:** 0938-AL93

**912. • HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FOR FY 2004 (CMS-1473-NC)**

**Priority:** Other Significant

**Legal Authority:** Not Yet Determined

**CFR Citation:** Not Yet Determined

**Legal Deadline:** Other, Statutory, June 28, 2003, notice must be published by 06/28/2003 deadline in order to meet statutory effective date of 10/01/2003.

**Abstract:** This notice with comment period sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies for FY 2004. (We must publish this notice by 06/28/04 to meet the statutory effective date of 10/01/04.)

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Susan Levy, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-05-27, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-9364

**RIN:** 0938-AL94

**913. • PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION HOSPITALS (CMS-1474-P)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** Social Security Act, sec 1886(j); PL 105-33; PL 106-554; PL 106-113

**CFR Citation:** 42 CFR 412 to 413

**Legal Deadline:** None

**Abstract:** This rule will address comments on the published proposed rule and finalizes a new prospective payment system for inpatient

rehabilitation facilities beginning on or after 1/1/2004.

**Timetable:** Next Action Undetermined

**Regulatory Flexibility Analysis**

**Required:** No

**Small Entities Affected:** No

**Government Levels Affected:** None

**Agency Contact:** Robert Kuhl, Technical Advisor, Bureau of Policy Development, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-11-06, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4597

**RIN:** 0938-AL95

**914. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2004 (CMS-1476-P)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395W-4

**CFR Citation:** Not Yet Determined

**Legal Deadline:** None

**Abstract:** Revisions to payment policies under the physician fee schedule for calendar year 2004.

**Timetable:**

Action	Date	FR Cite
NPRM	To Be	Determined

**Regulatory Flexibility Analysis**

**Required:** Yes

**Small Entities Affected:** Businesses

**Government Levels Affected:** Federal

**Agency Contact:** Latesha Walker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-1101

**RIN:** 0938-AL96

**Department of Health and Human Services (HHS)  
Centers for Medicare & Medicaid Services (CMS)**
**Completed Actions**
**915. MEDICARE PROGRAM;  
COVERAGE AND ADMINISTRATIVE  
POLICIES FOR CLINICAL  
DIAGNOSTIC LABORATORY TESTS  
(CMS-3250-F)**

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

**CFR Citation:** 42 CFR ch 410

**Completed:**

Reason	Date	FR Cite
Final Action	11/25/01	66 FR 50788

**Regulatory Flexibility Analysis  
Required:** No

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

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

**Agency Contact:** Jacqueline Sheridan  
Phone: 410 786-4635

**RIN:** 0938-AI92

**916. FEE SCHEDULE FOR PAYMENT  
OF AMBULANCE SERVICES AND  
REVISIONS TO THE PHYSICIAN'S  
CERTIFICATION REQUIREMENTS FOR  
COVERAGE OF NONEMERGENCY  
AMBULANCE SERVICES (CMS-1002-  
FC)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 410; 42 CFR 414

**Completed:**

Reason	Date	FR Cite
Final Rule	02/27/02	67 FR 9100

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** None

**Agency Contact:** Glenn McGuirk  
Phone: 410 786-5723

**RIN:** 0938-AK30

**917. MEDICARE PROGRAM;  
REPORTING AND REPAYMENT OF  
OVERPAYMENTS (CMS-6011-P)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 401.310

**Completed:**

Reason	Date	FR Cite
Merged With 0938-AD95	03/06/02	

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** None

**Agency Contact:** Barbara Wright  
Phone: 410 786-4292

**RIN:** 0938-AK45

**918. PROSPECTIVE PAYMENT  
SYSTEM FOR HOSPITAL OUTPATIENT  
SERVICES: CRITERIA FOR  
ESTABLISHING NEW PASS-THROUGH  
CATEGORIES FOR MEDICAL DEVICES  
(CMS-1179-IFC)**

**Priority:** Other Significant

**CFR Citation:** 42 CFR 419

**Completed:**

Reason	Date	FR Cite
Interim Final Rule with Comment Period	11/02/01	66 FR 55850

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** None

**Agency Contact:** Nancy Edwards  
Phone: 410 786-0378  
Email: nedwards@cms.hhs.gov

**RIN:** 0938-AK59

**919. QUALIFICATION REQUIREMENTS  
FOR DIRECTORS OF LABORATORIES  
PERFORMING HIGH COMPLEXITY  
TESTING (CMS-2094-P)**

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

**CFR Citation:** 42 CFR 493.1443

**Completed:**

Reason	Date	FR Cite
NPRM	12/28/01	66 FR 67163
Merged With 0938-AK24	03/21/02	

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** None

**Agency Contact:** Cecelia Hinkel  
Phone: 410 786-3347

**RIN:** 0938-AK83

**920. MEDICAID UPPER PAYMENT  
LIMIT FOR NON-STATE  
GOVERNMENT-OWNED OR  
-OPERATED HOSPITALS (CMS-2134-F)**

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

**CFR Citation:** 42 CFR 447.321

**Completed:**

Reason	Date	FR Cite
NPRM	11/23/01	66 FR 58694
Final Rule	01/18/02	67 FR 2602
Notice	03/19/02	67 FR 12479

