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Monday,
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Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

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 rulemaking actions under development or review by Federal departments and agencies. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration. Anyone wishing to communicate to the Department their views on the potential rulemakings outlined below is invited to do so.

When the Department publishes a regulatory proposal, information about it automatically becomes available to the public at www.regulations.gov, the Governmentwide Web site for submission of comments on proposed regulations. Citizens may submit comments by clicking the Submit a Comment on the Regulation link on this site, which will open a blank comment form that includes instructions on how to submit the comment and what information must be provided for the comment to be considered. Comments submitted via www.regulations.gov are transmitted to the Department daily, and, as legally required, all comments are reviewed and taken into account if a final regulation is developed.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided below reflects an effort to present for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of notices of proposed rulemaking, or final rules within the next 12 months. (Also included, in several Long-Term Action sections, are summaries of actions that we will probably not take any earlier than 12 months after publication of this agenda.) We welcome the views of all concerned with regard to these planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries. Or, if early attention at the Secretary's level is seen as required, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: June 9, 2004.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
813	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991–AB06
814	Claims Collection	0991–AB18
815	Salary Offset	0991–AB19
816	Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions to the Waiver Provisions of the OIG's Exclusion Authorities	0991–AB33

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
817	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
818	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
819	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
820	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23
821	Technical Revisions to HIPDB Data Collection Activities	0991–AB31

Office of the Secretary—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
822	Revisions to Regulations Addressing the OIG's Authority to Impose Civil Money Penalties and Assessments	0991–AB03
823	Health Insurance Portability and Accountability Act—Enforcement	0991–AB29

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Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
824	Tax Refund Offset	0991–AB17
825	Implementation of the Equal Access to Justice Act in Agency Proceedings	0991–AB22
826	OIG Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program	0991–AB30

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
827	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
828	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
829	Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice	0930–AA11
830	Mandatory Guidelines for Federal Workplace Drug Testing Programs; Specimen Validity Testing	0930–AA13

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
831	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
832	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

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
833	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
834	Food Labeling; Prominence of Calories	0910–AF22
835	Food Labeling; Serving Sizes	0910–AF23
836	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43

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Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
837	Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics	0910–AA49
838	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
839	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
840	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
841	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
842	Food Standards: General Principles and Food Standards Modernization	0910–AC54
843	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
844	Reporting Information Regarding Falsification of Data	0910–AC59
845	Definition of ''Serious Adverse Health Consequences'' Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AF06
846	Health Claims	0910–AF09
847	Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water	0910–AF10
848	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
849	Cochineal Extract and Carmine Label Declaration	0910–AF12
850	Charging for Investigational Drugs	0910–AF13
851	Treatment Use of Investigational Drugs	0910–AF14
852	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Derivatives of Blood	0910–AF16
853	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol	0910–AF18
854	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
855	Latex Condoms: Special Controls	0910–AF21
856	Blood Initiative—Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
857	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
858	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
859	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
860	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
861	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
862	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
863	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
864	Labeling for Human Prescription Drugs; Revised Format	0910–AA94
865	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement	0910–AB28
866	CGMP for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)	0910–AB76
867	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
868	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
869	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
870	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
871	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC39
872	Registration of Food and Animal Feed Facilities	0910–AC40
873	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
874	Presubmission Conferences	0910–AC44
875	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
876	Blood Initiative—Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma	0910–AF26

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Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
877	Over-the-Counter (OTC) Drug Review—Antiperspirant Products	0910–AF30
878	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
879	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
880	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
881	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
882	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
883	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
884	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
885	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
886	Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements	0910–AC50
887	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
888	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
889	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07
890	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
891	Current Good Manufacutring Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
892	Infant Formula Quality Factors	0910–AF28
893	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
894	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
895	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
896	Over-the-Counter (OTC) Drug Review	0910–AA01
897	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910–AA04
898	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910–AA89
899	Blood Initiative	0910–AB26
900	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products	0910–AB27
901	Supplements and Other Changes to an Approved Application	0910–AB61
902	Current Good Manufacturing Practice for Medicated Feeds	0910–AB70
903	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910–AB91
904	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910–AC19
905	Bar Code Label Requirements for Human Drug Products and Blood	0910–AC26
906	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC38
907	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910–AC43
908	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AC56
909	Revision of the Requirements for Spore-Forming Microorganisms	0910–AC57
910	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) **(Completion of a Section 610 Review)**	0910–AC58
911	Over-the-Counter (OTC) Drug Review—Antidiarrheal Products	0910–AF29

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Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
912	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
913	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44
914	Intestines Added to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA62
915	Notice of Proposed Rulemaking to Amend the Final Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906–AA63
916	National Vaccine Injury Compensation Program; Revisions and Additions to the Vaccine Injury Table	0906–AA66
917	Liability Protection for Certain Free Clinic Health Professionals	0906–AA67
918	National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy	0906–AA68

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
919	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
920	Smallpox Vaccine Injury Compensation Program: Administrative Implementation	0906–AA61
921	Requirements Establishing a Limitation on Administrative Expenses; Ryan White CARE Act Title IV Grants for Coordinated Services and Access to Research	0906–AA65

Health Resources and Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
922	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906–AA57

National Institutes of Health—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
923	Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health (NIH)	0925–AA10
924	National Institutes of Health Training Grants	0925–AA28
925	Standards for a National Chimpanzee Sanctuary System	0925–AA31
926	National Institutes of Health AIDS Research Loan Repayment Program	0925–AA32
927	National Institutes of Health Extramural Loan Repayment Program for Clinical Researchers	0925–AA33
928	National Institutes of Health Pediatric Research Loan Repayment Program	0925–AA34
929	National Institutes of Health Loan Repayment Program for Health Disparities Research	0925–AA35
930	National Institutes of Health Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds	0925–AA36
931	National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program	0925–AA41

National Institutes of Health—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
932	National Institutes of Health Loan Repayment Program for Research Generally	0925–AA18
933	National Institutes of Health Center Grants	0925–AA24

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National Institutes of Health—Completed Actions

Sequence Number	Title	Regulation Identifier Number
934	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	0925–AA20

Office of Public Health and Science—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
935	Human Subjects Protection Regulations: Additional Protections for Adult Individuals with Impaired Decisionmaking Capacity	0940–AA11

Office of Public Health and Science—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
936	Public Health Service Policies on Research Misconduct	0940–AA04

Office of Public Health and Science—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
937	Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940–AA01
938	Human Subjects Protection Regulations: Institutional Review Boards Registration Requirements	0940–AA06
939	Federal Policy for the Protection of Human Subjects Technical Amendment	0940–AA10

Office of Public Health and Science—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
940	Human Subjects Protection Regulations: Training and Education Requirements for Institutional Officials, Institutional Review Board Members and Staff, Human Protections Administrators, and Investigator	0940–AA08

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
941	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)	0938–AG81
942	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-P) **(Section 610 Review)**	0938–AG82
943	Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants (CMS-3835-P)	0938–AH17
944	Hospice Care—Conditions of Participation (CMS-3844-P)	0938–AH27
945	Standard Unique National Health Plan Identifiers (CMS-6017-P)	0938–AH87
946	Appeals of Carrier Determination that a Supplier Fails to Meet the Requirements for Medicare Billing Privileges (CMS-6003-P2)	0938–AI49
947	Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions and Establishment of a Quality Assessment and Improvement Program (CMS-1910-P2)	0938–AJ17
948	Supplier Standards for Home Oxygen, Therapeutic Shoes, and Home Nutrition Therapy (CMS-6010-P)	0938–AJ98
949	Health Insurance Reform: Claims Attachments Standards (CMS-0050-P)	0938–AK62
950	Organ Procurement Organization Conditions for Coverage (CMS-3064-P)	0938–AK81
951	Use of Restraint and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938–AL26

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Centers for Medicare & Medicaid Services—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
952	Provider Reimbursement Determinations and Appeals (CMS-1727-P)	0938–AL54
953	Health Coverage Portability's Request for Information on Benefit-Specific Waiting Periods (CMS-2150-NC)	0938–AL64
954	Revisions to Conditions for Coverage for Ambulatory Surgical Centers (CMS-3887-P)	0938–AL80
955	Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-P)	0938–AL88
956	Modifications to Electronic Transactions and Code Sets (CMS-0009-P)	0938–AM50
957	Changes to the Hospital Outpatient Prospective System and Calendar Year 2005 Payment Rates (CMS-1427-P)	0938–AM75
958	Ticket to Work: Defining Individuals with Potentially Severe Disabilities and Providing a Work Threshold (CMS-2172-P)	0938–AM79
959	Payment Error Rate Measurement (PERM) Program (CMS-2186-P)	0938–AM86
960	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938–AM87
961	Hospital Conditions of Participation: Requirements For History and Physical Examinations; Authentication of Verbal Orders, Securing Medications and Post-Anesthesia Evaluations (CMS-3122-P)	0938–AM88
962	Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005 (CMS-1429-P)	0938–AM90
963	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P)	0938–AM98
964	Physician Referral for Nuclear Medicine Services and Supplies (CMS-1261-P)	0938–AN04
965	Medicare Advantage Program Title II (CMS-4069-P)	0938–AN06
966	Special Rules for Employer-Sponsored Drug Programs: Subsidies to Encourage Retention (Title I) (CMS-2199-P)	0938–AN07
967	Medicare Drug Benefit Effective Calendar Year 2006 (Title I) (CMS-4068-P)	0938–AN08
968	Enhanced DSH Treatment for Certain Hospitals (CMS-2198-P)	0938–AN09
969	Prior Determination Process (CMS-6024-P)	0938–AN10
970	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-P)	0938–AN14
971	Update of the List of Covered Procedures for Ambulatory Surgical Centers for 2005 (CMS-1478-PN)	0938–AN23
972	Revisions to HIPAA Code Sets (CMS-0013-P)	0938–AN25
973	Payment for Clinical Laboratory Tests (CMS-1494-P)	0938–AN26
974	Prospective Payment System for Long Term Care Hospitals: Annual Payment Rate Updates and Policy Changes for 2006 (CMS-1483-P)	0938–AN28

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
975	Use of Restraint and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938–AJ96
976	Revisions to the Medicare Appeals Process (CMS-4004-FC)	0938–AL67
977	Electronic Medicare Claims Submission (CMS-0008-F)	0938–AM22
978	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2005 (CMS-1249-N)	0938–AM46
979	Title I: Non-Federal Governmental Plans Exempt From HIPAA (CMS-2033-F)	0938–AM71
980	Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-FC)	0938–AM73
981	Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles Scooter(CMS-3017-IFC)	0938–AM74
982	Hospice Wage Index FY 2005 (CMS-1264-N)	0938–AM78
983	Changes to the Hospital Inpatient Prospective Payment System and FY 2005 Rates (CMS-1428-F)	0938–AM80
984	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2005 (CMS-1360-N)	0938–AM82
985	Home Health Prospective Payment System Rate Update FY 2005 (CMS-1265-P)	0938–AM93
986	Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004—Correction Notice CMS-1372-IFC)	0938–AM97
987	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date (CMS-1809-F5)	0938–AM99
988	Time Limitation on Record keeping Requirements Under the Drug Rebate Program (CMS-2188-P)	0938–AN01
989	Extended Availability of Unexpended SCHIP Funds From the Appropriation for FYs 1998 Through 2004; Authority To Use a Portion of SCHIP Funds for Medicaid Expenditures (CMS-2187-N)	0938–AN03
990	FY 2005 SCHIP Allotments (CMS-2201-N)	0938–AN11
991	Schedule for Publishing Medicare Final Regulations After a Proposed or Interim Final Regulation (CMS-9026-N)	0938–AN12
992	Evaluation Criteria and Standards for Quality Improvement Program Contracts (CMS-3142-NC)	0938–AN13

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Centers for Medicare & Medicaid Services—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
993	Part A Premiums for Calendar Year 2005 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8022-N)	0938–AN15
994	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2005 (CMS-8021-N)	0938–AN16
995	Medicare Part B Monthly Actuarial Rates and Premium Rate Beginning January 1, 2005 (CMS-8020-N)	0938–AN18
996	Fee Schedule for Payment of Ambulance Services-Update for Calendar Year 2005 (CMS-1267-N)	0938–AN20
997	Procedure for Producing Guidance Documents Describing Medicare's Coverage Process (CMS-3141-N)	0938–AN21
998	Amendment to the Interim Final Regulation for Mental Health Parity (CMS-2152-F2)	0938–AN22
999	Medicare Ambulance Fee Schedule Update (CMS-1492-IFC)	0938–AN24
1000	Medicare Secondary Payer (MSP): Workmen's Compensation (CMS-1272-FC)	0938–AN27
1001	Random Prepayment Review (CMS-6022-IFC)	0938–AN31
1002	Additional Payments for Certain Medicare Part B Drugs (CMS-1280-FC)	0938–AN34
1003	Federal Enforcement in Group and Individual Health Insurance Markets (CMS-2019-F)	0938–AN35
1004	Fire Safety Requirements for Certain Health Care Facilities, Amendment (CMS-3047-F2)	0938–AN36

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
1005	Requirements for Establishing and Maintaining Medicare Billing Privileges (CMS-6002-F)	0938–AH73
1006	Medicare Outcome and Assessment Information Set (OASIS) Data Reporting Requirements (CMS-3006-F)	0938–AJ10
1007	Hospital Conditions of Participation: Laboratory Services (CMS-3014-F)	0938–AJ29
1008	Medicare Hospice Care Amendments (CMS-1022-F)	0938–AJ36
1009	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships—Phase II (CMS-1810-IFC)	0938–AK67
1010	Continuation of Medicare Entitlement When Disability Benefit Ends Because of Substantial Gainful Activity (CMS-4018-F)	0938–AK94
1011	Medicare Program; Interest Calculation (CMS-6014-F)	0938–AL14
1012	Health Coverage Portability for Group Health Plans and Group Health Insurance Issuers (CMS-2151-F)	0938–AL43
1013	Prospective Payment System for Inpatient Psychiatric Facilities FY 2004 (CMS-1213-F)	0938–AL50
1014	DMERC Service Areas and Related Matters (CMS-1219-F)	0938–AL76
1015	Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services (CMS-3119-F)	0938–AM36
1016	Hospital Patients' Rights CoP—Standard Safety Compliance Committees (CMS-3120-P)	0938–AM39
1017	Requirements for Nursing Homes To Identify the Number of Licensed and Unlicensed Nurses (CMS-3121-F)	0938–AM55
1018	Covered Outpatient Drugs Under the Medicaid Drug Rebate Program (CMS-2174-P)	0938–AM81
1019	Revisions to Cost Sharing Regulations (CMS-2144-P)	0938–AM94
1020	Medicare Program; Hospital Outpatient Prospective Payment System Payment Reform for Calendar Year 2004 CMS-1371-IFC	0938–AM96
1021	Payment for Respiratory Assist Devices with Bi-level Capability and a Back-up Rate (CMS-1167-F)	0938–AN02
1022	Manufacturers' Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals (CMS-1380-IFC)	0938–AN05
1023	Nondiscrimination In Post-Hospital Referral to Home Health Agencies and Other Entities (CMS-1224-F)	0938–AN19
1024	Nondiscrimination in Health Coverage and Bonafide Wellness Plans in the Group Market (CMS-2022-F)	0938–AN29
1025	Hospital Conditions of Participation: Patients' Rights (CMS-3018-F)	0938–AN30

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1026	Health Insurance Reform: Standard Unique Health Care Provider Identifier (CMS-0045-F)	0938–AH99
1027	Coverage of Religious Nonmedical Health Care Institutions (CMS-1909-F)	0938–AI93
1028	All Provider Bad Debt Payment (CMS-1126-F)	0938–AK02
1029	Review of National Coverage Determinations and Local Coverage Determinations (CMS-3063-F)	0938–AK60
1030	Rate of Reimbursement of Photocopy Expenses for Quality Improvement Organizations (CMS-3055-F)	0938–AK68

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Centers for Medicare & Medicaid Services—Completed Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
1031	Elimination of Statement of Intent Procedures for Filing Medicare Claims (CMS-1185-F)	0938–AK79
1032	Permitting Premium Reductions as Additional Benefits Under Medicare+Choice Plans (CMS-6016-F)	0938–AL49
1033	Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates (CMS-1471-F)	0938–AL91
1034	Criteria for Determining Whether a Drug is Considered Usually Self-Administered (CMS-1228-P)	0938–AM13
1035	Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for Calendar Year 2004 (CMS-8016-N)	0938–AM31
1036	Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2004 (CMS-8017-N)	0938–AM32
1037	Part A Premiums for Calendar Year 2004 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8018-N)	0938–AM33
1038	Grants to States for Operation of Qualified High Risk Pools (CMS-2179-FC)	0938–AM42
1039	Fee Schedule for Payment of Ambulance Services Update for Calendar Year 2004 (CMS-1232-FCC)	0938–AM44
1040	Exclusion of Medicare Benefits for Aliens Not Lawfully Present in the United States (CMS-1222-FC)	0938–AM47
1041	Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures (CMS-6146-P)	0938–AM54
1042	Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility (CMS-1262-F)	0938–AM72
1043	Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes (Effective 7/1/04) (CMS-1263-F)	0938–AM84
1044	Disproportionate Share Hospital (DSH) Payments Institutions for Mental Disease (IMDs) (CMS-2062-N)	0938–AM89
1045	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Extension of Partial Delay of Effective Date (CMS-1809-F4)	0938–AM95
1046	Notice of One-Time Appeal Process for Hospital Wage Index Classification (CMS-1373-N)	0938–AN00

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1047	Safeguarding Child Support and Expanded Federal Parent Locator Services (FPLS) Information	0970–AC01
1048	Developmental Disabilities and Bill of Rights Act	0970–AC07
1049	Administrative Costs for Children in Title IV-E Foster Care	0970–AC14
1050	Administrative Cost Sharing Under TANF	0970–AC15

Administration for Children and Families—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
1051	Child Support Enforcement Program; Federal Tax Refund Offset	0970–AC09
1052	Head Start Transportation	0970–AC16

Administration for Children and Families—Completed Actions

Sequence Number	Title	Regulation Identifier Number
1053	Child Support Enforcement for Indian Tribes	0970–AB73
1054	Charitable Choice Provisions Applicable to the Temporary Assistance for Needy Families Program	0970–AC12
1055	Community Services Block Grant Charitable Choice	0970–AC13

HHS

Administration on Aging—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
1056	Grants for State and Community Programs on Aging, Training, Research, and Discretionary Programs; Vulnerable Elder Rights; Grants to Indians and Native Hawaiians	0985–AA00

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

Proposed Rule Stage

813. 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 federally qualified health centers and certain service providers where a significant community benefit exists.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

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

Related RIN: Related to 0991–AA91

RIN: 0991–AB06

814. CLAIMS COLLECTION

Priority: Substantive, Nonsignificant

Legal Authority: 31 USC 3711; 31 CFR 900 to 904

CFR Citation: 45 CFR 30

Legal Deadline: None

Abstract: The Department will amend part 30 of title 45 of the Code of Federal Regulations (CFR) to reflect the amendments to the Federal Claims Collection Act made by the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, as implemented by the Department of the Treasury at 31 CFR 900-904. The proposed rule will prescribe the standards and procedures for the Department's use in the administrative collection, offset, compromise, and suspension or termination of debts owed to the Department. The proposed rule is required in order to bring the Department's claims collection provisions in compliance with the Department of the Treasury regulations.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	
NPRM Comment Period End	09/00/04	
Final Rule	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB18

815. SALARY OFFSET

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 5 USC 5514; 5 CFR 550

CFR Citation: 45 CFR 33

Legal Deadline: None

Abstract: The Department will add a new part 33 to title 45 of the Code of Federal Regulations (CFR) to implement the salary offset provisions of the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104-134, 110 Stat. 1321 to 1358, codified at 5 U.S.C. 5514, as implemented by the Office of Personnel Management at 5 CFR part 550, subpart K. The proposed rule is required in order to bring the Department's salary offset provisions in compliance with Governmentwide regulations published by the Office of Personnel Management.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	
NPRM Comment Period End	09/00/04	
Final Rule	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews, Associate General Counsel, Department of Health and Human Services, Office of the Secretary, Office of the General Counsel, Room 5362, HHS Cohen Building, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–0150

RIN: 0991–AB19

816. • MEDICARE AND FEDERAL HEALTH CARE PROGRAMS: FRAUD AND ABUSE; REVISIONS TO THE WAIVER PROVISIONS OF THE OIG'S EXCLUSION AUTHORITIES

Priority: Substantive, Nonsignificant

Legal Authority: Sec 949, PL 108–173; Sec 4331, PL 105–33; Sec 1128(c)(3)(b), Social Security Act

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: In accordance with section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act

HHS—OS **Proposed Rule Stage**

of 2003, this rule would revise the OIG's exclusion authority to permit any Federal healthcare program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), (a)(3), or (a)(4) of the Social Security Act.

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	
NPRM Comment Period End	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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–AB33

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

Final Rule Stage

817. 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	12/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

Related RIN: Related to 0991–AB06

RIN: 0991–AA91

818. 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. Major status under 5 USC 801 is undetermined.

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
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

Agency Contact: Robinsue Frohboese, Principal Deputy Director, Office for Civil Rights, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW., Washington, DC 20202 Phone: 202 619–0403

RIN: 0991–AB10

819. SAFE HARBOR FOR WAIVER OF BENEFICIARY COINSURANCE AND DEDUCTIBLE AMOUNTS FOR A MEDICARE SELECT POLICY

Priority: Substantive, Nonsignificant

Legal Authority: PL 100–93, sec 14(a)

CFR Citation: 42 CFR 1001

Legal Deadline: None

Abstract: This final rule will expand the existing safe harbor for certain waivers of beneficiary coinsurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will protect waivers of coinsurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.

Timetable:

Action	Date	FR Cite
NPRM	09/25/02	67 FR 60202
NPRM Comment Period End	10/25/02	
Final Rule	04/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

HHS—OS

Final 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

RIN: 0991–AB16

820. CLARIFICATION OF TERMS AND APPLICATION OF PROGRAM EXCLUSION AUTHORITY FOR SUBMITTING CLAIMS CONTAINING EXCESSIVE CHARGES

Priority: Substantive, Nonsignificant

Legal Authority: Sec 112B (6) (6)(A) of the Social Security Act

CFR Citation: 42 CFR 1001

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	09/15/03	68 FR 53939
NPRM Comment Period End	11/14/03	
Final Action	01/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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

RIN: 0991–AB23

821. • TECHNICAL REVISIONS TO HIPDB DATA COLLECTION ACTIVITIES

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

Legal Authority: Sec 221(a), PL 104–91; Sec 1128E(b)(2), Social Security Act

CFR Citation: 45 CFR 61

Legal Deadline: None

Abstract: This rule makes technical changes to the Healthcare Integrity and Protection Data Bank data collection reporting requirements by clarifying the types of personal numeric identifiers that may be reported to the data bank in connection with adverse actions. The rule classifies that in lieu of a Social Security Number (SSN), an individual taxpayer identification number (ITIN) may be reported to the data bank when, in those limited situations, an individual does not have a SSN.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/00/04	
Interim Final Rule Comment Period End	11/00/04	

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–AB31

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

Long-Term Actions

822. REVISIONS TO REGULATIONS ADDRESSING THE OIG'S AUTHORITY TO IMPOSE CIVIL MONEY PENALTIES AND ASSESSMENTS

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

823. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT—ENFORCEMENT

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

Legal Authority: Subtitle F of title II of PL 104–191; 42 USC 1320d–5

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rulemaking would seek to establish a framework for enforcing compliance with the ''administrative simplification'' provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 — subtitle F of title II of Public Law 104-191, through the imposition of civil money penalties.

HHS—OS **Long-Term Actions**

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Conrad, Department of Health and Human Services, Room 5347, Office of the General Counsel, 330 Independence Avenue SW., Washington, DC 20201 Phone: 202 690–1840

RIN: 0991–AB29

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

824. TAX REFUND OFFSET

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

CFR Citation: 45 CFR 31

Completed:

Reason	Date	FR Cite
Final Rule	12/18/03	68 FR 70444

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews Phone: 202 619–0150

RIN: 0991–AB17

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

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

CFR Citation: 45 CFR 13

Completed:

Reason	Date	FR Cite
Final Rule	01/21/04	69 FR 2843

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Katherine M. Drews Phone: 202 619–0150

Related RIN: Previously reported as 0990–AA02

RIN: 0991–AB22

826. • OIG CIVIL MONEY PENALTIES UNDER THE MEDICARE PRESCRIPTION DRUG DISCOUNT CARD PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: Sec 101, PL 108–173; Sec 1860D–31, Social Security Act

CFR Citation: 42 CFR 1003

Legal Deadline: None

Abstract: This rule sets forth the OIG's new authority for imposing civil money penalties against endorsed sponsors under the medicare prescription drug discount card program that knowingly engage in false or misleading marketing practicies; overcharge program enrollees; or misuse transtional assistance funds.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/19/04	69 FR 28842
Interim Final Rule Comment Period End	07/19/04	

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–AB30

Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) — Proposed Rule Stage

827. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

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

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 nonmedical, 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:

Action	Date	FR Cite
NPRM	11/00/04	

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: Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn, Rockville, MD 20857 Phone: 301 443–2619

RIN: 0930–AA10

Department of Health and Human Services (HHS) — Final Rule Stage
Substance Abuse and Mental Health Services Administration (SAMHSA)

828. MANDATORY GUIDELINES FOR THE FEDERAL WORKPLACE DRUG TESTING PROGRAM

Priority: Other Significant

Legal Authority: PL 100–71; 5 USC 7301

CFR Citation: None

Legal Deadline: NPRM, Statutory, December 2003.

Abstract: HHS is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluids at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

Timetable:

Action	Date	FR Cite
Notice	04/13/04	69 FR 19673
Final Action	04/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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
Fax: 301 443–1450
Email: jfaha@samhsa.gov

RIN: 0930–AA12

Department of Health and Human Services (HHS) — Completed Actions
Substance Abuse and Mental Health Services Administration (SAMHSA)

829. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) CHARITABLE CHOICE

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

CFR Citation: 42 CFR 54, sec 54.1—13; 42 CFR 54a, sec 54a.1—14

Completed:

Reason	Date	FR Cite
Final Rule	09/30/03	68 FR 56429

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

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

Agency Contact: Winnie Mitchell
Phone: 301 443–2324
Fax: 301 443–0247

RIN: 0930–AA11

830. • MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS; SPECIMEN VALIDITY TESTING

Priority: Other Significant

Legal Authority: PL 100–71, sec 503

CFR Citation: None

Legal Deadline: None

Abstract: HHS is establishing standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These standards ensure that specimen validity testing (SVT) and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

Timetable:

Action	Date	FR Cite
Notice	04/13/04	69 FR 19644

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Agency Contact: Walter F. Vogel, CSAP, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, CSAP, Suite 815, Rockville II, Rockville, MD 20857
Phone: 301 443–6014

RIN: 0930–AA13

Department of Health and Human Services (HHS) — Proposed Rule Stage
Centers for Disease Control and Prevention (CDC)

831. AMENDMENTS TO QUALITY ASSURANCE AND ADMINISTRATIVE PROVISION FOR APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

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

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	10/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Roland Berry Ann, Acting Chief, Respirator Branch, National Personal Protection Technology Laboratory, Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236
Phone: 412 386–4000

RIN: 0920–AA04

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

Completed Actions

832. 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

CFR Citation: 42 CFR 83

Completed:

Reason	Date	FR Cite
Final Action	05/28/04	69 FR 30763

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Larry Elliott
Phone: 513 841–4498

RIN: 0920–AA07

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

Prerule Stage

833. 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 to 263–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 to 360j; 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 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 add to or revise current reporting requirements; to revise certain reporting time frames; and propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Comment Review End	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Elizabeth J Sadove, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and ResearchAdministration, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562

RIN: 0910–AA97

834. • FOOD LABELING; PROMINENCE OF CALORIES

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 101.9

Legal Deadline: None

Abstract: In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the nation's obesity problem. The ANPRM will request comments on ways to give more prominence to ''calories'' on the food label.

Timetable:

Action	Date	FR Cite
ANPRM	10/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Shellee Anderson, Team Leader, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1450
Fax: 301–436–2636
Email: shellee.anderson@hhs.fda.gov

RIN: 0910–AF22

835. • FOOD LABELING; SERVING SIZES

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

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 101.9(b)

Legal Deadline: None

Abstract: In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the agency will issue an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the nation's obesity problem. The ANPRM will request comments on changes to the agency's nutrition labeling regulations on serving size and comments on allowance of truthful, nonmisleading and useful approaches for promoting consumption of smaller portion sizes.

Timetable:

Action	Date	FR Cite
ANPRM	10/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

HHS—FDA **Prerule Stage**

Federalism: Undetermined

Agency Contact: Lori LeGault, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–840, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1791
Fax: 301–436–2635
Email: llegault@cfsan.fda.gov

RIN: 0910–AF23

836. • OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	11/00/04	
NPRM (UVA/UVB)	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF43

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

Proposed Rule Stage

837. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR DRUGS AND BIOLOGICS

Priority: Other Significant

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; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514; 21 CFR 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271

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 drugs or biologics regulated as drugs. 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 revise the requirements for the National Drug Code number and would require the electronic submission of most registration and listing information.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AA49

838. 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	07/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AB34

839. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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: 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 a plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

FDA intends to discuss 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 consider whether it should require provisions for certain retail establishments that serve populations most at risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC14

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

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 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 381

CFR Citation: 21 CFR 50.23

Legal Deadline: None

Abstract: FDA is proposing an amendment to the exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AC25

841. MEDICAL DEVICES; ANESTHESIOLOGY DEVICES; PROPOSED RECLASSIFICATION OF PRESSURE REGULATORS FOR USE WITH MEDICAL OXYGEN

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352; 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 (FDA) 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 proposed rule will phase-in a 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	12/00/04	

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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC30

842. FOOD STANDARDS: GENERAL PRINCIPLES AND FOOD STANDARDS MODERNIZATION

Priority: Other Significant

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

CFR Citation: 21 CFR 130.5

Legal Deadline: None

Abstract: In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine whether any were still needed, and if so, which ones should be modified or streamlined. To request public comment to assist them in their review of the need for food standards, both agencies published advance notices of proposed rulemaking (ANPRMs) on food standards in December, 1995 (60 FR 47453 and 60 FR 67492). These ANPRMs discussed the agencies' regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The agencies also agreed with the comments that stated that the agencies should work in concert to develop consistent food standards regulations. FDA and FSIS are now proposing a set of general principles that define how modern food standards should be structured. If this proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 7 CFR part 410 be submitted in accordance with the general principles. Conversely, the agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

Timetable:

Action	Date	FR Cite
ANPRM	12/29/95	60 FR 67492
ANPRM Comment Period End	04/29/96	
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC54

843. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

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

Unfunded Mandates: Undetermined

Legal Authority: PL 105–115, sec 121

CFR Citation: 21 CFR 220

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

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

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: Federal, State

URL For More Information: www.fda.gov/cder/regulatory/pet

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Related RIN: Previously reported as 0910–AB63

RIN: 0910–AC55

844. REPORTING INFORMATION REGARDING FALSIFICATION OF DATA

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 341 to 343; 21 USC 348; 21 USC 349; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 360c; 21 USC 360e; 21 USC 360i to 360k; 21 USC 361; 21 USC 371; 21 USC 379e; 42 USC 262

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

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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Related RIN: Previously reported as 0910–AC02

RIN: 0910–AC59

845. DEFINITION OF ''SERIOUS ADVERSE HEALTH CONSEQUENCES'' UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

Legal Authority: 21 USC 334(h)(1)(A); 21 USC 335a(b)(3); 21 USC 343(v); 21 USC 350c(a) and (b); 21 USC 371; 21 USC 374(a)(1); 21 USC 381(j)(1) and (m)(2)(B)(ii); 21 USC 398(a)

CFR Citation: 21 CFR 1.3(c)

Legal Deadline: None

Abstract: The proposed rule would define the term ''serious adverse health consequences'' for purposes of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and any implementing regulations. The term is used to describe part of the standard that is the basis for FDA to exercise certain authorities provided in sections 303, 304, 306, 307, 308, and 310 of title III (Protecting Safety and Security of the Food and Drug Supply), subtitle A (Protection of Food Supply), of the Bioterrorism Act.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ms. Karen Carson, Deputy Director, Office of Plant and Dairy Foods and Beverages, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Rm 3 A–001, College Park, MD 20740
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RIN: 0910–AF06

846. HEALTH CLAIMS

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 343; 21 USC 371

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: On November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. This ANPRM was signaled in the July 11, 2003 (68 FR 41387)notice that announced the availability of the final report of the FDA Task Force on the Consumer Health Information for Better Nutrition Initiative.

Comments on the regulatory alternatives and additional topics identified in the ANPRM will inform FDA decisions about regulation of qualified health claims.

Timetable:

Action	Date	FR Cite
ANPRM	11/25/03	68 FR 66040
ANPRM Comment Period Extended	01/27/04	69 FR 3868
ANPRM Comment Period End	02/25/04	
NPRM	01/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0910–AF09

847. QUALITY STANDARD REGULATION ESTABLISHING ALLOWABLE LEVEL FOR ARSENIC IN BOTTLED WATER

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

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 343–1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

CFR Citation: 21 CFR 165.110(b)

Legal Deadline: Final, Statutory, July 27, 2005.

Abstract: Under section 410 of the Federal Food, Drug, and Cosmetic Act (the Act), not later than 180 days before the effective date of a National Primary Drinking Water Regulation (NPDWR) issued by the Environmental Protection Agency (EPA) for a contaminant under section 1412 of the Safe Drinking Water Act, the Food and Drug Administration (FDA) is required to issue a standard of quality regulation for that contaminant in bottled water or make a finding that such a regulation is not necessary to protectthe public health because the contaminant is contained in water in public water systems but not in water used for bottled water. The effective date for any such standard of quality regulation is to be the same as the effective date of the NPDWR. On January 22, 2001, EPA published a final rule revising the existing 0.05 mg/L maximum contaminant level (MCL) for arsenic in public drinking water to 0.01 mg/L (10 ppb). The effective date for this rule was temporarily delayed for 60 days from March 23, 2001, to a new effective date of May 22, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan'' (66 FR 7701; January 24, 2001). On May 22, 2001, EPA announced that it would further delay the effective date for the rule until February 22, 2002, to allow time to complete a reassessment of the information on which the revised arsenic standard is based. On February 22, 2002, the arsenic MCL of 0.01 mg/L in public drinking water rule became effective and water systems must comply with the new standard for arsenic in public drinking water by January 23, 2006. In accordance with section 410 of the Act, FDA is required to issue a standard of quality regulation for arsenic in bottled drinking water by July 27, 2005, with an effective date of January 23, 2006, or make a finding

that such a regulation is not necessary to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	
NPRM Comment Period End	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AF10

848. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION

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 358; 21 USC 360; 21 USC 360(b); 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 201.57

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations concerning the format and content of the ''Pregnancy,'' ''Labor and Delivery,'' and ''Nursing Mothers'' subsections of the ''Use in Specific Populations'' section of the labeling for human prescription drugs. The proposal would require that labeling include a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF11

849. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

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

Legal Authority: 21 USC 379e(b)

CFR Citation: 21 CFR 73.100 (d); 21 CFR 73.1100 (c); 21 CFR 73.2087 (c); 21 CFR 101.22 (k); 21 CFR 701.3; 21 CFR 740.20

Legal Deadline: None

Abstract: The purpose of this proposed rule is to protect consumers who have allergies to the color additives carmine and cochineal extract by requiring label declaration on products under FDA jurisdiction. This action responds to adverse event reports received by FDA and to a citizen petition submitted to FDA.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF12

850. CHARGING FOR INVESTIGATIONAL DRUGS

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 371; 42 USC 262

CFR Citation: 21 CFR 312.7; 21 CFR 312.8

Legal Deadline: None

Abstract: The proposed rule would amend FDA's investigational new drug exemption regulations concerning charging for investigational drugs. The proposed rule describes the types of investigational uses for which a sponsor may be able to charge, including uses for which charging was not previously expressly permitted, and the criteria for allowing charging for the identified investigational uses. The proposed rule would also describe the types of costs that can be recovered when charging for an investigational drug.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF13

851. TREATMENT USE OF INVESTIGATIONAL DRUGS

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 353; 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 312.42; 21 CFR 312.400; 21 CFR 312.405; 21 CFR 312.410; 21 CFR 312.415; 21 CFR

312.420; 21 CFR 312.425; 21 CFR 312.430; 21 CFR 312.435

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations governing investigational new drug exemptions (INDs) to describe the way patients may obtain investigational drugs for treatment use. Treatment use of investigational drugs would be available to: 1) individual patients, including in emergencies; 2) intermediate size patient; and 3) larger populations under a treatment protocol or IND.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3059 (HFD–7), Center for Drug Evaulation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF14

852. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES; DERIVATIVES OF BLOOD

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

Legal Authority: 21 USC 351 to 353; 21 USC 371; 21 USC 374

CFR Citation: 21 CFR 203.3(q); 21 CFR 203.22(h); 21 CFR 205.3(h)

Legal Deadline: Other, Statutory, April 1, 2004, Effective date of final rule, 64 FR 67720, December 3, 1999.
Date final rule takes effect: ''Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures.''.

Abstract: FDA is proposing to amend the implementing regulation of the Prescription Drug Marketing Act of 1987, as modified by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997. Certain provisions of that final rule that published on December 3, 1999, (64 FR 67720), do not allow a registered blood establishment that provides health care services related to its activities as a blood establishment to concurrently distribute derivatives of blood. The effective date of those provisions of that rule is December 1, 2006, as published on February 3, 2004, (69 FR 8105). FDA is amending the final rule to allow a registered blood establishment that concurrently provides health care services to also distribute derivatives of blood.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Kathleen E. Swisher, Supervisory Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike Suite 200N, Rockville, MD 20852
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RIN: 0910–AF16

853. USE OF OZONE–DEPLETING SUBSTANCES: REMOVAL OF ESSENTIAL USE DESIGNATION; ALBUTEROL

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

Unfunded Mandates: Undetermined

Legal Authority: 15 USC 402; 15 USC 409; 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 343; 21 USC 346a; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 42 USC 7671 et seq

CFR Citation: 21 CFR 2.125

Legal Deadline: None

Abstract: Under the Clean Air Act, the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services, in consultation with the Environmental Protection Agency, is required to determine whether an FDA-regulated product that releases an ozone-depleting substance (ODS) is essential. The two agencies have tentatively determined that the two currently marketed non-ODS metered-dose inhalers (MDIs) will be satisfactory alternatives to albuterol MDIs that contain ODS, and are proposing to remove the essential use designations for albuterol MDIs. If the essential use designation is removed, albuterol MDIs that contain an ODS could not be marketed after a suitable transition period. The proposed rule will specifically ask for comments on which phase-out period length will best ensure a smooth transition and minimize any adverse affects on the public health.