**Regulatory Flexibility Analysis  
Required:** No

**Government Levels Affected:** State

**Agency Contact:** Larry Reed  
Phone: 410 786-3325

**RIN:** 0938-AL05

**921. • PHYSICIANS' REFERRALS TO  
HEALTH CARE ENTITIES WITH WHICH  
THEY HAVE FINANCIAL  
RELATIONSHIPS; DELAY OF  
EFFECTIVE DATE OF THE "SET IN  
ADVANCE" PROVISION (CMS-1809-  
IFC)**

**Priority:** Other Significant

**Legal Authority:** 42 USC 1395

**CFR Citation:** 42 CFR 411.354(d)(1)

**Legal Deadline:** None

**Abstract:** This final rule temporarily delays for a one-year period the effective date of the "set in advance" provision in section 411.354(d)(1) contained in the rule entitled "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships," published in the Federal Register on January 4, 2001 (66 FR 856).

**Timetable:**

Action	Date	FR Cite
Interim Final Rule	12/03/01	66 FR 60154
Interim Final Rule Comment Period End	02/01/02	

**Regulatory Flexibility Analysis  
Required:** No

**Small Entities Affected:** Businesses

**Government Levels Affected:** None

**Agency Contact:** Joanne Sinsheimer, Technical Advisor, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 410 786-4620

**RIN:** 0938-AL29

**922. • DEDUCTIBLE AMOUNT FOR  
MEDIGAP HIGH DEDUCTIBLE  
OPTIONS FOR CALENDAR YEAR 2002  
(CMS-2135-N)**

**Priority:** Other Significant

**Legal Authority:** None

**CFR Citation:** None

**Legal Deadline:** None

## HHS—CMS

## Completed Actions

**Abstract:** This notice announces the annual deductible amount for the Medicare supplemental health insurance (Medigap) high deductible options for 2002. The deductible amount represents the annual out-of-pocket expenses (excluding premiums) that a beneficiary who chooses one of these options must pay before the policy begins paying benefits.

**Timetable:**

Action	Date	FR Cite
Notice	12/28/01	66 FR 67266

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

**Agency Contact:** Kathryn McCann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-7623

**RIN:** 0938-AL34

**923. • PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT SERVICES; DELAY IN EFFECTIVE DATE OF CALENDAR YEAR 2002 PAYMENT RATES AND THE PRO RATA REDUCTION ON TRANSITIONAL PASS-THROUGH PAYMENT (CMS-1159-F3)**

**Priority:** Substantive, Nonsignificant**Legal Authority:** 42 USC 1395L**CFR Citation:** 42 CFR 419**Legal Deadline:** None

**Abstract:** This final rule delays the effective date of the payment rates announced for Medicare hospital outpatient services paid under the prospective payment system for calendar year 2002. These rates were announced in a November 30, 2001 final rule (66 FR 59856). In addition, this final rule delays the effective date of the uniform reduction to be applied to each of the transitional pass-through payments for CY 2002.

**Timetable:**

Action	Date	FR Cite
NPRM	08/24/01	66 FR 44672
NPRM Comment Period End	10/03/01	
Final Action	12/31/01	66 FR 67494
Final Action Effective	04/01/02	

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

**Agency Contact:** James Hart, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-2033

**RIN:** 0938-AL35

**924. • DISAPPROVAL OF ALCON LABORATORIES REQUEST FOR AN ADJUSTMENT IN PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES FURNISHED BY AMBULATORY SURGICAL CENTERS (CMS-3061-FN)**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 1832(a)(2)(F)(i) of the Social Security Act; 42 USC 1833(i)(2)(A) of the Social Security Act; 42 USC 1395K(a)(2)(F)(i); 42 USC 13951(i)(2)(A)

**CFR Citation:** None

**Legal Deadline:** Other, Statutory, February 22, 2002, Notice.

**Abstract:** This final notice responds to comments received and announces which lenses will qualify as new technology intraocular lenses.

**Timetable:**

Action	Date	FR Cite
Notice	02/22/02	67 FR 8270

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

**Agency Contact:** Lori Davis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244  
Phone: 410 786-0710

**RIN:** 0938-AL36

**925. • CORRECTION OF CERTAIN CALENDAR YEAR 2003 PAYMENT RATES UNDER THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND THE PRO RATA REDUCTION ON TRANSITIONAL PASS-THROUGH PAYMENT (CMS-1159-F4)**

**Priority:** Other Significant**Legal Authority:** 42 USC 1395L; BBA 97; BBRA 99; BIPA 00**CFR Citation:** 42 CFR 419**Legal Deadline:** None

**Abstract:** This final rule corrects errors that affect the amount and factors used to determine the payment rates for services paid under the hospital prospective payment system as published in the November 30, 2001 final rule. This final rule also corrects the amount of the uniform reduction to be applied to each of the transitional pass-through payments CY 2002.