Timetable:

Action	Date	FR Cite
NPRM	06/16/04	69 FR 33602
NPRM Comment Period End	08/16/04	
Final Action	03/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF18

854. • REVOCATION OF THE STATUS OF SPECIFIC PRODUCTS; GROUP A STREPTOCOCCUS

Priority: Info./Admin./Other

Legal Authority: 42 USC 262

CFR Citation: 21 CFR 610.19

Legal Deadline: None

Abstract: FDA is issuing a direct final rule and companion proposed rule to revoke 21 CFR 610.19, Status of specific products; Group A streptococcus. The current regulation was based on the panel report for bacterial vaccines with ''No U.S.

Standard of Potency.'' The vaccines had been licensed by the National Institutes of Health prior to 1972, when regulatory authority over these vaccines was transferred to FDA. The regulation prohibits the use of Group A streptococcus organisms and derivatives of Group Astreptococcus as ingredients in Bacterial Vaccines and Bacterial Antigens with ''No U.S. Standard of Potency.'' The regulation was never intended to refer to purified streptococcus vaccines, which were not developed at that time. Therefore, the regulation is being revoked.

Timetable:

Action	Date	FR Cite
NPRM – Companion to Direct Final Rule	04/00/05	
Direct Final Rule	04/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF20

855. • LATEX CONDOMS: SPECIAL CONTROLS

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

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360c

CFR Citation: 21 CFR 884.5300; 21 CFR 884.5310

Legal Deadline: None

Abstract: The classification regulations for male condoms would be amended to specify a labeling guidance document as a special control for condoms made from NR latex. The new special control guidance document would provide detailed recommendations for labeling meeting the requirements of 21 CFR 801, that together with the general controls, provides a resaonable assurance of the safety and effectiveness of these devices. The rule will demonstrate how the agency is moving forward to meet the congressionaldirective of Public Law 106-554 that FDA review condom labeling to assure that the information regarding sexually transmitted disease transmission is medically accurate.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AF21

856. • BLOOD INITIATIVE—REGULATIONS FOR HUMAN BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

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; ...

CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; ...

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) 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 FDA's comprehensive review of the biologics regulations. 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, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include: labeling of blood and blood components (0910-AF26). These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

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
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Related RIN: Split from 0910–AB26

RIN: 0910–AF25

857. • OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of

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Related RIN: Split from 0910–AA01

RIN: 0910–AF32

858. • OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	09/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF33

859. • OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
NPRM (Phenylephrine Bitartrate)	09/00/04	
NPRM (Phenyl-propanolamine)	09/00/04	
NPRM (Amendment) (Sinusitis Claim)	10/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF34

860. • OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Labeling)	08/00/04	
NPRM (Amendment) (Pediatric)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF36

861. • OVER–THE–COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

HHS—FDA **Proposed Rule Stage**

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	08/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF37

862. • OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
NPRM (Phenyl-propanolamine)	09/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF45

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) — Final Rule Stage

863. 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 final rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the 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	06/19/02	67 FR 41642
Final Action	09/00/04	

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 and Planning, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AA61

864. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

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 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 C.F.R. 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.

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	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AA94

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865. CURRENT GOOD TISSUE PRACTICE FOR HUMAN CELL, TISSUE, AND CELLULAR AND TISSUE–BASED PRODUCT ESTABLISHMENTS; INSPECTION AND ENFORCEMENT

Priority: Other Significant

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

CFR Citation: 21 CFR 1270; 21 CFR 1271

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based products (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program. FDA is also issuing regulations pertaining to 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	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

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RIN: 0910–AB28

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866. CGMP FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV INFECTION (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 263a; 42 USC 264

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 FDA's comprehensive review of the biologics regulations and on reports by the U.S. House of Representatives Committee on Government Reform and Oversight's, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute ofMedicine, as well as on 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 Period End	02/14/01	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Related to 0910–AB26

RIN: 0910–AB76

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867. 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 proposed in the Federal Register of March 13, 2003 (68 FR

12158), current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, or holding dietary ingredients of dietary supplements, they do so in a manner that will not adulterate and misbrand such dietary ingredientsor dietary supplements. FDA also proposed to require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule 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, e.g., which have the identity and provide the quantity of dietary ingredients declared in labeling.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AB88

868. 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: Final, Statutory, April 17, 2001.

Abstract: The final rule will finalize the interim rule that published in April 2001, providing 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 Action	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AC07

869. 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	03/31/03	68 FR 15404
NPRM Comment Period End	06/30/03	
Final Rule	12/00/04	

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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC32

870. AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X–RAY SYSTEMS AND THEIR MAJOR COMPONENTS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360e to 360j; 21 USC 360hh to 360ss; 21 USC 371; 21 USC 381

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, 1020.32, and 1020.33 to address the changes in technology and practice.

Timetable:

Action	Date	FR Cite
NPRM	12/10/02	67 FR 76056
Final Action	06/00/04	

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, HFZ–215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910–AC34

871. ESTABLISHMENT AND MAINTENANCE OF RECORDS PURSUANT TO THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107–188, sec 306

CFR Citation: 21 CFR 1

Legal Deadline: None

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 414(b) of the Federal Food, Drug and Cosmetic Act (FFDCA), which was added by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. The Act authorizes regulations that require the establishment and maintenance of records, for not longer than two years, that would allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging. The required records would be those that are needed by FDA in order to address credible threats of serious adverse health consequences or death to humans or animals. Specific covered entities are those that manufacture, process, pack, transport, distribute, receive, hold, or import food. Farms and restaurants are excluded. The Secretary is directed to take into account the size of a business in promulgating these regulations. Section 306 of the Act also added section 414(a) and amended section 704(a) of FFDCA to permit FDA to inspect these records and other information if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Timetable:

Action	Date	FR Cite
NPRM	05/09/03	68 FR 25188
NPRM Comment Period End	07/08/03	
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

URL For More Information: www.fda.gov/oc/bioterrorism/bioact.html

URL For Public Comments: www.fda.gov/ohrms/dockets/02n0277/02n0277.htm

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RIN: 0910–AC39

872. REGISTRATION OF FOOD AND ANIMAL FEED FACILITIES

Priority: Economically Significant. Major under 5 USC 801.

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

Legal Authority: PL 107–188, sec 305

CFR Citation: 21 CFR 1

Legal Deadline: Final, Statutory, December 12, 2003.
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 305, directs the Secretary, through FDA, to issue a final regulation establishing registration requirements by December 12, 2003. The statute is self-implementing on this date if FDA does not issue a final regulation that is effective by December 12, 2003.

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism and other foodborne illness emergencies. Section 415 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), directs the Secretary to require facilities engaged in manufacturing, processing, packing, or holding of food for consumption in theUnited States to be registered with the Secretary. Section 415 directs the Secretary, to promulgate final regulations implementing the requirements by December 12, 2003. The owner, operator, or agent in charge of the facility must submit the registration. Foreign facilities must include the name of the United States agent for the facility. The registration must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. If the Secretary determines it is necessary through guidance, the registration must include the general food category (as identified under 21 CFR 170.3) of foods manufactured, processed, packed, or held at the facility. The registrant is required to notify the Secretary of changes to the information contained in the registration in a timely manner. Under the interim final rule (IFR) published on October 10, 2003 (68 FR 58894), upon receipt of the completed registration form, FDA will notify the registrant of receipt of the registration and assign a unique registration number to the facility. Section 415 requires the Secretary to compile and maintain an up-to-date list of registered facilities. This list and any registration documents submitted to the Secretary are not subject to disclosure under the Freedom of Information Act. For purposes of section 415, ''facility'' includes any factory, warehouse, or establishment engaged in the manufacturing, processing, packing, or holding of food. Exempt from the registration requirement are farms, restaurants, other retail food

establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in 21 CFR 123.3(k)). Foreign facilities required to register include only those from which food is exported to the United States without further processing or packaging outside the United States. The Bioterrorism Act provides that if food from an unregistered foreign facility is offered for import into the United States without having registered, the food will be held at the port of entry or at a secure facility, until the foreign facility has registered. On April 14, 2004, FDA issued a notice reopening for 30 days, on a limited range of issues, the comment period on the IFR. FDA took this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in order to ensure that those commenting on the IFRhave had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration system.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5377
Interim Final Rule	10/10/03	68 FR 58894
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19766
Interim Final Rule Comment Period Reopened End	05/14/04	
Final Rule	03/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AC40

873. PRIOR NOTICE OF IMPORTED FOOD UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: PL 107–188, sec 307

CFR Citation: 21 CFR 1.276 et seq

Legal Deadline: Final, Statutory, December 12, 2003.
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 307, directs the Secretary, through FDA, to issue final regulations establishing prior notice requirements for all imported food by December 12, 2003. If FDA fails to issue final regulations by this date, the statute is self-executing on this date, and requires FDA to receive prior notice of not less than eight hours, nor more than five days until final regulations are issued.

Abstract: This rulemaking is one of a number of actions being taken to improve FDA's ability to respond to threats of bioterrorism. Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, authorizes the Secretary, through FDA, to promulgate final regulations by December 12, 2003. Section 801(m) requires notification to FDA prior to the entry of imported food. The required priornotice would provide the identity of the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. The regulation identifies the parties responsible for providing the notice and explains the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 307 also states that if FDA does not receive prior notice or receives inadequate prior notice, the imported food shall be refused admission and held at the port of entry until proper notice is provided.

Timetable:

Action	Date	FR Cite
NPRM	02/03/03	68 FR 5428
Interim Final Rule	10/10/03	68 FR 58974
Interim Final Rule Comment Period Reopened	04/14/04	69 FR 19763
Interim Final Rule Comment Period Reopened End	06/14/04	
Final Rule	03/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

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RIN: 0910–AC41

874. PRESUBMISSION CONFERENCES

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b

CFR Citation: 21 CFR 514

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	08/25/00	65 FR 51782
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Gail Schmerfeld, Special Assistant, Department of Health

and Human Services, Food and Drug Administration, HFV–100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827–0205

Related RIN: Previously reported as 0910–AB68

RIN: 0910–AC44

875. HUMAN SUBJECT PROTECTION; FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN INVESTIGATIONAL NEW DRUG APPLICATION

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 355(d)(5); 21 USC 355(i); 21 USC 371(a); 42 USC 262(a)(2)(A); 42 USC 262(a)(2)(B)(i)(l)

CFR Citation: 21 CFR 312.120

Legal Deadline: None

Abstract: The proposed rule would update the standards for the acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. We are proposing to replace the requirement in 21 CFR 312.120 that non-IND foreign clinical studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki. We would replace that with a requirement that such studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee. The proposed GCP standard is consistent with the standard of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for GCP and is sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical research and obtain the informed consent of patients.

Timetable:

Action	Date	FR Cite
NPRM	06/10/04	69 FR 32467
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF15

876. • BLOOD INITIATIVE—REVISIONS TO LABELING AND STORAGE REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA

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; . . .

CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; . . .

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) 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 FDA's comprehensive review of the biologics regulations. 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, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include: donor eligibility requirements (0910-AF25). These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 400S (HFM–17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448
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Related RIN: Split from 0910–AB26

RIN: 0910–AF26

877. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIPERSPIRANT PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Partial Stay)	09/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF30

878. • OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Common Cold)	10/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF31

879. • OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Emergency First Aid Eyewashes)	11/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF39

880. • OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	12/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF42

881. • OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	11/00/04	

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF44

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

Long-Term Actions

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

Priority: Routine and Frequent

Legal Authority: 21 USC 331 to 334; 21 USC 335b; 21 USC 335c; 21 USC 341 to 344; 21 USC 348; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 361; 21 USC 362; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 376; 21 USC 381; 21 USC 393; 42 USC 262; 42 USC 264

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 would include recordkeeping requirements to ensure that the correct sample is collectedand analyzed, and a notification requirement if a person intends to use a sampling service or 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	04/29/04	69 FR 23460
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

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 and Planning, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AB96

883. 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 goats, and Creutzfeldt-Jakob disease (CJD) in humans. The disease has been identified in wild and farmed elk and wild deer populations.

CWD has been found in cervid populations in certain areas of Wisconsin, Colorado, Nebraska, Wyoming, Kansas, Montana, Oklahoma, South Dakota, New Mexico, Minnesota, and Canada. In 1999, the World Health Organization said there is no evidence that CWD transmits to humans. However, it also suggested any part of a deer or elk believed to be diseased should not be eaten. Results of some studies using in vitro techniques have suggested that transmission to humans could possibly occur. However, if it does occur, it is likely to be through a very inefficient process.

Currently, there are no validated analytical tests to identify animals in the preclinical phase of CWD, or any other TSE. In addition, no test exists to ensure food safety. CWD typically exhibits a long incubation period, during which time animals appear normal but are potentially infectious. Therefore, DA 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	01/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AC21

884. 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 to 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
NPRM	10/29/03	68 FR 61640
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Aileen Ciampa, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFD–7, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20857
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RIN: 0910–AC23

885. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Priority: Other Significant

Legal Authority: 21 USC 355b

CFR Citation: 21 CFR 201; 21 CFR 208; 21 CFR 209

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

Abstract: To require the labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, 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
NPRM	04/22/04	69 FR 21778
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
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RIN: 0910–AC35

886. FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING: CONSUMER RESEARCH TO CONSIDER NUTRIENT CONTENT AND HEALTH CLAIMS AND POSSIBLE FOOTNOTE OR DISCLOSURE STATEMENTS

Priority: Other Significant

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

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: The Food and Drug Administration issued an advance noitce of proposed rulemaking on July 11, 2003 (68 FR 41507), to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The agency also requested comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Timetable:

Action	Date	FR Cite
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End	10/09/03	
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Julie Schrimpf, Department of Health and Human Services, Food and Drug Administration, (HFS–832), HFS–800, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Related to 0910–AB66

RIN: 0910–AC50

887. SUBMISSION OF STANDARDIZED ELECTRONIC STUDY DATA FROM CLINICAL STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

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

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend the regulations governing the format in which clinical study data (CSD) are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that CSD submitted for NDAs, ANDAs, BLAs, and their supplements and amendments be provided in electronic format and require the use of standard data structure, terminology, and code sets. The proposal would improve the efficiency of the exchange of information from clinical studies through the adoption of standards for study data submitted in an electronic form that FDA can process, review, and archive.

Timetable:

Action	Date	FR Cite
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AC52

888. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

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

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 353

CFR Citation: 21 CFR 201.161(a); 21 CFR 210.3(b); 21 CFR 211.94

Legal Deadline: None

Abstract: The Food and Drug Administration is proposing to amend its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These proposed amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas mixups, do not occur in the future.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Elaine H. Tseng, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AC53

889. FOOD LABELING: FOOD ALLERGEN INGREDIENT LABELING

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

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

CFR Citation: 21 CFR 101

Legal Deadline: None

Abstract: The purpose of this rulemaking is to reduce mortality and morbidity by providing sensitive individuals with additional food allergen information to help them protect themselves from serious allergic reactions, including life-threatening anaphylactic shock. The eight most common food allergens are: 1) peanuts; 2) soybeans; 3) milk; 4) eggs; 5) fish; 6) crustacea (e.g., lobster, crab, shrimp); 7) tree nuts (e.g., almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, pistachios, pine nuts); and 8) wheat. The rule would propose to require that foods that contain ingredients derived from these eight allergens include information on the label in plain English terms that clearly identifies the allergenic source of these ingredients.

The agency is also proposing to require individual label declaration of spices, flavors, noncertified colors and incidental additives. Currently, section 403(i) of the Federal Food, Drug, and Cosmetic Act allows spices, flavors and noncertified colors used as ingredients of foods to be declared collectively on the label without naming each one. Federal regulations at 21 C.F.R. 101.100(a)(3) exempt incidental additives from ingredient declaration on the label if they are present in the food at an insignificant level and do not have any technical or functional effect in the finished food.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

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RIN: 0910–AF07

890. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; REVISION OF CERTAIN LABELING CONTROLS

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

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 351

CFR Citation: 21 CFR 211.122

Legal Deadline: None

Abstract: The proposed rule would amend the packaging and labeling control provisions of the current good manufacturing practice regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. The proposal would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used.

Timetable:

Action	Date	FR Cite
NPRM	07/29/97	62 FR 40489
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

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, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
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RIN: 0910–AF08

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891. CURRENT GOOD MANUFACUTRING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; 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. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end onAugust 26, 2003.

Timetable:

Action	Date	FR Cite
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Split from 0910–AA04

RIN: 0910–AF27

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892. INFANT FORMULA QUALITY FACTORS

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. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end onAugust 26, 2003.

Timetable:

Action	Date	FR Cite
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Split from 0910–AA04

RIN: 0910–AF28

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893. • OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable: Next Action Undetermined

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
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Related RIN: Split from 0910–AA01

RIN: 0910–AF35

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894. • OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable: Next Action Undetermined

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

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Related RIN: Split from 0910–AA01

RIN: 0910–AF38

895. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910–AA01

RIN: 0910–AF40

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

Completed Actions

896. 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 201; 21 CFR 310; 21 CFR 330 to 358

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:

Action	Date	FR Cite
Actions Will Continue Under Separate Rulemakings	06/08/04	
Anorectal Products (0910–AC65)		
Final Action (Amendment)	08/26/03	(68 FR 51167)
Antidiarrheal Products (0910–AC82)		
NPRM (Amendment) (Trav. Diar)	04/17/03	(68 FR 18915)
Merged With 0910-AF29	06/08/04	
Antiemetic Products (0910–AC71)		
Final Action (Amendment) (Warning)	12/06/02	(67 FR 72555)
Antiperspirant Products (0910–AC89)		
Final Action	06/09/03	(68 FR 34273)
Final Action (Partial Stay) Merged With 0910-AF30	06/08/04	
Cough/Cold (Antihistamine) Products (0910–AD31)		
Merged With 0910-AF31	06/08/04	
Cough/Cold (Antitussive) Products (0910–AD24)		
Final Action (Amendment) (Warning)	12/06/02	(67 FR 72555)
Cough/Cold (Bronchodilator) Products (0910–AD33)		
Merged With 0910-AF32	06/08/04	
Cough/Cold (Combination) Products (0910–AD25)		
Final Action	12/23/02	(67 FR 78158)
NPRM (Amendment) Merged With 0910-AF33	06/08/04	
Cough/Cold (Nasal Decongestant) Products (0910–AD43)		
Merged With 0910-AF34	06/08/04	
External Analgesic Products (0910–AD06)		
Final Action (Amendment)(Warning)	12/06/02	(67 FR 72555)
NPRM (Amendment)(Patches)	07/17/03	(68 FR 42324)
Merged With 0910-AF35	06/08/04	
Ingrown Toenail Relief Products (0910–AD21)		
NPRM	10/04/02	(67 FR 62218)
Final Action	05/07/03	(68 FR 24347)
Internal Analgesic Products (0910–AD07)		
NPRM (Amendment)(Ibuprofen)	08/21/02	(67 FR 54139)
Merged With 0910-AF36	06/08/04	
Labeling of Drug Products for OTC Human Use (0910–AD47)		
NPRM (Sodium Labeling)	03/24/04	(69 FR 13765)
Final Action (Sodium Labeling)	03/24/04	(69 FR 13717)
Final Action (Ca/Mg/K/Na)	03/24/04	(69 FR 13725)
Laxative Drug Products (0910–AC85)		
NPRM (Amendment) (Psyllium Granular Dosage Form)	08/05/03	(68 FR 46133)
Merged With 0910-AF38	06/08/04	
Nighttime Sleep Aid Products (0910–AD11)		
Final Action (Amendment)(Warning)	12/06/02	(67 FR 72555)
Ophthalmic Products (0910–AC72)		
NPRM (Emergency First Aid Eyewashes)	02/19/03	(68 FR 7951)
Final Action (Technical Amendment)	02/19/03	(68 FR 7919)
Final Action (Name Change)	06/03/03	(68 FR 32981)
Final Action (Emerg. First Aid Eyewashes) Merged With 0910-AF39	06/08/04	
Oral Health Care Products (0910–AC98)		
ANPRM (Plaque/Gingivitis)	05/29/03	(68 FR 32232)
Merged With 0910-AF40	06/08/04	
Pediculicide Products (0910–AC79)		
NPRM (Labeling Amendment)	05/10/02	(67 FR 31739)
Final Action (Labeling Amendment)	12/31/03	(68 FR 75414)
Salicylate (Reye's Syndrome) (0910–AD13)		
Final Action (Warning)	04/17/03	(68 FR 18861)

Skin Protectant Products (0910–AC96)
Final Action 06/04/03 (68 FR 33362)
NPRM (Astringent) 06/13/03 (68 FR 35346)
Final Action (Astringent) 06/13/03 (68 FR 35290)
Final Action (Astringent) (Confirm Effective Date) 10/09/03 (68 FR 58273)
Final Action (Technical Amendment) 12/09/03 (68 FR 68509)
Final Action (Technical Amendment) Merged With 0910-AF42 06/08/04
Sunscreen Products (0910–AC68)
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (Bug and Insect Repellent) and NPRM (UVA/UVB) Merged With 0910-AF43 06/08/04
Vaginal Contraceptive Products (0910–AD19)
NPRM (Amendment) 01/16/03 (68 FR 2254)
Merged With 0910-AF44 06/08/04
Weight Control Products (0910–AC93)
Merged With 0910-AF45 06/08/04

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA01

897. 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. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end onAugust 26, 2003.

Timetable:

Action	Date	FR Cite
Actions Will Continue Under Separate Rulemakings	06/04/04	
Current Good Mfg. Practices; Qual. Control Proc.; Quality Factors (0910–AD81)		
NPRM 07/09/96 (61 FR 36154)		
NPRM Comment Period End 12/06/96		
NPRM Comment Period Reopened 04/28/03 (68 FR 22341)		
NPRM Comment Period Extended 06/27/03 (68 FR 38247)		
NPRM Comment Period End 08/26/03		
Merged With 0910-AF27 06/04/04		
Infant Form Cons Comp, Micro Test & Recd Retention Req (0910–AD80)		
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 (0910–AD77)		
NPRM Comment Period End 12/06/96		
NPRM Comment Period Reopened 04/28/03 (68 FR 22341)		
NPRM Comment Period Extended 06/27/03 (68 FR 38247)		
NPRM Comment Period End 08/26/03		
Merged With 0910-AF28 06/04/04		

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AA04

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

Priority: Other Significant

CFR Citation: 21 CFR 50; 21 CFR 312

Completed:

Reason	Date	FR Cite
Withdrawn	06/10/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Philip L. Chao
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RIN: 0910–AA89

899. BLOOD INITIATIVE

Priority: Other Significant

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 630; 21 CFR 640; 21 CFR 660; 21 CFR 680

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) 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 FDA's comprehensive review of the biologics regulations. 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, and the Institute of Medicine, as well as on public comments. The remaining subjects intended to be addressed in the rulemakings include: labeling of blood and blood components and donor eligibility requirements. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
Actions Will Continue Under Separate Rulemakings	06/04/04	
Albumin (Human), Plasma Protein Fraction (Human) and Immune Globulin (Human); Revision of Requirements (0910–AE95)		
NPRM 05/14/99 (64 FR 26344)		
Direct Final Rule 05/14/99 (64 FR 26282)		
Direct Final Rule - Confirmation in Part and Technical Amendment 03/14/00 (65 FR 13678)		
Final Action 08/28/00 (65 FR 52016)		

General Requirements for Blood, Blood Components, and Plasma Derivatives; Notification of Deferred Donors (0910–AE99)
NPRM 08/19/99 (64 FR 45355)
Final Action 06/11/01 (66 FR 31165)
Plasma Derivatives and Similar Recombinant–Based Products; Requirements for Notification of Recalls and Withdrawals (0910–AF02)
ANPRM 08/19/99 (64 FR 45383)
Withdrawn 06/04/04
Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (0910–AF00)
Merged With 0910-AF25 06/04/04
Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents (0910–AE98)
NPRM 08/19/99 (64 FR 45340)
Final Action 06/11/01 (66 FR 31146)
Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma (0910–AE96)
NPRM 07/30/03 (68 FR 44678)
Correction Notice 10/27/03 (68 FR 61172)
NPRM Comment Period End 10/30/03
Merged With 0910-AF26 06/04/04
Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma (0910–AE89)
NPRM 08/19/99 (64 FR 45375)
Direct Final Rule 08/19/99 (64 FR 45366)
Direct Final Rule - Confirmation in Part and Technical Amendment 01/10/01 (66 FR 1834)
Final Action 08/06/01 (66 FR 40886)

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
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Related RIN: Related to 0910–AB76

RIN: 0910–AB26

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900. ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS

Priority: Other Significant

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

Completed:

Reason	Date	FR Cite
Final Action	05/24/04	69 FR 29786

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: State

Agency Contact: Paula S. McKeever
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RIN: 0910–AB27

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901. SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Priority: Other Significant

CFR Citation: 21 CFR 314

Completed:

Reason	Date	FR Cite
Final Action	04/08/04	69 FR 18728

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Howard P. Muller
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RIN: 0910–AB61

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902. CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

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

CFR Citation: 21 CFR 225

Completed:

Reason	Date	FR Cite
Withdrawn	05/19/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: George Graber
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RIN: 0910–AB70

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

Priority: Other Significant

CFR Citation: 21 CFR 314; 21 CFR 601

Completed:

Reason	Date	FR Cite
Final Action	12/11/03	68 FR 69009

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Nicole K. Mueller
Phone: 301 594–2041
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RIN: 0910–AB91

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904. USE OF MATERIALS DERIVED FROM BOVINE AND OVINE ANIMALS IN FDA–REGULATED PRODUCTS

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

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Withdrawn	05/19/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Rebecca Buckner
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RIN: 0910–AC19

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905. BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS AND BLOOD

Priority: Economically Significant. Major under 5 USC 801.

CFR Citation: 21 CFR 201.25; 21 CFR 601.67

Completed:

Reason	Date	FR Cite
Final Rule	02/26/04	69 FR 9119

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Philip L. Chao
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RIN: 0910–AC26

906. ADMINISTRATIVE DETENTION OF FOOD FOR HUMAN OR ANIMAL CONSUMPTION UNDER THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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

CFR Citation: 21 CFR 1; 21 CFR 10.45(d); 21 CFR 16.1(b)(1)

Completed:

Reason	Date	FR Cite
Final Action	06/04/04	69 FR 31660

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Kelli Giannattasio
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RIN: 0910–AC38

907. REQUIREMENTS FOR LIQUID MEDICATED FEED AND FREE–CHOICE MEDICATED FEED

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 558.5; 21 CFR 510.455

Completed:

Reason	Date	FR Cite
Final Action	05/27/04	69 FR 30194

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Deaman Momailovic
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Related RIN: Previously reported as 0910–AB50

RIN: 0910–AC43

908. BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW

Priority: Substantive, Nonsignificant

CFR Citation: 21 CFR 201.59; 21 CFR 610.21

Completed:

Reason	Date	FR Cite
Final Action	01/05/04	69 FR 255

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Astrid L. Szeto
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RIN: 0910–AC56

909. REVISION OF THE REQUIREMENTS FOR SPORE–FORMING MICROORGANISMS

Priority: Other Significant

CFR Citation: 21 CFR 600.10(c); 21 CFR 600.11(e)

Completed:

Reason	Date	FR Cite
NPRM–Companion to Direct Final Rule	12/30/03	68 FR 75179
Direct Final Rule	12/30/03	68 FR 75116
Confirmation of Effective Date	05/14/04	69 FR 26768

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Valerie Butler
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RIN: 0910–AC57

910. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD (PART 110) (COMPLETION OF A SECTION 610 REVIEW)

Priority: Other Significant

Legal Authority: 21 USC 342; 21 USC 371; 21 USC 374; 42 USC 264

CFR Citation: 21 CFR 110

Legal Deadline: None

Abstract: Part 110 (21 CFR part 110) describes regulations for current good manufacturing practice in manufacturing, packing, and holding human food. Part 110 contains regulations describing sanitary practices for personnel, buildings and facilities, and equipment. It also includes regulations on production and process controls for manufacturing practices and on defect action levels for natural or unavoidable defects in food for human use that present no health hazard. FDA is undertaking a review of part110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) the continued need for the regulations in part 110; (2) the nature of complaints or comments received concerning the regulations in part 110; (3) the complexity of the regulations in part 110; (4) the extent to which the regulations in part 110 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 110.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the princples set forth in the Executive order. The combined effect of the two reviews will be to determine if it is possible to redesign current good manufacturing practices in ways that will maintain or increase the effectiveness of preventive and sanitary controls, and, at the same time, reduce compliance and other costs associated with the regulations.

Timetable:

Action	Date	FR Cite
Begin Review	05/01/03	
End Review	12/31/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Richard A. Williams, Director, Division of Market Studies, Department of Health and Human Services, Food and Drug Administration, HFS–725, Center for Food Safety and Applied Nutrition,

HHS—FDA **Completed Actions**

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RIN: 0910–AC58

911. • OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIDIARRHEAL PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

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.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Trav. Diar)	05/12/04	69 FR 26301

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

Related RIN: Split from 0910–AA01

RIN: 0910–AF29

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

Proposed Rule Stage

912. 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 notice of proposed rulemaking (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 careservices 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
Second NPRM	04/00/04	

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, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20957
Phone: 301 443–2300
Fax: 301 443–6725

RIN: 0906–AA41

913. 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 and Primary Care Health Professional Shortage Areas. This notice of proposed rulemaking (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
Second NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Andy Jordan, Acting Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, Room 8C26, National Center for Health Workforce Analysis, Bureau of Health Professions, Parklawn Building, Rockville, MD 20857
Phone: 301 594–0197
Email: dsd@hrsa.gov

RIN: 0906–AA44

914. • INTESTINES ADDED TO THE DEFINITION OF ORGANS COVERED BY THE RULES GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Legal Authority: 42 USC 274e, sec 301; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: The Department of Health and Human Services proposes to add intestines to the definition of organs covered by the rules governing the operation of the OPTN. After a review of intestinal transplants, HHS believes that intestines should now be included within the definition. The notice of proposed rulemaking provides the history of intestinal transplants, the factors that have persuaded HHS of the advisability of including intestines within the scope of the regulations governing the operation ofthe OPTN, and the anticipated consequences of this proposal.

As the field of intestinal transplantation evolves, it becomes more critical that intestinal organ allocation policies keep pace with the advances in the field; that policy development include performance indicators to assess how well the policies achieve the goals of an equitable transplant system; that those policies are enforceable; and that patients and physicians have timely access to accurate data that will assist them in making decisions regarding intestinal transplantation.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Laura St. Martin, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 202 690–8476
Email: lstmartin@hrsa.gov

RIN: 0906–AA62

915. • NOTICE OF PROPOSED RULEMAKING TO AMEND THE FINAL RULE GOVERNING THE OPERATION OF THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Legal Authority: 42 USC 274e, sec 301, 1984; 42 USC 273 to 274d, sec 371 to 376; 42 USC 1320b–8, sec 1138

CFR Citation: 42 CFR 121

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) proposes to amend the final rule governing the operation of the OPTN.

This notice of proposed rulemaking provides the legislative and regulatory history of the current rule, the factors that persuaded HHS of the advisability of amending the final rule governing the operation of the OPTN, and the anticipated consequences of this proposal. As required rapid changes in response to better understanding of the clinical scientific issues have become evident, HHS has determined that the current process for approving and enforcing policies must be amended.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Hui—Hsing Wong, Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Mail Stop 16C–17, Parklawn Bldg., Rockville, MD 20857
Phone: 301 443–8104
Fax: 301 594 6095
Email: hwong@hrsa.gov

RIN: 0906–AA63

916. • NATIONAL VACCINE INJURY COMPENSATION PROGRAM; REVISIONS AND ADDITIONS TO THE VACCINE INJURY TABLE

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

Legal Authority: 42 USC 300aa–14, sec 2114; PL 103–66, sec 13632(a)

CFR Citation: 42 CFR 100

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) is proposing to revise and make additions to the Vaccine Injury Table (Table). Section 2114(e) (2) of the Public Health Service Act provides for the inclusion of additional vaccines in the National Vaccine Injury Compensation Program when they are recommended by the Centers for Disease Control and Prevention for routine administration to children. In compliance with the Omnibus Budget Reconciliation Act of 1993, which added a new section 2114(e)(3) to the Act, a vaccine added to the Table through Section 2114(e) will be included in the Table, effective when an excise tax to provide funds for the payment of compensation with respect to such vaccines takes effect. HHS has determined that there are no resources required to implement these changes. Section 2114 (c) permits the Secretary of HHS to modify the Table.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857
Phone: 301 443–4198
Fax: 301 443 8196
Email: gevansr@hrsa.gov

RIN: 0906–AA66

917. • LIABILITY PROTECTION FOR CERTAIN FREE CLINIC HEALTH PROFESSIONALS

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

Legal Authority: 42 USC 233(o); PL 108–199, title II

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This notice of proposed rulemaking (NPRM) provides information on the implementation of 42 U.S.C. 233(o), which makes

available medical malpractice liability protection for certain volunteer health professionals in free clinics. This is accomplished by deeming eligible volunteers to be employees of the Public Health Service and, thereby, protected by the Federal Tort Claims Act (FTCA). The NPRM provides information whereby en entity or person can determine when and the extent to which a volunteer health professional at a free clinic is deeemed to be a Public Health Service Employee and, therefore, afforded the protections of the FTCA.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Dr. Felicia Collins, Branch Chief, Clinical Quality Systems Branch HRSA/BPHC/ Division of Clinical Quality, Department of Health and Human Services, Health Resources and Services Administration, 4350 East West Hwy, Bethesda, MD 20814
Phone: 301 594–0818
Fax: 301 594 5224

RIN: 0906–AA67

918. • NATIONAL VACCINE INJURY COMPENSATION PROGRAM: CALCULATION OF AVERAGE COST OF A HEALTH INSURANCE POLICY

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 100, sec 100.2

Legal Deadline: None

Abstract: The Department of Health and Human Services (HHS) is proposing to revise the current method for calculating the average cost of a health insurance policy, which an amount deducted from the award of compensation in certain cases. According to the Final Rule published on June 24, 1992, which established the current calculation, ''lf, over time, the average cost of health insurance, as calculated by the method described above, significantly differs from subsequent HIAA survey results or other authoritative sources then available, the Secretary of HHS will consider appropriate revisions of this rule.'' 57 FR 28098 (June 24, 1992). When the latest average monthly of an individual health insurance policy was calculated based on the current methodology, it was significantly different from that the Kaiser Family Foundation/Health Research and Educational Trust average monthly cost of an individual health insurance policy for the same time period. Therefore, the Secretary is proposing a new methodology to calculate the average cost of a health insurance policy.

Subtitle 2 of title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended, (the Act) governs the National Vaccine Injury Compensation Program (VICP). The VICP, administered by the Secretary of Health and Human Services (the Secretary) provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary, and the filing of a petition with the United States Court of Federal Claims (the Court). In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and the ''average cost of a health insurance policy, as determined by the Secretary.'' The elements of compensation that may be awarded to a successful petitioner are set out in section 2115 of the Public Service Act, 42 U.S.C. section 300aa-15. Subsection (a)(3)(B) specifically provides for compensation

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Thom E. Balbier Jr., Director, Division of Vaccine Injury Compen., Department of Health and Human Services, Health Resources and Services Administration, Room 8A–46, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–6593
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Email: tbalbier@hrsa.gov

RIN: 0906–AA68

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

Final Rule Stage

919. INTERIM FINAL RULE FOR THE SMALLPOX EMERGENCY PERSONNEL PROTECTION PROGRAM: SMALLPOX (VACCINIA) VACCINE INJURY TABLE

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

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

Abstract: To establish a table identifying adverse effects (including injuries, disabilities, conditions, and deaths) that shall be presumed to result from the administration of, or exposure to, the smallpox vaccine, and the time interval in which the first symptom or manifestation of each listed injury must manifest in order for such presumption to apply.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/27/03	68 FR 51492
Final Action	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Dr. Vito Caserta, Chief Medical Officer, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor, 4350 East West Highway, Bethesda, MD 20814
Phone: 301 443–4956
Email: smallpox@hrsa.gov

RIN: 0906–AA60

HHS—HRSA **Final Rule Stage**

920. SMALLPOX VACCINE INJURY COMPENSATION PROGRAM: ADMINISTRATIVE IMPLEMENTATION

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

Legal Authority: PL 108–20, 117 Stat 638

CFR Citation: 42 CFR 102

Legal Deadline: None

Abstract: To provide benefits to certain persons harmed as a result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a result of contracting vaccinia through accidental exposure to certain persons. The Secretary may also provide death benefits to certain survivors of people who died as a direct result of these injuries.

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Department of Health and Human Services, Health Resources and Services Administration, 10th Floor HRSA/OSP, 4350 East West Highway, Bethesda, MD 20814
Phone: 888 496–0338
Email: small@hrsa.gov

Related RIN: Related to 0906–AA60

RIN: 0906–AA61

921. • REQUIREMENTS ESTABLISHING A LIMITATION ON ADMINISTRATIVE EXPENSES; RYAN WHITE CARE ACT TITLE IV GRANTS FOR COORDINATED SERVICES AND ACCESS TO RESEARCH

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

Legal Authority: 42 USC 300ff–71

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule finalizes the determination to establish a limitation on administrative expenses for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act title IV Grants for Coordinated Services and Access to Research for Women, Infants, Children, and Youth. The rule establishes the limitation on administrative expenses as a percentage of the grant award, provides guidance on the procedures and processes for implementation of the limitation on administrative expenses, and clarifies the individual expenses that shall be categorized as administrative. The rule specifies the date for implementation as grants funded using FY 2005 grant dollars.

Timetable:

Action	Date	FR Cite
NPRM	08/12/03	68 FR 47923
NPRM Comment Period End	09/11/03	
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Wayne E. Sauseda Mr., Director, Division of Community Based Programs, Department of Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, Rm. 7A–30, Rockville, MD 20857
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Email: wsauseda@hrsa.gov

RIN: 0906–AA65

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) **Long-Term Actions**

922. 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 that 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.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

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, Health Resources and Services Administration, 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) **Proposed Rule Stage**
National Institutes of Health (NIH)

923. UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY THE NATIONAL INSTITUTES OF HEALTH (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 NIH. For each year of scholarship support, the recipient agrees to service (employment) after graduation, at NIH, for one year. Additionally, the individual agrees to at least 10 consecutive weeks of service (employment) at 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	11/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA10

924. NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 285g–10

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 Public Health Service (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 to the PHS Act that authorizes the Director of the National Institute of Child Health and Human Development, in consultation with the Administrator of the Health Resources and Services Administration, to support activities to provide for an increase in the number and size of institutional training grants supporting pediatric training.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA28

925. STANDARDS FOR A NATIONAL CHIMPANZEE SANCTUARY SYSTEM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 287a–3a

CFR Citation: 42 CFR 9

Legal Deadline: NPRM, Statutory, June 18, 2001.