**Timetable:**

Action	Date	FR Cite
Final Action	03/01/02	67 FR 9556
Final Action Effective	04/01/02	

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

**Agency Contact:** Joan H. Sanow, Center for Health Plans and Providers, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4-11-16, Baltimore, MD 21244  
Phone: 410 786-5763

**RIN:** 0938-AL42

**926. • PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—CORRECTION NOTICE (CMS-1163-CN)**

**Priority:** Other Significant**Legal Authority:** None**CFR Citation:** None**Legal Deadline:** None

**Abstract:** This correction notice will clarify special responsibilities of Medicare hospitals that offer services for treatment of emergency medical conditions, to promote consistent application of the Emergency Treatment and Labor Act to situations not discussed in current regulations.

## HHS—CMS

## Completed Actions

## Timetable:

Action	Date	FR Cite
Notice	03/27/02	67 FR 13278

**Regulatory Flexibility Analysis Required:** No

**Government Levels Affected:** None

**Agency Contact:** William Ullman, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4-13-15, 7500 Security Boulevard, Baltimore, MD 21244-1850

Phone: 401 786-5667

**Related RIN:** Previously reported as 0938-AK47

**RIN:** 0938-AL47

**Department of Health and Human Services (HHS)  
Administration for Children and Families (ACF)**

## Proposed Rule Stage

**927. PROGRAM PERFORMANCE STANDARDS FOR THE OPERATION OF HEAD START PROGRAMS**

**Priority:** Other Significant

**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	12/00/02	

**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

**928. SAFEGUARDING CHILD SUPPORT AND EXPANDED FPLS INFORMATION**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** 42 USC 652 to 654A; 42 USC 663

**CFR Citation:** 45 CFR 303.3; 45 CFR 303.21; 45 CFR 303.70

**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	12/00/02	

**Regulatory Flexibility Analysis Required:** No

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

**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

**929. DEVELOPMENTAL DISABILITIES AND BILL OF RIGHTS ACT**

**Priority:** Substantive, Nonsignificant

**Legal Authority:** PL 106-402; USC 15001 et seq

**CFR Citation:** 45 CFR 1385 to 1388

**Legal Deadline:** Final, Statutory, October 30, 2001, The final rule for the "Indicator of Progress" must be effective by October 1, 2001. All other changes to the regulation are required to be made by October 30, 2001.

**Abstract:** A notice of proposed rulemaking will be published in the Federal Register 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	12/00/02	

**Regulatory Flexibility Analysis Required:** No

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

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

**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

**Department of Health and Human Services (HHS)**  
**Administration for Children and Families (ACF)**

**Final Rule Stage**

**930. 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	08/00/02	

**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

**931. 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
Final Action	12/00/02	

**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

**932. 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	11/00/02	

**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

**933. 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	12/00/02	

**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

**934. 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 that 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	12/00/02	

**Regulatory Flexibility Analysis Required:** No

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

**Government Levels Affected:** None

**Agency Contact:** Douglas Klafehn, Deputy Associate Commissioner, Head Start, Department of Health and Human Services, Administration for Children and Families, 330 C Street SW., Washington, DC 20447  
 Phone: 202 205-8569

HHS—ACF

Final Rule Stage

Email: dklafehn@acf.dhhs.gov

RIN: 0970—AC00

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**Department of Health and Human Services (HHS)**  
**Administration for Children and Families (ACF)**

Completed Actions

**935. HIGH PERFORMANCE BONUS AWARDS UNDER THE TANF PROGRAM****Priority:** Substantive, Nonsignificant**CFR Citation:** 45 CFR 270**Completed:**

Reason	Date	FR Cite
Withdrawn	03/15/02	

**Regulatory Flexibility Analysis Required:** No**Government Levels Affected:** State**Agency Contact:** Stephanie Fanjul  
Phone: 202 690-6782  
Email: sfanjul@acf.dhhs.gov**RIN:** 0970—AC06

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**Department of Health and Human Services (HHS)**  
**Administration on Aging (AOA)**

Proposed Rule Stage

**936. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, 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; 45 CFR 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 issue a notice of proposed rulemaking by fall of 2002.

**Timetable:**

Action	Date	FR Cite
NPRM	10/00/02	

**Regulatory Flexibility Analysis Required:** Yes**Small Entities Affected:** Businesses, Governmental Jurisdictions**Government Levels Affected:** State, Tribal**Federalism:** Undetermined**Additional Information:** Incorrectly reported as under Section 610 Review in April 2001.**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

[FR Doc. 02—11100 Filed 05—10—02; 8:45 am]

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