Abstract: NIH proposes to establish standards for operating a national chimpanzee sanctuary system to provide for the retirement of federally-owned or supported chimpanzees no longer needed for research.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

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
Fax: 301 402–0169
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RIN: 0925–AA31

926. NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 216; 42 USC 288–1

CFR Citation: 42 CFR 68

Legal Deadline: None

Abstract: Section 487A of the Public Health Service Act creates a program through which appropriately qualified health professionals may obtain federally funded repayment of educational loans by conducting AIDS research as NIH employees. NIH is issuing regulations that will govern the program.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA32

927. NATIONAL INSTITUTES OF HEALTH EXTRAMURAL LOAN REPAYMENT PROGRAM FOR CLINICAL RESEARCHERS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5a

CFR Citation: 42 CFR 68g

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for the

Extramural Loan Repayment Program for Clinical Researchers, authorized under section 487F of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct clinical research.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

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
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Email: jm40z@nih.gov

RIN: 0925–AA33

928. NATIONAL INSTITUTES OF HEALTH PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–6

CFR Citation: 42 CFR 68e

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for Pediatric Research Loan Repayment Program, authorized under section 487F of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct pediatric research.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA34

929. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR HEALTH DISPARITIES RESEARCH

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 287c–33

CFR Citation: 42 CFR 68f

Legal Deadline: None

Abstract: NIH proposes to establish implementing regulations for the Loan Repayment Program for Health Disparities Research, authorized under section 485G of the Public Health Service Act. The program provides for the repayment of the existing educational loan debt of qualified health professionals who agree to conduct minority-health or other health-disparities research for a minimum of two years.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA35

930. NATIONAL INSTITUTES OF HEALTH CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–5

CFR Citation: 42 CFR 68a

Legal Deadline: None

Abstract: NIH proposes to amend the regulations governing the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds to reflect the new maximum annual loan amount of $35,000 and a change in program eligibility to include qualified health professionals who are not NIH employees, as well as to amend the definition of ''disadvantaged.''

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA36

931. NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM

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

Legal Authority: 42 USC 216; 42 USC 288–2

CFR Citation: 42 CFR 68c

Legal Deadline: None

Abstract: NIH proposes to amend its current regulations governing the National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program to make the eligibility requirements of the Program consistent with the eligibility requirements of the other extramural loan repayment programs administered by NIH.

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

HHS—NIH **Proposed Rule Stage**

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
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RIN: 0925–AA41

Department of Health and Human Services (HHS) National Institutes of Health (NIH) — Final Rule Stage

932. NATIONAL INSTITUTES OF HEALTH LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 288–3

CFR Citation: 42 CFR 68d

Legal Deadline: None

Abstract: Regulations will be issued to govern the awarding of educational loan repayments to qualified health professionals who agree to conduct research as employees of the National Institutes of Health.

Timetable:

Action	Date	FR Cite
NPRM	08/05/02	67 FR 50622
Final Action	07/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA18

933. NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 216; 42 USC 284g; 42 USC 285a–6(c)(1)(E); 42 USC 285a–7(c)(1)(G); 42 USC 285b–4; 42 USC 285c–5; 42 USC 285c–8; 42 USC 285d–6; 42 USC 285e–2; 42 USC 285e–3; 42 USC 285e–10a; . . .

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, 445I, 452E, and 485F of the Public Health Service Act. Section 409C concerns centers of excellence regarding research on autism; section 445I concerns centers of excellence in Alzheimer's disease research and treatment; section 452E concerns centers regarding research on ''fragile X;'' and section 485F concerns centers of excellence for research education and training for individualswho are members of minority health disparity populations.

Timetable:

Action	Date	FR Cite
NPRM	11/12/02	67 FR 68548
Final Action	07/00/04	

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
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA24

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

934. SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 52h

Completed:

Reason	Date	FR Cite
Final Rule	01/05/04	69 FR 272

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Jerry Moore
Phone: 301 496–4606
Fax: 301 402–0169
Email: jm40z@nih.gov

RIN: 0925–AA20

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

Prerule Stage

935. • HUMAN SUBJECTS PROTECTION REGULATIONS: ADDITIONAL PROTECTIONS FOR ADULT INDIVIDUALS WITH IMPAIRED DECISIONMAKING CAPACITY

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: Through this advance notice of proposed rulemaking (ANPRM), the Office for Human Research Protections (OHRP), Office of Public Health and Science, and the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) are seeking comment on whether it is necessary to develop additional safeguards to help protect adult individuals with impaired decisionmaking capacity who are potential subjects in research,, and if so, suggestions for appropriate safeguards. This ANPRM stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission entitled ''Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity'' (December 1998), and from subsequent recommendations by the Nation Human Research Protections Advisory Committee. The goal of these efforts is to maximize the safety and welfare of adult subjects with impaired decisionmaking capacity who participate in research supported, conducted, or regulated by HHS.

Timetable:

Action	Date	FR Cite
ANPRM	09/00/04	
ANPRM Comment Period End	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Julie A. Kaneshiro, Policy Team Leader, Office for Human Research Protections, Department of Health and Human Services, Office of Public Health and Science, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–2071
Email: jakaneshiro@ophs.dhhs.gov

RIN: 0940–AA11

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

Proposed Rule Stage

936. PUBLIC HEALTH SERVICE 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 basicguidelines 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	01/00/04	
NPRM Comment Period End	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Suite 750, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 443–3400
Fax: 301 443–5351

Related RIN: Related to 0940–AA01

RIN: 0940–AA04

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

Final Rule Stage

937. 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	01/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Office of Public Health and Science, Suite 750, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 443–3400
Fax: 301 443–5351

Related RIN: Related to 0940–AA04

RIN: 0940–AA01

938. HUMAN SUBJECTS PROTECTION REGULATIONS: INSTITUTIONAL REVIEW BOARDS REGISTRATION REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart F to Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, to require registration of institutional review boards (IRBs) with HHS. The registration information would include contact information, approximate numbers of active protocols involving research conducted or supported by HHS, accreditation status, IRB membership, and staffing for the IRB. The proposed registration requirements will make it easier for the Office for Human Research Protections (OHRP) to convey information to IRBs, and will support the current IRB registration operated by OHRP. Under the current OHRP IRB registration system, the submission of certain registration information is required by human subjects protection regulations, and certain other information may be submitted voluntarily. This proposed information collection was submitted to the Office of Management and Budget under the Paperwork Reduction Act. Under the proposed rule, all registration information will be required, making the IRB registration system uniform with IRB registration requirements of the Food and Drug Administration (FDA), and creating a single, HHS IRB Registration system. FDA will simultaneously publish a proposed rule regarding FDA IRB registration requirements.

Timetable:

Action	Date	FR Cite
NPRM	04/16/04	69 FR 20777
NPRM Comment Period End	06/15/04	
Final Action	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Irene Stith–Coleman Ph.D, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA06

939. • FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS TECHNICAL AMENDMENT

Priority: Substantive, Nonsignificant

Legal Authority: 5 USC 301; 42 USC 289; 42 USC 300v–1(b)

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This final rule amends the Department of Health and Human Services (HHS) regulations for the protection of human subjects by changing all references to the Office for Protection from Research Risks (OPRR) to the Office for Human Research Protections (OHRP) and revising the footnote at the end of 45 CFR 46.101(i) by deleting the references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B of 45 CFR part 46. This technical amendment is being made in conjunction with the other federal departments and agencies that have promulgated the Federal Policy for the Protection of Human Subjects.

Timetable:

Action	Date	FR Cite
Final Action	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA10

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

Long-Term Actions

940. HUMAN SUBJECTS PROTECTION REGULATIONS: TRAINING AND EDUCATION REQUIREMENTS FOR INSTITUTIONAL OFFICIALS, INSTITUTIONAL REVIEW BOARD MEMBERS AND STAFF, HUMAN PROTECTIONS ADMINISTRATORS, AND INVESTIGATOR

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

Legal Authority: 5 USC 301; 42 USC 289

CFR Citation: 45 CFR 46

Legal Deadline: None

Abstract: This notice of proposed rulemaking proposes to add subpart E to the Department of Health and Human Services (HHS) regulations for protection of human subjects, 45 CFR part 46, and would require that institutions engaged in human subjects research covered by an assurance of compliance filed with the Office for Human Research Protections ensure that institutional officials, institutional review board (IRB) chairpersons, and human protection administrators receive appropriate training and education about the institution's assurance and that IRB chairpersons and members, IRB staff, investigators, and other personnel involved in the conduct or oversight of human subjects research receive appropriate training and education about relevant human subjects protection requirements. The proposed training and education requirements will help to ensure that responsible individuals at assured institutions understand and meet their regulatory responsibilities for human subjects protection.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Michael A. Carome MD, Department of Health and Human Services, Office of Public Health and Science, Suite 200, The Tower Building, Suite 200, 1101 Wootten Parkway, Rockville, MD 20852
Phone: 301 496–7005
Fax: 301 402–0527

RIN: 0940–AA08

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

Proposed Rule Stage

941. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P)

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 proposed rule would revise 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 Period End	06/09/97	
Second NPRM	02/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Mercedes Benitex–McCray, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5716

Scott Cooper, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9465

RIN: 0938–AG81

942. 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; 42 CFR 488; 42 CFR 489; 42 CFR 494; 42 CFR 413; 42 CFR 414

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	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Robert Miller, Health Insurance Specialist, 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
Phone: 410 786–6797

Teresa Casey, Health Insurance Specalist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–05–04, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7215

RIN: 0938–AG82

943. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN 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	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Eva Fung, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–06–6, Office of Clinical Standards and Quality, S3–06–06, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7539

Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9614

RIN: 0938–AH17

944. 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 revises the existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. 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	05/00/05	

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, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6051

Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6617

RIN: 0938–AH27

945. STANDARD UNIQUE NATIONAL HEALTH PLAN IDENTIFIERS (CMS–6017–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 proposed 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 that have a national scope beyond Medicare and Medicaid.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

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, Office of Information Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–7448

RIN: 0938–AH87

946. APPEALS OF CARRIER DETERMINATION THAT A SUPPLIER FAILS TO MEET THE REQUIREMENTS FOR MEDICARE BILLING PRIVILEGES (CMS–6003–P2)

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 extends 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. In addition, certain appeal provisions are revised to correspond with the existing appeal provisions in those other sections of our regulations. The rule also extends appeal rights to all suppliers not covered by existing regulations to ensure they have a full and fair opportunity to be heard. Rule will incorporate provisions from section 936 of the MMA.

Timetable:

Action	Date	FR Cite
NPRM	10/25/99	64 FR 57431
Second NPRM	01/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ralph Goldberg, Division of Provider and Supplier Enrollment, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–4870

RIN: 0938–AI49

947. RURAL HEALTH CLINICS: AMENDMENTS TO PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS AND ESTABLISHMENT OF A QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM (CMS–1910–P2)

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. It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limits nonphysician practitioner staffing requirements. This rule imposes payment limits on provider-based RHCs and prohibits the use of RHC space, professional staff, equipment, and other RHC resources by another Medicare entity. The rule also requires RHCs to establish a quality assessment and performance improvement program.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74792
Second NPRM	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: David Worgo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–15–18, Center for Medicare Management, 7500 Security Boulevard, C4–15–18, Baltimore, MD 21244
Phone: 410 786–5919

RIN: 0938–AJ17

948. SUPPLIER STANDARDS FOR HOME OXYGEN, THERAPEUTIC SHOES, AND HOME NUTRITION THERAPY (CMS–6010–P)

Priority: Substantive, Nonsignificant

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 424.57

Legal Deadline: None

Abstract: This proposed rule would implement certain provisions in the statute relating to suppliers of durable medical equipment, prosthetics, orthotics, and supplies and establish service standards for suppliers of home oxygen equipment and therapeutic shoes home nutrition therapy. Establishing these standards would ensure that suppliers are qualified to provide the appropriate health care services and help safeguard the Medicare program and its beneficiaries from any instances of fraudulent or abusive billing practices.

Timetable:

Action	Date	FR Cite
NPRM	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ralph Goldberg, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–02–16, Center for Medicaid and State Operations, 7500 Security Boulevard, C3–02–16, Baltimore, MD 21244
Phone: 410 786–4870

RIN: 0938–AJ98

949. 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 rule proposes an electronic standard for claims attachments. The standard is required by the Health Insurance Portability and Accountability Act of 1996. It would be used to transmit clinical data, in addition to those data contained in the claims standard, to help establish medical necessity for coverage.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Lorraine Doo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Health Insurance Portability and Account Act Standards, S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6597

RIN: 0938–AK62

950. ORGAN PROCUREMENT ORGANIZATION CONDITIONS FOR COVERAGE (CMS–3064–P)

Priority: Other Significant

Legal Authority: 42 USC 1320b–8(b)(1)(A)(i); 42 USC 273(b)(2)

CFR Citation: 42 CFR 486.301

Legal Deadline: Final, Statutory, January 1, 2002, Requires promulgation of new conditions.

Abstract: This rule would 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. The Organ Procurement Organization Certification Act of 2000 requires CMS to increase the certification cycle for OPOs from two years to four years and to promulgate new performance standards for OPOs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/28/01	66 FR 67109
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Marcia Newton, Office of Clinical Standards and

Quality, Department of Health and Human Services, Centers for Medicare . Medicaid Services, S3–02–01, 7500 Security Boulevard, S3–05–18, Baltimore, MD 21244–1850
Phone: 410 786–5265

RIN: 0938–AK81

951. 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.

Legal Authority: PL 106–554, (BIPA 2000 of the Children's Health Act)

CFR Citation: 42 CFR 101; 42 CFR 418; 42 CFR 482; 42 CFR 483; 42 CFR 485

Legal Deadline: None

Abstract: This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care 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	04/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Carla McGregor, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S2–09–23, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7089

RIN: 0938–AL26

952. PROVIDER REIMBURSEMENT DETERMINATIONS AND APPEALS (CMS–1727–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1878 of the Social Security Act

CFR Citation: 42 CFR 405

Legal Deadline: None

Abstract: This proposed rule would redefine, clarify, and update the guidelines and procedures for Provider Reimbursement Review Board appeals, based on recent court decisions.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Morton Marcus, Heal Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4477

RIN: 0938–AL54

953. HEALTH COVERAGE PORTABILITY'S REQUEST FOR INFORMATION ON BENEFIT–SPECIFIC WAITING PERIODS (CMS–2150–NC)

Priority: Info./Admin./Other

Legal Authority: Not Yet Determined

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
NPRM	12/00/04	

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, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AL64

954. 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: Sec 1102 of the Social Security Act; Sec 1832 of the Social Security Act; Sec 1871 of the Social Security Act

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. The focus would be to improve outcomes of health care and satisfaction for Medicare beneficiaries, while streamlining structural and procedural requirements when possible.

Timetable:

Action	Date	FR Cite
NPRM	05/00/05	

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, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5526

Jacqueline Morgan, Health Insurance Specialist, 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
Phone: 410 786–4282

RIN: 0938–AL80

955. 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 300gg; 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. It would also 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	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Federal, Local, State

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

RIN: 0938–AL88

956. MODIFICATIONS TO ELECTRONIC TRANSACTIONS AND CODE SETS (CMS–0009–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1171 to 1179 of the Social Security Act

CFR Citation: 42 CFR 162.1002; 42 CFR 162.1802

Legal Deadline: None

Abstract: This proposed rule would revise the electronic transactions and code set standards mandated by the Health Insurance Portability and Accountability Act of 1966.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

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

Agency Contact: Stanley B. Nachimson, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–16–03, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6153

RIN: 0938–AM50

957. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM AND CALENDAR YEAR 2005 PAYMENT RATES (CMS–1427–P)

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

Legal Authority: 42 USC 1395L; Balanced Budget Act of 1997; Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999; Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

CFR Citation: Not Yet Determined

Legal Deadline: NPRM, Statutory, January 1, 2004.

Abstract: The proposed rule would revise the Medicare hospital outpatient prospective payment system beginning January 1, 2005. (The statute requires that this proposed rule and subsequent final rule be published by November 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	08/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Cindy Read, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Mangement, 7500 Security Boulevard, C4–05–07, Baltimore, MD 21244
Phone: 410 786–1852

RIN: 0938–AM75

958. TICKET TO WORK: DEFINING INDIVIDUALS WITH POTENTIALLY SEVERE DISABILITIES AND PROVIDING A WORK THRESHOLD (CMS–2172–P)

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

Legal Authority: Ticket to Work and Work Incentives Improvement Act of 1999

CFR Citation: None

Legal Deadline: None

Abstract: This proposed rule would provide a definition of ''medically determinable severe impairment'' under the Ticket to Work and Work Incentives Improvement Act of 1999.

Timetable:

Action	Date	FR Cite
NPRM	02/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carey Appold, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S2–14–26, Baltimore, MD 21224
Phone: 410 786–2117

RIN: 0938–AM79

959. PAYMENT ERROR RATE MEASUREMENT (PERM) PROGRAM (CMS–2186–P)

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

Legal Authority: Sec 1902 (a)(6) of the Social Security Act; Sec 2107 (b)(1) of the Social Security Act; Improper Payments Information Act of 2002 (IPIA) (PL 107–300)

CFR Citation: None

Legal Deadline: None

Abstract: Sections 1902(a)(6)and 2107(b)(1) of the Act, governing Medicaid and State Children's Health Insurance Program, respectively, require States to provide to the Secretary information to monitor program performance. This rule would require States under the current statutory provisions and the Improper Payments Information Act of 2002 and through this regulation to estimate improper payments using the CMS PERM methodolgy for the reporting year in the Medicaid and State Children's Health Insurance Program. The States are further required to submit payment error rates to CMS for the purpose of calculating a national level payment error rate as required by the Improper Payments Information Act of 2002.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Federalism: Undetermined

Agency Contact: Wayne Alden Slaughter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, S3–13–15, Baltimore, MD 21244
Phone: 410 786–0038

RIN: 0938–AM86

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960. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P)

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

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1395i–3; 42 USC 1396r

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This proposed rule would establish a Condition of Participation (CoP) for hospice services that long term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. We are proposing this new CoP to ensure that quality hospice are is to eligible residents. This proposed rule is intended to assist in meeting the Administration's goals for broad-based improvements in the quality of health care furnished through the Medicare and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Anita Panicker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Bloulevard, S3–04–26, Baltimore, MD 21244
Phone: 410 786–5646

RIN: 0938–AM87

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961. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HISTORY AND PHYSICAL EXAMINATIONS; AUTHENTICATION OF VERBAL ORDERS, SECURING MEDICATIONS AND POST–ANESTHESIA EVALUATIONS (CMS–3122–P)

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

Legal Authority: 42 USC 1395 x; 42 USC 1396 d; 42 USC 1395 bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would revise four of the conditions of participation that hospitals must meet to participate in the Medicare and Medicaid programs to decrease the burden on hospitals to conform to current standards of practice. They must establish and maintain policies and procedures that ensure that the hospital meets these requirements by using standard practices related to history and physical examinations, and completion of the post-anesthesia evaluation.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Organizations

Government Levels Affected: None

Agency Contact: Patricia Chmielewski, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899

RIN: 0938–AM88

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962. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 2005 (CMS–1429–P)

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

Legal Authority: 42 USC 1395W–4

CFR Citation: 42 CFR 410; 42 CFR 414

Legal Deadline: NPRM, Statutory, June 1, 2004, Revisions to Payment Policies.

Abstract: This rule would make several changes affecting Medicare part B payment. (The statute requires that the final rule be published by November 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Latesha Walker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1101

RIN: 0938–AM90

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963. • REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule proposes revisions to the 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 and Medicaid programs.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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–AM98

964. • PHYSICIAN REFERRAL FOR NUCLEAR MEDICINE SERVICES AND SUPPLIES (CMS–1261–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1877 of the Social Security Act

CFR Citation: 42 CFR 411.351

Legal Deadline: None

Abstract: This proposed rule would amend the definitions of ''radiology and certain other imaging services'' and ''radiation therapy services and supplies'' to include diagnostic and therapeutic nuclear medicine services and supplies, respectively.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4620
Email: jsinsheimer@cms.hhs.gov

RIN: 0938–AN04

965. • MEDICARE ADVANTAGE PROGRAM TITLE II (CMS–4069–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: 42 CFR 417; 42 CFR 422

Legal Deadline: None

Abstract: This proposed rule would implement title II of the Medicare Prescription Drug and Improvement Modernization Act establishing the Medicare Advantage program that would replace the existing Medicare+Choice program. Medicare Advantage offers improved managed care plans with coordinated care and competitive bidding, to promote greater efficiency and responsiveness to Medicare beneficiaries. (Rule needs to be published at least one year before January 1, 2006 implementation to award contracts.)

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Jane Andrews, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, C4–13–01, Baltimore, MD 21244–1850
Phone: 410 786–3133
Email: jandrews@cms.hhs.gov

RIN: 0938–AN06

966. • SPECIAL RULES FOR EMPLOYER–SPONSORED DRUG PROGRAMS: SUBSIDIES TO ENCOURAGE RETENTION (TITLE I) (CMS–2199–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: P.L. 108–173, 1860D–22

CFR Citation: 42 CFR 423

Legal Deadline: NPRM, Statutory, January 1, 2006.
Statute requires that payments to sponsors begin in 2006.

Abstract: Section 1860(D-22) of the Social Security Act (as added by the Medicare Prescription Drug Improvement and Modernization Act) establishes special rules for employer sponsored drug programs, beginning January 1, 2006, concerning payments to sponsors of retiree prescription drug plans.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: James Mayhew, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–9344
Email: jmayhew@cms.hhs.gov

RIN: 0938–AN07

967. • MEDICARE DRUG BENEFIT EFFECTIVE CALENDAR YEAR 2006 (TITLE I) (CMS–4068–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: PL 108–173 (MMA)

CFR Citation: 42 CFR 417; 42 CFR 423

Legal Deadline: None

Abstract: This proposed rule would implement title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) that establishes a new voluntary outpatient prescription drug benefit under a new Medicare part D, beginning January 1, 2006. Options for coverage of the drug benefit include private prescription drug plans (PDPs) that offer drug only coverage; Medicare Advantage plans; or preferred provider plans (PPOs) that would offer prescription drug and nondrug coverage. Plans would offer a standard drug benefit but have the

flexibility to vary the drug benefit within actuarial equivalency parameters. Assistance with premiums and cost sharing would be provided to eligible low-income beneficiaries.

Timetable:

Action	Date	FR Cite
NPRM	06/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal, State, Tribal

Federalism: Undetermined

Agency Contact: Tracey McCutcheon, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6715
Email: tmccutcheon@cms.hhs.gov

RIN: 0938–AN08

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968. • ENHANCED DSH TREATMENT FOR CERTAIN HOSPITALS (CMS–2198–P)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Section 1923(i) of the Social Security Act

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This regulation will implement section 1923(i) of the Social Security Act (the Act). Section 1923(i) of the Act requires States to report DSH payment information (name of DSH providers and amount of payment they received) to CMS. Under the law, States must also furnish CMS with an independent audit that verifies DSH payment to hospitals.

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: James Frizzera, Director, National Institutional Payment Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3263
Email: jfrizzera@cms.hhs.gov

RIN: 0938–AN09

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969. • PRIOR DETERMINATION PROCESS (CMS–6024–P)

Priority: Other Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: Sec 938 of the Medicare Modernization Act of 2003

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, June 8, 2005.

Abstract: Section 938 of the Medicare Modernization Act requires that physicians and beneficiaries be able to receive a prior determination regarding coverage of certain items and physicians' services beginning June 8, 2005. (The final rule must be published by March 25, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Misty D. Whitaker, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–3087
Email: mwhitaker@cms.hhs.gov

RIN: 0938–AN10

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970. • COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES (CMS–1270–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Public Law 108, MMA

CFR Citation: 42 CFR 414.200; 42 CFR 405.502 (g); 42 CFR 424.57; 42 CFR 410.38

Legal Deadline: NPRM, Statutory, April 1, 2005.
Final, Statutory, May 1, 2006.

Abstract: Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will also create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. (The statute requires competitive bidding be implemented by January 1, 2007. Proposed and final rules must be published six months prior to implementation.)

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, State

Agency Contact: Michael Patrick, Health Policy Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4495
Email: mkeane@cms.hhs.gov

RIN: 0938–AN14

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971. • UPDATE OF THE LIST OF COVERED PROCEDURES FOR AMBULATORY SURGICAL CENTERS FOR 2005 (CMS–1478–PN)

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

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: NPRM, Statutory, July 1, 2005.

Abstract: This proposed notice updates the list of Medicare-covered ASC procedures. (The subsequent final notice must be published by March 25, 2005, to be effective July 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Bob Cereghino, Health Insurance Specialist, Department of Health and Human

Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD
Phone: 410 786–4645
Email: bcereghino@cms.hhs.gov

RIN: 0938–AN23

972. • REVISIONS TO HIPAA CODE SETS (CMS–0013–P)

Priority: Economically Significant. Major under 5 USC 801.

Unfunded Mandates: Undetermined

Legal Authority: PL 104–191

CFR Citation: 45 CFR 162

Legal Deadline: None

Abstract: This rule will propose revisions to the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003. The Secretary intends to propose any replacements for specific code sets.

Timetable:

Action	Date	FR Cite
NPRM	03/00/05	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected: Federal, Local, State, Tribal

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

Energy Effects: Statement of Energy Effects planned as required by Executive Order 13211.

Agency Contact: Maria A. Friedman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6333
Email: mfriedman@cms.hhs.gov

RIN: 0938–AN25

973. • PAYMENT FOR CLINICAL LABORATORY TESTS (CMS–1494–P)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1833(h)(8) of the MMA; Sec 416 of the MMA; PL 108–173

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The Medicare Modernization Act of 2003 (MMA), Public Law 108-173, requires codification of the payment basis for determining Medicare payments for new clinical laboratory tests under the clinical laboratory fee schedule. Also, MMA's section 416 eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the two-year period beginning on July 1, 2004. Section 1833(h) of the Act mandates payment for outpatient clinical laboratory tests under a clinical laboratory fee schedule.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anita Greenberg, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4601
Email: agreenberg@cms.hhs.gov

RIN: 0938–AN26

974. • PROSPECTIVE PAYMENT SYSTEM FOR LONG TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES FOR 2006 (CMS–1483–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Sec 123, PL 106–113; Sec 307(b), PL 106–554

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This rule proposes the payment rate update for the 2006 prospective payment system for Medicare long-term care hospitals. The new rates will be based on cost reports from the first LTC PPS rate year. The proposed and final rules must be published by April 29, 2005, to be effective July 1, 2005.)

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Judy Richter, Health Insurance Specialist, CMS/CMM/HAPG/DAC, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2590
Email: jrichter@cms.hhs.gov

RIN: 0938–AN28

Department of Health and Human Services (HHS) **Final Rule Stage**

Centers for Medicare & Medicaid Services (CMS)

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

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1396d

CFR Citation: 42 CFR 441 to 442; 42 CFR 483

Legal Deadline: None

Abstract: This final 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
60–Day Delay of Effective Date To 05/22/2001	03/21/01	66 FR 15800
Interim Final Rule Comment Period End	03/23/01	
Interim Final Rule Effective	03/23/01	
Interim Final Rule Amendment with Clarification	05/22/01	66 FR 28110
Interim Final Rule Comment Period End	07/23/01	
Final Action	04/00/05	

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, Center for Medicaid and State Operations, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–5903

RIN: 0938–AJ96

976. REVISIONS TO THE MEDICARE APPEALS PROCESS (CMS–4004–FC)

Priority: Other Significant

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 405

Legal Deadline: NPRM, Statutory, October 1, 2002, Statutory effective date October 1, 2002.

Abstract: This final rule with comment period addresses one discrete aspect of the November 15, 2002, proposed rule, ''Changes to the Medicare Claims Appeal Procedures'' (67 FR 69312). As required by section 1869(b)(1)(F) of the Social Security Act, this rule establishes expedited determination and reconsideration procedures for beneficiaries who are informed by a provider that Medicare coverage of their services is about to end. This rule implements section 937 of the Medicare Modernization Act which requires a process for correction of minor errors and omissions without pursing the appeals process.

Timetable:

Action	Date	FR Cite
NPRM	11/15/02	67 FR 69312
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Undetermined

Agency Contact: Janet Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–14–26, S1–06–04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1588

RIN: 0938–AL67

977. ELECTRONIC MEDICARE CLAIMS SUBMISSION (CMS–0008–F)

Priority: Other Significant

Legal Authority: PL 107–105

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This final rule implements the requirements for electronic submission of Medicare claims, submitted on or after October 16, 2003. In addition, this rule also implements the conditions upon which a waiver could be granted for these requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/15/03	68 FR 48805
Interim Final Rule Comment Period End	10/16/03	
Final Action	09/00/06	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Stewart Streimer, Director, Division of Operations Standards, Office of Program Administration, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 1–C–6 Meadows East Building, 6325 Security Boulevard, Baltimore, MD 21207
Phone: 410 786–9318

RIN: 0938–AM22

978. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2005 (CMS–1249–N)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Sec 1888(e) of the Social Security Act

CFR Citation: 42 CFR 413.330 to 413.350

Legal Deadline: NPRM, Statutory, July 30, 2004, Statue requires the final rule to be published by August 1, 2004.

Abstract: This annual notice updates the payment rates used under the skilled nursing facilities prospective payment system beginning October 1, 2004.

Timetable:

Action	Date	FR Cite
Notice	07/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: William Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–13–15, Center for Medicaid and State Operations, 7500 Security Boulevard, C5–07–08, Baltimore, MD 21244
Phone: 401 786–5667

RIN: 0938–AM46

979. TITLE I: NON–FEDERAL GOVERNMENTAL PLANS EXEMPT FROM HIPAA (CMS–2033–F)

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

Legal Authority: Sec 2721(b)(2) of the Public Health Service Act

CFR Citation: 45 CFR 146.180

Legal Deadline: None

Abstract: This final rule adopts as final the exemption election requirements that apply to self-funded non-Federal governmental plans. Since we received no public comments on the July 26, 2002, interim final with comment period, this rule finalizes the circumstances under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the Public Health Service Act and provides guidance on the procedures, limitations, and documentation associated with exemption elections.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment Period	07/26/02	67 FR 48802
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

Agency Contact: Dave Holstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Insurance Standards Team, S3–16–16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1564

Related RIN: Related to 0938–AK00

RIN: 0938–AM71

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980. REVISIONS TO THE APPEALS PROCESS FOR INITIAL CLAIM DETERMINATIONS (CMS–4064–FC)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 521 of BIPA

CFR Citation: 42 CFR 40S

Legal Deadline: None

Abstract: This final rule will revise the Medicare appeals process by adding five-tiered (five levels) of review. It will remove the distinction between the processing of initial determination and appeals under part A and part B required by section 521 of Benefits Improvement and Protection Act of 2000 (BIPA).

Timetable:

Action	Date	FR Cite
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Janet Miller, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, N2–14–26, S1–06–04, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1588

Related RIN: Related to 0938–AK69

RIN: 0938–AM73

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981. CONDITIONS FOR COVERAGE OF POWER MOBILITY DEVICES, INCLUDING POWERED WHEELCHAIRS AND POWER–OPERATED VEHICLES SCOOTER(CMS–3017–IFC)

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

Legal Authority: Sec 1102 of the Social Security Act; Sec 1871 of the Social Security Act

CFR Citation: 42 CFR ch IV, sec 410, subpart B; 42 CFR 410.38

Legal Deadline: None

Abstract: This rule will make the requirements to purchase power operated vehicles, functioning as wheelchairs, less stringent.

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Lorrie Ballantine, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7543

RIN: 0938–AM74

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982. HOSPICE WAGE INDEX FY 2005 (CMS–1264–N)

Priority: Routine and Frequent. Major status under 5 USC 801 is undetermined.

Legal Authority: 1814(i)(A)

CFR Citation: 42 CFR 418.306(d)

Legal Deadline: Final, Statutory, October 1, 2004, effective date. Wage Index update is effective October 1, of each year.

Abstract: This notice announces the annual update to the hospice wage index for FY 2005. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on the recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Timetable:

Action	Date	FR Cite
Notice	08/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Terri Deutseh, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–08–28, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–9462

RIN: 0938–AM78

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983. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FY 2005 RATES (CMS–1428–F)

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

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

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

Legal Deadline: NPRM, Statutory, April 1, 2004.
Final, Statutory, August 1, 2004.

Abstract: This proposed rule would revise the Medicare acute hospital inpatient prospective payment system for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, the Addendum,

describes changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes apply to discharges on or after October 1, 2004. This proposed rule also setsforth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the prospective payments systems. (The statute requires that this proposed and subsequent final rule be published by August 1, 2004.)

Timetable:

Action	Date	FR Cite
NPRM	05/18/04	69 FR 28195
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Tzvi Hefter, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–07–07, Center for Medicare Management, 7500 Security Boulevard, C4–07–07, Baltimore, MD 21244
Phone: 410 786–4487

RIN: 0938–AM80

984. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2005 (CMS–1360–N)

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

Legal Authority: Sec 1886(j) of the Social Security Act; PL 105–33; PL 106–554; PL 106–113

CFR Citation: None

Legal Deadline: Final, Statutory, August 1, 2004, Rates for PPS.

Abstract: This notice updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2005. (The statute requires that this notice be published by August 1, 2004.)

Timetable:

Action	Date	FR Cite
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Robert Kuhl, Division Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–11–06, Center for Medicare Management, 7500 Security Boulevard, C5–06–24, Baltimore, MD 21244
Phone: 410 786–4597

RIN: 0938–AM82

985. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE FY 2005 (CMS–1265–P)

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

Legal Authority: Sec 1895 of the Social Security Act, ; Sec 421 of the MMA; Sec 701 of the MMA

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would set 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. It also proposes to rebase and revise the home health market basket to reflect total cost and modify certain variables for some of the cost categories. It implements sections 421 (one-year increase in rural areas) and 701 (move to CY updates) of the Medicare Modernization Act (effective April 1, 2004). (The proposed and final rules must be published by September 30, 2004, to allow three months for systems changes.)

Timetable:

Action	Date	FR Cite
NPRM	06/02/04	69 FR 31248
Final Action	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Randy Throndset, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0131

RIN: 0938–AM93

986. • CHANGES TO MEDICARE PAYMENT FOR DRUGS AND PHYSICIAN FEE SCHEDULE PAYMENTS FOR CALENDAR YEAR 2004—CORRECTION NOTICE CMS–1372–IFC)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: Medicare Prescription Drug, Improvement and Modernization Act of 2003

CFR Citation: 42 CFR 405; 42 CFR 414

Legal Deadline: Final, Statutory, January 1, 2004.

Abstract: This final rule with comment implements section 602 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Specifically, it revises the payment methodology under Medicare for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis; makes adjustments to payment for certain drug administration services under the physician fee schedule; makes revisions to the geographic practice expense cost indices used for determining payment under the physician fee schedule and announces a 1.5 percent increase in the calendar year 2004 physician fee schedule conversion factor.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/07/04	69 FR 1084
Interim Final Rule Comment Period End	03/08/04	
Correction	03/26/04	69 FR 15703
Correction	06/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal

Agency Contact: Marc Hartstein, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–4539
Email: mhartstein@cms.hhs.gov

RIN: 0938–AM97

987. • PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS: EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE (CMS–1809–F5)

Priority: Routine and Frequent

Legal Authority: Sec 1877 of the Social Security Act

CFR Citation: None

Legal Deadline: None

Abstract: This final rule delays for six months the effective date of the last sentence of 42 CFR 411.354(d)(1) of the physician self-referral rule published on January 4, 2001. This sentence defines compensation that is ''set in advance'' as it relates to percentage compensation methodologies.

Timetable:

Action	Date	FR Cite
Final Action	07/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Karen Raschke, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–0016
Email: kraschke@cms.hhs.gov

Related RIN: Related to 0938–AL29, Related to 0938–AM21, Related to 0938–AM58, Related to 0938–AM95

RIN: 0938–AM99

988. • TIME LIMITATION ON RECORD KEEPING REQUIREMENTS UNDER THE DRUG REBATE PROGRAM (CMS–2188–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: This proposed rule would establish ten-year record keeping requirements for drug manufacturers under the Medicaid drug rebate program.

Timetable:

Action	Date	FR Cite
NPRM	01/06/04	69 FR 565
Final Action	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Marge Watchorn, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4361
Email: mwatchorn@cms.hhs.gov

RIN: 0938–AN01

989. • EXTENDED AVAILABILITY OF UNEXPENDED SCHIP FUNDS FROM THE APPROPRIATION FOR FYS 1998 THROUGH 2004; AUTHORITY TO USE A PORTION OF SCHIP FUNDS FOR MEDICAID EXPENDITURES (CMS–2187–N)

Priority: Other Significant

Legal Authority: 42 USC 1302

CFR Citation: None

Legal Deadline: None

Abstract: This notice extends availability of unexpended SCHIP funds from the appropriation for fiscal years 1998 through 2004 and provides the authority for qualifying States to use a portion of SCHIP funds for Medicaid expenditures.

Timetable:

Action	Date	FR Cite
Final Action	06/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Governmental Jurisdictions

Government Levels Affected: State

Agency Contact: Richard Strauss, Division Director, Division of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN03

990. • FY 2005 SCHIP ALLOTMENTS (CMS–2201–N)

Priority: Economically Significant

Legal Authority: Title XXI of the Social Security Act, sec 2104

CFR Citation: 42 CFR 457

Legal Deadline: None

Abstract: This notice sets forth the final allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year 2005. (The notice must be published as soon as possible so that the funds can be distributed to the States before September 30, 2004, as required by the statute.)

Timetable:

Action	Date	FR Cite
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Richard Strauss, Director, Division of Financial Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore , MD 21244
Phone: 410 786–2019
Email: rstrauss@cms.hhs.gov

RIN: 0938–AN11

991. • SCHEDULE FOR PUBLISHING MEDICARE FINAL REGULATIONS AFTER A PROPOSED OR INTERIM FINAL REGULATION (CMS–9026–N)

Priority: Info./Admin./Other

Legal Authority: Sec 902 of the Medicare Modernization Act of 2003

CFR Citation: None

Legal Deadline: None

Abstract: In accordance with Section 902 of the Medicare Modernization Act of 2003, this rule establishes a regular timeline for the publication of final regulations based on the previous publication of a proposed or interim final regulation.

Timetable:

Action	Date	FR Cite
Notice	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Renee Swann, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4492
Email: rswann@cms.hhs.gov

RIN: 0938–AN12

992. • EVALUATION CRITERIA AND STANDARDS FOR QUALITY IMPROVEMENT PROGRAM CONTRACTS (CMS–3142–NC)

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: Sec 1153(h)(2) of the Social Security Act

CFR Citation: None

Legal Deadline: Final, Statutory, August 31, 2004.
There is a 60 day comment period required for the evaluation criteria used in evaluating the Quality Improvement Organizations.

Abstract: Section 1153(h)(2) of the Act requires the Secretary to publish in the Federal Register the general criteria and standards that will be used to evaluate the Quality Improvement Organizations (QIOs), and provide opportunity for public comment. This notice will describe the evaluation criteria CMS will use to evaluate the QIOs. There should be no additional costs associated with this requirement. The evaluation portion of the contract has already been factored into the award. (This notice with comment period must be published by May 28, 2004, to allow sufficient time for receipt and response to comments prior to the first round of QIO evaluations beginning November 2004. Delaying the first round of evaluations will delay the statutory requirement to notify QIOs of nonrenewal of their current contracts 90 days prior to their expiration, as well as extend the QIOs' work beyond the current contract period.)

Timetable:

Action	Date	FR Cite
Notice	09/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Maria L, Hammel, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1775
Email: mhammel@cms.hhs.gov

RIN: 0938–AN13

993. • PART A PREMIUMS FOR CALENDAR YEAR 2005 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8022–N)

Priority: Other Significant

Legal Authority: 42 USC 1395–2(d)(2); 42 USC 1395i–2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)

CFR Citation: None

Legal Deadline: NPRM, Statutory, January 1, 2005.

Abstract: This notice announces the hospital insurance premium for Calendar Year 2005 under Medicare's Hospital Insurance Program (Medicare part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

Action	Date	FR Cite
Notice	10/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov

RIN: 0938–AN15

994. • INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2005 (CMS–8021–N)

Priority: Other Significant

Legal Authority: 42 USC 1395–2 (b) (2); Social Security Act section 1813 (b) (2)

CFR Citation: None

Legal Deadline: NPRM, Statutory, January 1, 2005.

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in Calendar Year 2005 under Medicare's Hospital Insurance program (Medicare part A). The Medicare statute specifies the formula used to determine these amounts. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

Action	Date	FR Cite
Notice	10/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6390
Email: cmcfarland@cms.hhs.gov

RIN: 0938–AN16

995. • MEDICARE PART B MONTHLY ACTUARIAL RATES AND PREMIUM RATE BEGINNING JANUARY 1, 2005 (CMS–8020–N)

Priority: Other Significant

Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811

CFR Citation: None

Legal Deadline: NPRM, Statutory, September 30, 2004.

Abstract: Section 629 of the Medicare Modernization Act requires indexing the part B deductible to inflation beginning January 1, 2005. This notice announces the monthly actuarial rates for aged (65 and over) and disabled

(under age 65) enrollees in part B of Medicare for 2005. It also announces the monthly Part B premium to be paid by all enrollees during 2005. (CMS generally publishes this notice to coincide with the SSA Cola announcement.)

Timetable:

Action	Date	FR Cite
Final Action	10/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carter Warfield, Deputy Director, Medicare & Medicaid Cost Estimates Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6396
Email: cwarfield@cms.hhs.gov

RIN: 0938–AN18

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996. • FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES–UPDATE FOR CALENDAR YEAR 2005 (CMS–1267–N)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 1861(S)(7); 1834(I)(3)(B); 221 BIPA

CFR Citation: 414.620(f) CFR; 414.610(c)(5) CFR; 414.615 CFR; 414.605 CFR

Legal Deadline: Final, Statutory, January 1, 2004.

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act. (This nonmajor rule must be published by December 1, 2004, to be effective January 1, 2005)

Timetable:

Action	Date	FR Cite
Notice	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Ann Tayloe, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4546
Email: atayloe@cms.hhs.gov

RIN: 0938–AN20

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997. • PROCEDURE FOR PRODUCING GUIDANCE DOCUMENTS DESCRIBING MEDICARE'S COVERAGE PROCESS (CMS–3141–N)

Priority: Info./Admin./Other. Major status under 5 USC 801 is undetermined.

Legal Authority: Sec 731 of the MMA

CFR Citation: None

Legal Deadline: Other, Statutory, January 1, 2004, Required by Section 731 of the MMA.

Abstract: Section 731 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) requires that the Secretary make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. This notice describes a proposed method of developing and making public guidance documents consistent with these requirements and invites public comment on this process beginning January 1, 2005.

Timetable:

Action	Date	FR Cite
Final Action	08/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Vadim Lubarsky, Technical Adivsor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov

RIN: 0938–AN21

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998. • AMENDMENT TO THE INTERIM FINAL REGULATION FOR MENTAL HEALTH PARITY (CMS–2152–F2)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: 45 CFR 146.136

Legal Deadline: None

Abstract: The amendment to the interim final rule changes the sunset date of regulations under the Mental Health Parity Act of 1996 (MHPA). The MHPA as initially enacted had a sunset date of September 30, 2001. The implementing regulations published in 1997 included a corresponding sunset date. Subsequent legislation enacted on January 10, 2002, extended the sunset date of the MHPA to December 31, 2002. Legislation enacted on December 2, 2002, extended the sunset date again, to December 31, 2003. Therefore, this amendment to the 1997 regulations extends the sunset date of the regulations to December 31, 2004, consistent with the MHPA.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/27/03	68 FR 38206
Final Action	07/00/04	

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, Center for Medicaid and State Operations, 7500 Security Boulevard, S3–16–26, Baltimore, MD 21244
Phone: 410 786–6851

RIN: 0938–AN22

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999. • MEDICARE AMBULANCE FEE SCHEDULE UPDATE (CMS–1492–IFC)

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

Legal Authority: Sec 1834(i) of the Social Security Act; Sec 414 of the MMA

CFR Citation: 42 CFR 414, subpart H

Legal Deadline: Final, Statutory, July 1, 2004, Interim final.

Abstract: Section 414 of the Medicare Modernization Act provides for temporary increases to the Medicare ambulance fee schedule beginning July 7, 2004. It also increases mileage payments for certain long trips.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/04	

HHS—CMS **Final Rule Stage**

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local

Federalism: Undetermined

Agency Contact: Robert Niemann, Health Insurance Specialist, CMS/CMM/HAPG/DAS, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4596
Email: rnieman@cms.hhs.gov

RIN: 0938–AN24

1000. • MEDICARE SECONDARY PAYER (MSP): WORKMEN'S COMPENSATION (CMS–1272–FC)

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

Legal Authority: Sec 301 of the Medicare Prescripition Drug, Improvement, and Modernization Act of 2003

CFR Citation: 42 CFR 411

Legal Deadline: Final, Statutory, December 8, 2003.

Abstract: Section 301 of the Medicare Modernization Act clarifies when CMS may make a conditional Medicare payment when other insurance cannot reasonably be expected to make a prompt payment (effective December 8, 2003).

Timetable:

Action	Date	FR Cite
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Undetermined

Agency Contact: Suzanne Ripley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0970
Email: sripley@cms.hhs.gov

RIN: 0938–AN27

1001. • RANDOM PREPAYMENT REVIEW (CMS–6022–IFC)

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Sec 934 of the MMA

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, December 8, 2004.

Abstract: Section 934 of the Medicare Modernization Act establishes requirements for prepayment medical review of a provider beginning December 8, 2004. This regulation will establish contractor standards relating to the initiation and termination of nonrandom prepayment reivew.

Timetable:

Action	Date	FR Cite
Interim Final Rule With Comment Period	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Ann Casey, Health Insurance Specialist, CMS/OFM/PIG, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore , MD 21244
Phone: 410 786–7861
Email: acasey@cms.hhs.gov

RIN: 0938–AN31

1002. • ADDITIONAL PAYMENTS FOR CERTAIN MEDICARE PART B DRUGS (CMS–1280–FC)

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

Legal Authority: Sec 303(e)(2) of the Medicare Modernization Act of 2003

CFR Citation: 42 CFR 414.1000 to 414.1002

Legal Deadline: None

Abstract: This final rule with comment period continues the implementation of section 303(e)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 by establishing a separate billable fee to be paid to pharmacies for supplying certain Medicare part B drugs and biologicals.

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Angela Mason, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244
Phone: 410 786–7452
Email: amason@cms.hhs.gov

RIN: 0938–AN34

1003. • FEDERAL ENFORCEMENT IN GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS (CMS–2019–F)

Priority: Other Significant

Legal Authority: 42 USC 300gg–22; 42 USC 300gg–31

CFR Citation: 45 CFR 150.101 to 150.465

Legal Deadline: None

Abstract: This rule finalizes, without any substantive changes, an interim final regulation (HCFA-2019-IFC) that sets forth the process by which CMS enforces the HIPAA title I requirements with regards to State and local governmental group health plans. It also finalizes the process by which CMS assumes direct enforcement responsibility in a State with regard to group and individual market health insurance issues.

Timetable:

Action	Date	FR Cite
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Local, State

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

RIN: 0938–AN35

HHS—CMS — Final Rule Stage

1004. • FIRE SAFETY REQUIREMENTS FOR CERTAIN HEALTH CARE FACILITIES, AMENDMENT (CMS–3047–F2)

Priority: Other Significant

Legal Authority: Not Yet Determined

CFR Citation: None

Legal Deadline: None

Abstract: This final rule amends the fire safety standard for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long term care facilities, intermediate care facilities for the mentally retarded, and critical access hospitals that participate in Medicare and Medicaid. The rule would adopt a change made to the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). We adopted the 2000 edition of the LSC in January 2003. The LSC change will allow facilities to place alcohol-based hand sanitizer dispensers in exit corridors under certain conditions. These sanitizers have proven to be effective in increasing hand hygiene and have the potential to improve infection control practice. Adopting the LSC change would increase a provider's flexibility in meeting infection control goals while minimizing potential fire safety concerns.

Timetable:

Action	Date	FR Cite
Final Action	05/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6617

RIN: 0938–AN36

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) — Long-Term Actions

1005. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING MEDICARE BILLING PRIVILEGES (CMS–6002–F)

Priority: Other Significant

Legal Authority: 42 USC 1302; 42 USC 1395hh

CFR Citation: 42 CFR 424

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM	04/25/03	68 FR 22064
Final Action	04/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Michael Collett, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, C3–02–06, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–6121

RIN: 0938–AH73

1006. MEDICARE OUTCOME AND ASSESSMENT INFORMATION SET (OASIS) DATA REPORTING REQUIREMENTS (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 Action	11/00/06	

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: Aucha Prachanronarong, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, MD 21244 Phone: 410 786–9614

RIN: 0938–AJ10

1007. 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 rule requires hospitals that transfuse blood and blood products to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased risk for transmitting HCV; quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Mary Collins, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–3189

RIN: 0938–AJ29

1008. MEDICARE HOSPICE CARE AMENDMENTS (CMS–1022–F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105–33, sec 1961(dd) ; PL 105–33, sec 1814(i); PL 105–33, sec 4441 to 4444; PL 105–33, sec 4448; PL 106–113, sec 131; PL 106–554, sec 321; PL 106–554, sec 322; PL 105–33, sec 4449

CFR Citation: 42 CFR 418

Legal Deadline: None

Abstract: This final rule revises certain regulations governing coverage and payments for hospice care under the Medicare program as required by the Balanced Budget Act of 1997.

Timetable:

Action	Date	FR Cite
NPRM	11/22/02	67 FR 70363
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Thomas Saltz, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C4–05–27, Centers for Medicare Management, 7500 Security Boulevard, C4–05–27, Baltimore, MD 21244
Phone: 410 786–4480

Related RIN: Previously reported as 0938–AH73

RIN: 0938–AJ36

1009. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS—PHASE II (CMS–1810–IFC)

Priority: Other Significant

Legal Authority: 42 USC 1877

CFR Citation: 42 CFR 411 & 424

Legal Deadline: None

Abstract: This intermin final rule with comment period incorporates into regulation certain statutory provisions that preclude payment for services under Medicare if a physician makes a referral to a facility in which he/she has a financial interest. It addresses comments from the January 9, 1998, proposed rule concerning the ownership, investment, and compensation exceptions. It also addresses comments from the January 4, 2001, final rule with comment period.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/26/04	69 FR 16054
Interim Final Rule Comment Period End	06/24/04	
Final Action	03/00/07	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Joanne Sinsheimer, Technical Advisor, CMM, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–25–02, Baltimore, MD 21244
Phone: 410 786–4620

RIN: 0938–AK67

1010. CONTINUATION OF MEDICARE ENTITLEMENT WHEN DISABILITY BENEFIT ENDS BECAUSE OF SUBSTANTIAL GAINFUL ACTIVITY (CMS–4018–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 202 of the TWWIIA of 1999; PL 106–170

CFR Citation: 42 CFR 406.12

Legal Deadline: None

Abstract: This final rule implements the Ticket to Work and Work Incentives Improvement Act of 1999. It provides working disabled individuals with continued Medicare entitlement for an additional 54 months beyond the current limit, for a total of 78 months of Medicare coverage following the 15th month of the extended period of eligibility.

Timetable:

Action	Date	FR Cite
NPRM	07/25/03	68 FR 43998
Final Action	07/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Denise Cox, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Health Insurance Specialist, 7500 Security Boulevard, S1–05–06, Baltimore, MD 21244
Phone: 410 786–3195

RIN: 0938–AK94

1011. MEDICARE PROGRAM; INTEREST CALCULATION (CMS–6014–F)

Priority: Other Significant

Legal Authority: Sec 1815(d) of the Social Security Act; Sec 1833 (j) of the Social Security Act

CFR Citation: 42 CFR 405.378; 42 CFR 411.24

Legal Deadline: None

Abstract: This final rule will change the formula for computing interest on provider and supplier overpayments and underpayments to make it consistent with the new CMS accounting system, Healthcare Integrated General Ledger Accounting System.

Timetable:

Action	Date	FR Cite
NPRM	07/25/03	68 FR 43995
Final Action	07/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Organizations

Government Levels Affected: None

Agency Contact: Nancy Braymer, Financial Management Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C3–14–21, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4323

RIN: 0938–AL14

1012. 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 146.111; 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.119; 45 CFR 146.120; 45 CFR 146.125; 45 CFR 146.143; . . .

Legal Deadline: None

Abstract: This final rule provides portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan under the Health Insurance Portability and Accountability Act of 1996. This regulation addresses limitations or preexisting exclusion periods on 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	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

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

RIN: 0938–AL43

1013. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT PSYCHIATRIC FACILITIES FY 2004 (CMS–1213–F)

Priority: Other Significant

Legal Authority: PL 106–113; Sec 124 of the BBRA ; Sec 1886 of the Social Security Act

CFR Citation: 42 CFR 412, subpart N; 42 CFR 413; 42 CFR 424

Legal Deadline: NPRM, Statutory, October 1, 2002, Public Law 106–113, Sec 124.

Abstract: This final rule sets forth a prospective payment system (PPS) for inpatient psychiatric facilities and psychiatric units.

Timetable:

Action	Date	FR Cite
NPRM	11/28/03	68 FR 66919
Final Action	11/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Lana Price, Director, Division of Chronic Care Management, Chronic Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, C5–05–27, Center for Medicare Management, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4533

RIN: 0938–AL50

1014. DMERC SERVICE AREAS AND RELATED MATTERS (CMS–1219–F)

Priority: Substantive, Nonsignificant

Legal Authority: Sec 1842 of the Social Security Act; Sec 1834(a)(12) of the Social Security Act; Sec 1834(h)(3) of the Social Security Act; Sec 1834(j)(1) of the Social Security Act

CFR Citation: 42 CFR 421.210

Legal Deadline: None

Abstract: This rule allows flexibility in making changes to the DMERC contractor structure.

Timetable:

Action	Date	FR Cite
NPRM	03/26/04	69 FR 15755
Final Action	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Kim Nyland, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S1–14–27, Center for Medicare Management, 7500 Security Boulevard, S1–14–27, Baltimore, MD 21244
Phone: 410 786–2289

RIN: 0938–AL76

1015. PROCEDURES FOR MAINTAINING CODE LISTS IN THE NEGOTIATED NATIONAL COVERAGE DETERMINATIONS FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES (CMS–3119–F)

Priority: Other Significant

Legal Authority: 42 USC 1395h(a); 42 USC 1395e; 42 USC 1395u(a); 42 USC 1395x; 42 USC 1395y(a)(1)(A); 42 USC 1395y(a)(7)

CFR Citation: None

Legal Deadline: None

Abstract: This final rule establishes the procedures to be used for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in 66 FR 58788 on November 25, 2001.

Timetable:

Action	Date	FR Cite
NPRM	12/24/03	68 FR 74607
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jacqueline Sheridan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, C1–09–06, Baltimore, MD 21244
Phone: 410 786–4635

RIN: 0938–AM36

1016. HOSPITAL PATIENTS' RIGHTS COP—STANDARD SAFETY COMPLIANCE COMMITTEES (CMS–3120–P)

Priority: Economically Significant. Major under 5 USC 801.

Legal Authority: 42 USC 1395bb; 42 USC 1395x; 42 USC 1396d

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This proposed rule would allow hospitals to waive the current requirement that a physician or licensed independent practitioner perform a one-hour face-to-face

evaluation of a patient in restraint or seclusion for the purpose of behavior management. Under this proposed rule, a hospital could choose to have the one-hour assessment performed by another practitioner, such as a registered nurse, if that hospital established a Protections Compliance Committee to oversee the use of restraint or seclusion

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Organizations

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: 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–AM39

1017. REQUIREMENTS FOR NURSING HOMES TO IDENTIFY THE NUMBER OF LICENSED AND UNLICENSED NURSES (CMS–3121–F)

Priority: Other Significant

Legal Authority: Sec 1819(b) of the Social Security Act; 42 USC 1395i–3(b)

CFR Citation: 42 CFR 483

Legal Deadline: None

Abstract: This final rule implements section 941 of the Medicare, Medicaid, and SCHIP benefits Improvement and Protection Act and requires nursing homes to post daily, for each shift, the number of full-time equivalents (FTEs) of registered nurses, licensed practical nurses, licensed vocational nurses, and certified nurse aides who are directly responsible for resident care.

Timetable:

Action	Date	FR Cite
NPRM	02/27/04	69 FR 9282
NPRM Comment Period End	04/27/04	
Final Action	02/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Anita Panicker, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3–04–26, Office of Clinical Standards and Quality, 7500 Security Boulevard, S3–02–01, Baltimore, MD 21244
Phone: 410 786–5646

RIN: 0938–AM55

1018. COVERED OUTPATIENT DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM (CMS–2174–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1905 (a) (12) of the Social Security Act; Sec 1903 (a) of the Social Security Act ; Sec 1902 (a) (54) of the Social Security Act ; Sec 1903 (i) (10) of the Social Security Act ; Sec 1927 of the Social Security Act

CFR Citation: 42 CFR 441 ; 42 CFR 447

Legal Deadline: None

Abstract: This proposed rule will repropose and request public comments on numerous provisions related to the Medicaid drug rebate program. The agency published a proposed rule on September 19, 1995. However, in light of new issues, the agency seeks an opportunity to propose new provisions and seeks comments.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Marge Watchorn, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, S2–05–16, Baltimore, MD 21244
Phone: 410 786–4361

RIN: 0938–AM81

1019. REVISIONS TO COST SHARING REGULATIONS (CMS–2144–P)

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

Unfunded Mandates: Undetermined

Legal Authority: Sec 1916 of the Social Security Act ; Sec 1902(a)(4) of the Social Security Act

CFR Citation: 42 CFR 447.51 to 447.56

Legal Deadline: None

Abstract: This proposed rule would revise the cost sharing requirements in our current regulation to allow for the imposition of higher levels of cost sharing and more flexibility in the way in which cost sharing is imposed and administered under current statutory requirements. (The cost sharing requirements have remained unchanged since 1974. States have requested that we update the cost sharing requirements.)

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Federal, State

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

Agency Contact: Alissa Deboy, Special Assistant, Department of Health and Human Services, Centers for Medicare & Medicaid Services, CMSO, S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6041

RIN: 0938–AM94

1020. • MEDICARE PROGRAM; HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PAYMENT REFORM FOR CALENDAR YEAR 2004 CMS–1371–IFC

Priority: Other Significant. Major under 5 USC 801.

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: Final, Statutory, January 1, 2004.

Abstract: This rule revises payment rates for drugs in 2004 and 2005. (Section 621 of MMA requires the rule to be implemented by January 1, 2004.)

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/06/04	69 FR 820
Final Action	01/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Dana Buley, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–4547
Email: dbuley@cms.hhs.gov

RIN: 0938–AM96

1021. • PAYMENT FOR RESPIRATORY ASSIST DEVICES WITH BI–LEVEL CAPABILITY AND A BACK–UP RATE (CMS–1167–F)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: 42 USC 1395(m)(3)

CFR Citation: 42 CFR 414.222(a)(1)

Legal Deadline: Final, Statutory, August 22, 2006, MMA Section 902.

Abstract: This final rule clarifies that respirator assist devices with bi-level capability and a back-up rate must be classified as capped rental Durable Medical equipment (DME) in accordance with section 1834(a)(3) of the Social Security Act (42 USC 1395(m)(3)).

Timetable:

Action	Date	FR Cite
Final Action	08/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Joel Kaiser, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, 7500 Security Boulevard, C5–07–26, Baltimore, MD 21244
Phone: 410 786–4499
Email: jkaiser@cms.hhs.gov

Related RIN: Related to 0938–AL27

RIN: 0938–AN02

1022. • MANUFACTURERS' SUBMISSION OF AVERAGE SALES PRICE DATA FOR MEDICARE PART B DRUGS AND BIOLOGICALS (CMS–1380–IFC)

Priority: Other Significant

Unfunded Mandates: Undetermined

Legal Authority: Sec 303(c) of the MMA 2003

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: Section 303(c) of the Medicare Prescription Drug Improvement and Modernization Act requires manufacturers to submit average sales price data on Medicare part B drugs. This regulation provides instruction to manufacturers on the data submission requirements.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/06/04	69 FR 17935
Final Action	04/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Federal

Agency Contact: Angela Mason, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, 7500 Security Boulevard, C4–05–17, Baltimore, MD 21244
Phone: 410 786–7452
Email: amason@cms.hhs.gov

RIN: 0938–AN05

1023. • NONDISCRIMINATION IN POST–HOSPITAL REFERRAL TO HOME HEALTH AGENCIES AND OTHER ENTITIES (CMS–1224–F)

Priority: Substantive, Nonsignificant

Legal Authority: PL 105–33, sec 4321 of the BBA

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule establishes a process for collecting and maintaining information about hospitals referring Medicare patients to home health agencies (HHAs) with which the hospitals have a financial interest. Collected information will be available to the public to enhance its understanding and awareness of the availability of Medicare-certified HHAs to serve the Medicare population. (This final rule must be published by November 22, 2005, to meet the three-year publication deadline.)

Timetable:

Action	Date	FR Cite
NPRM	11/22/02	67 FR 70373
Final Action	11/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Elizabeth Carmody, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–7533
Email: ecarmody@cms.hhs.gov

RIN: 0938–AN19

1024. • NONDISCRIMINATION IN HEALTH COVERAGE AND BONAFIDE WELLNESS PLANS IN THE GROUP MARKET (CMS–2022–F)

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

Legal Authority: 42 USC 300gg

CFR Citation: 45 CFR 146.121

Legal Deadline: None

Abstract: This document contains final rules governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1966. It also addresses comments we received on the Bonafide Wellness Plan proposed rule (CMS-2078-P).

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Comment Period End	07/17/97	
Interim Final Rule Effective	07/17/97	

HHS—CMS **Long-Term Actions**

Action	Date	FR Cite
Interim Final Rule	01/08/01	66 FR 1378
Interim Final Rule Effective	03/09/01	
Interim Final Rule Comment Period End	04/09/01	
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: Local, State

Agency Contact: David Mlawsky, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6851
Email: dmlawsky@cms.hhs.gov

RIN: 0938–AN29

1025. • HOSPITAL CONDITIONS OF PARTICIPATION: PATIENTS' RIGHTS (CMS–3018–F)

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

Legal Authority: 42 USC 1395x; 42 USC 1396d; 42 USC 1395bb

CFR Citation: 42 CFR 482

Legal Deadline: None

Abstract: This final rule sets forth standards for the use of restraints and seclusion in Medicare- and Medicaid-participating hospitals as part of the Patients' Rights Condition of Participation (CoP) and finalizes other patients' rights afforded by that CoP. It finalizes six standards that ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: 1) notification of his or her rights; 2) the exercise of his or her rights in regard to his or her care; 3) privacy and safety; 4) confidentiality of patient records; 5) freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and 6) freedom from seclusion and restraint for behavior management unless clinically necessary.

Timetable:

Action	Date	FR Cite
Final Action	12/00/06	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Patricia Chmielewski, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6899
Email: pchmielewski@cms.hhs.gov

RIN: 0938–AN30

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

Completed Actions

1026. HEALTH INSURANCE REFORM: STANDARD UNIQUE HEALTH CARE PROVIDER IDENTIFIER (CMS–0045–F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 160; 42 CFR 162

Completed:

Reason	Date	FR Cite
Final Action	01/23/04	69 FR 3434

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal, Local, State, Tribal

Agency Contact: Patricia Peyton
Phone: 410 786–1812

RIN: 0938–AH99

1027. COVERAGE OF RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTIONS (CMS–1909–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 403.736; 42 CFR 403. 738; 42 CFR 489.102

Completed:

Reason	Date	FR Cite
Final Action	11/28/03	68 FR 66710

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Jean Marie Moore
Phone: 410 786–3508

RIN: 0938–AI93

1028. ALL PROVIDER BAD DEBT PAYMENT (CMS–1126–F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: 42 CFR 413.80; 42 CFR 413.178

Completed:

Reason	Date	FR Cite
Withdrawn	06/02/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: None

Agency Contact: Katie Walker
Phone: 410 786–7278

RIN: 0938–AK02

1029. REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS (CMS–3063–F)

Priority: Other Significant

CFR Citation: 42 CFR 405

Completed:

Reason	Date	FR Cite
Final Action	11/07/03	68 FR 63691

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Vadim Lubarsky
Phone: 410 786–0840
Email: vlubarsky@cms.hhs.gov

RIN: 0938–AK60

1030. RATE OF REIMBURSEMENT OF PHOTOCOPY EXPENSES FOR QUALITY IMPROVEMENT ORGANIZATIONS (CMS–3055–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 476.78

Completed:

Reason	Date	FR Cite
Final Action	12/05/03	68 FR 67955

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Les Caplan
Phone: 410 786–7223

RIN: 0938–AK68

1031. ELIMINATION OF STATEMENT OF INTENT PROCEDURES FOR FILING MEDICARE CLAIMS (CMS–1185–F)

Priority: Other Significant

CFR Citation: 42 CFR 424

Completed:

Reason	Date	FR Cite
Final Action	04/23/04	69 FR 21963

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, State

Agency Contact: David Walczak
Phone: 410 786–4475

RIN: 0938–AK79

1032. PERMITTING PREMIUM REDUCTIONS AS ADDITIONAL BENEFITS UNDER MEDICARE+CHOICE PLANS (CMS–6016–F)

Priority: Substantive, Nonsignificant

CFR Citation: 42 CFR 408

Completed:

Reason	Date	FR Cite
Final Action	11/28/03	68 FR 66721

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Federal, Local, State

Agency Contact: Michele Sanders
Phone: 410 786–0808

RIN: 0938–AL49

1033. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND CALENDAR YEAR 2004 PAYMENT RATES (CMS–1471–F)

Priority: Other Significant. Major under 5 USC 801.

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Final Action	11/07/03	68 FR 63398

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Federal

Agency Contact: Cindy Read
Phone: 410 786–1852

RIN: 0938–AL91

1034. CRITERIA FOR DETERMINING WHETHER A DRUG IS CONSIDERED USUALLY SELF–ADMINISTERED (CMS–1228–P)

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

CFR Citation: Not Yet Determined

Completed:

Reason	Date	FR Cite
Withdrawn	04/26/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Angela Mason
Phone: 410 786–7452
Email: amason@cms.hhs.gov

RIN: 0938–AM13

1035. INPATIENT HOSPITAL DEDUCTIBLE AND HOSPITAL AND EXTENDED CARE SERVICES COINSURANCE AMOUNTS FOR CALENDAR YEAR 2004 (CMS–8016–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/24/03	68 FR 60995

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786–6390

RIN: 0938–AM31

1036. MONTHLY ACTUARIAL RATES AND MONTHLY SUPPLEMENTARY MEDICAL INSURANCE PREMIUM RATE BEGINNING JANUARY 1, 2004 (CMS–8017–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/24/03	68 FR 60997

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Carter S. Warfield
Phone: 410 786–6396

RIN: 0938–AM32

1037. PART A PREMIUMS FOR CALENDAR YEAR 2004 FOR THE UNINSURED AGED AND FOR CERTAIN DISABLED INDIVIDUALS WHO HAVE EXHAUSTED OTHER ENTITLEMENT (CMS–8018–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	10/24/03	68 FR 61002

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Clare McFarland
Phone: 410 786–6390

RIN: 0938–AM33

1038. GRANTS TO STATES FOR OPERATION OF QUALIFIED HIGH RISK POOLS (CMS–2179–FC)

Priority: Other Significant

CFR Citation: 45 CFR 148

Completed:

Reason	Date	FR Cite
Final Action	03/26/04	69 FR 15695

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: James Mayhew
Phone: 410 786–9244

RIN: 0938–AM42

1039. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES UPDATE FOR CALENDAR YEAR 2004 (CMS–1232–FCC)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Final Rule	12/05/03	68 FR 67960

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Anne Tayloe
Phone: 410 786–4546

RIN: 0938–AM44

1040. EXCLUSION OF MEDICARE BENEFITS FOR ALIENS NOT LAWFULLY PRESENT IN THE UNITED STATES (CMS–1222–FC)

Priority: Other Significant

CFR Citation: 42 CFR 411.11

Completed:

Reason	Date	FR Cite
Withdrawn	11/28/03	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Frederick William Grabau
Phone: 410 786–0206

RIN: 0938–AM47

1041. REVISED CIVIL MONEY PENALTIES, ASSESSMENTS, EXCLUSIONS, AND RELATED APPEALS PROCEDURES (CMS–6146–P)

Priority: Other Significant

CFR Citation: 42 CFR 402, subpart C & 402.3

Completed:

Reason	Date	FR Cite
Withdrawn	05/11/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Joel Cohen
Phone: 410 786–3349

Related RIN: Duplicate of 0938–AM98

RIN: 0938–AM54

1042. CHANGES TO THE CRITERIA FOR BEING CLASSIFIED AS AN INPATIENT REHABILITATION FACILITY (CMS–1262–F)

Priority: Economically Significant

CFR Citation: 42 CFR 412

Completed:

Reason	Date	FR Cite
Final Rule	05/07/04	69 FR 25751

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Robert Kuhl
Phone: 410 786–4597

Related RIN: Split from 0938–AL95

RIN: 0938–AM72

1043. PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES (EFFECTIVE 7/1/04) (CMS–1263–F)

Priority: Other Significant

CFR Citation: 42 CFR 412 ; 42 CFR 413

Completed:

Reason	Date	FR Cite
NPRM	01/30/04	69 FR 4754
Final Action	05/07/04	69 FR 25673

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Tzvi Hefter
Phone: 410 786–4487

RIN: 0938–AM84

1044. DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS INSTITUTIONS FOR MENTAL DISEASE (IMDS) (CMS–2062–N)

Priority: Other Significant

CFR Citation: None

Completed:

Reason	Date	FR Cite
Notice	03/26/04	69 FR 15850

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Jim Frizzera
Phone: 410 786–9535

RIN: 0938–AM89

1045. • PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS: EXTENSION OF PARTIAL DELAY OF EFFECTIVE DATE (CMS–1809–F4)

Priority: Other Significant

Legal Authority: None

CFR Citation: None

Legal Deadline: None

Abstract: This final rule delays for six months the effective date of the last sentence of 42 CFR 411.354(d)(1) of the physician self-referral rule published on January 4, 2001. This sentence defines compensation that is ''set in advance'' as it relates to percentage compensation methodologies. (The rule will be published only if Stark II, Phase II (CMS-1810-FC) is not published by December 31, 2003.)

Timetable:

Action	Date	FR Cite
Final Action	12/24/03	68 FR 74491

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Karen Raschke, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244
Phone: 410 786–0016
Email: kraschke@cms.hhs.gov

Related RIN: Related to 0938–AL29, Related to 0938–AM58

RIN: 0938–AM95

1046. • NOTICE OF ONE–TIME APPEAL PROCESS FOR HOSPITAL WAGE INDEX CLASSIFICATION (CMS–1373–N)

Priority: Info./Admin./Other

Legal Authority: Sec 508(a) of the Medicare Prescription Drug Improvement and Moderization Act of 2003

HHS—CMS **Completed Actions**

CFR Citation: None

Legal Deadline: None

Abstract: This notice implements section 508(a) of Public Law 108-173. This section provides that, by January 1, 2004, the Secretary must establish by instruction or otherwise, a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital. (Statute requires notice be implemented and announced by 1/1/04, and applications be received by 2/15/04.)

Timetable:

Action	Date	FR Cite
Notice	01/06/03	68 FR 661
Notice	02/13/04	69 FR 7340

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Stephen Phillips, Deputy Division Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4548
Email: sphillips@cms.hhs.gov

Related RIN: Related to 0938–AN17

RIN: 0938–AN00

Department of Health and Human Services (HHS) Administration for Children and Families (ACF)

Proposed Rule Stage

1047. SAFEGUARDING CHILD SUPPORT AND EXPANDED FEDERAL PARENT LOCATOR SERVICES (FPLS) INFORMATION

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 652 to 654A; 42 USC 663; 42 USC 1302

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 enforcementagencies. The legislation has rendered obsolete or inconsistent several regulations at 45 CFR chapter III, Office of Child Support Enforcement, including the regulations on the Federal Parent Locator Service, the State Parent Locator Services, offset of Federal payments for purposes of collecting child support, and safeguarding of information. This regulation would update various sections in 45 CFR chapter III to reflect the statutory changes.

Timetable:

Action	Date	FR Cite
NPRM	01/00/05	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Local, Tribal

Agency Contact: Eileen C. Brooks, Deputy Director, Policy Division, 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
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AC01

1048. 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.

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	01/00/05	

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

1049. ADMINISTRATIVE COSTS FOR CHILDREN IN TITLE IV–E FOSTER CARE

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 672; 42 USC 674; 42 USC 1302

CFR Citation: 45 CFR 1356.60(c)

Legal Deadline: None

Abstract: This notice of proposed rulemaking implements the title IV-E foster care eligibility and administrative cost provisions in sections 472 and 474 of the Social Security Act. We propose to prohibit the reimbursement of administrative costs claimed on behalf of children in unlicensed foster family homes, with the exception of children in relative foster family homes while the State is in the process of licensing the home. We also propose to prohibit the reimbursement of administrative costs claimedon behalf of children in unallowable facilities, with the exception of the month prior to a child's transition into an allowable facility.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

HHS—ACF **Proposed Rule Stage**

Agency Contact: Kathleen McHugh, Divison Director, Children's Bureau Policy, Department of Health and Human Services, Administration for Children and Families, Room 2411, 330 C Street SW., Washington, DC 20447
Phone: 202 401–5789
Fax: 202 205–8221
Email: kmchugh@acf.hhs.gov

RIN: 0970–AC14

1050. ADMINISTRATIVE COST SHARING UNDER TANF

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

Legal Authority: 42 USC 1302

CFR Citation: 45 CFR 263; 45 CFR 263.14

Legal Deadline: None

Abstract: This proposed rule will enable States (including the District of Columbia) and territories to use either the ''primary program'' cost allocation methodology previously allowed under the Aid to Families with Dependent Children (AFDC) program to allocate the common administrative costs of determining eligibility in the Temporary Assistance for Needy Families (TANF) program, the Medicaid program, and the Food Stamp programs or to continue to use a ''benefiting'' cost allocation methodology. Pursuant to a determination by Secretary Thompson, States and territories would be able to elect to use their Federal TANF funds to pay for costs that are common to the administration of the TANF, Medicaid, and Food Stamps Programs, in accordance with the primary program cost allocation methodology previously allowed under the former AFDC program.

Timetable:

Action	Date	FR Cite
NPRM	10/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: Local, State

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

Agency Contact: April Kaplan, Deputy Director, Office of Family Assistance, Department of Health and Human Services, Administration for Children and Families, 5th Floor East, 370 L'Enfant Promenade SW., Washington, DC 20447
Phone: 202 401–5138
Email: akaplan@acf.hhs.gov

RIN: 0970–AC15

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

Final Rule Stage

1051. CHILD SUPPORT ENFORCEMENT PROGRAM; FEDERAL TAX REFUND OFFSET

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 664; 42 USC 1302

CFR Citation: 45 CFR 303.72

Legal Deadline: None

Abstract: This interim final rule will revise existing regulations on collecting child support arrears through the Federal Tax Refund Offset process. The revisions are needed to reflect changes in data processing protocols with the Department of the Treasury. We are also updating the regulation to reflect current business practices and requests from the state child support agencies.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/26/03	68 FR 37978
Final Action	01/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: Eileen C. Brooks, Deputy Director, Policy Division, 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
TDD Phone: 800 877–8339
Fax: 202 401–4054
Email: ebrooks@acf.hhs.gov

RIN: 0970–AC09

1052. • HEAD START TRANSPORTATION

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

Legal Authority: Not Yet Determined

CFR Citation: 45 CFR 1310

Legal Deadline: None

Abstract: This interim final rule will extend for 150 days those parts of the Head Start transportation regulation that deal with the requirement that each vehicle used to transport children is equipped for use of child safety restraint systems and the requirement that each bus have a bus monitor. Additionally, these rules will provide Head Start grantees the opportunity to request further extension of the effective date when such an extension is in the best interest of the children they serve.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/04	69 FR 2513
Final Action	12/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Windy Hill, Associate Commisioner, Head Start Bureau, Department of Health and Human Services, 330 C Street SW., Washington, DC 20447
Phone: 202 205–8573
Email: whill@acf.hhs.gov

RIN: 0970–AC16

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)

Completed Actions

1053. CHILD SUPPORT ENFORCEMENT FOR INDIAN TRIBES

Priority: Other Significant

CFR Citation: 45 CFR 309

Completed:

Reason	Date	FR Cite
Final Rule	03/30/04	69 FR 16638

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State, Tribal

Agency Contact: Paige Biava
Phone: 202 401–9386

RIN: 0970–AB73

1054. CHARITABLE CHOICE PROVISIONS APPLICABLE TO THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM

Priority: Other Significant

CFR Citation: 45 CFR 260.30; 45 CFR 260.34

Completed:

Reason	Date	FR Cite
Final Rule	09/30/03	68 FR 56449

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: State

Agency Contact: April Kaplan
Phone: 202 401–5138
Email: akaplan@acf.hhs.gov

RIN: 0970–AC12

1055. COMMUNITY SERVICES BLOCK GRANT CHARITABLE CHOICE

Priority: Substantive, Nonsignificant

CFR Citation: 45 CFR 1050

Completed:

Reason	Date	FR Cite
Final Rule	09/30/03	68 FR 56466

Regulatory Flexibility Analysis Required: No

Government Levels Affected: Federal

Agency Contact: Clarence Carter
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Email: ccarter@acf.hhs.gov

RIN: 0970–AC13

Department of Health and Human Services (HHS)
Administration on Aging (AOA)

Proposed Rule Stage

1056. GRANTS FOR STATE AND COMMUNITY PROGRAMS ON AGING, TRAINING, RESEARCH, AND DISCRETIONARY PROGRAMS; VULNERABLE ELDER RIGHTS; 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 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 2004.

Timetable:

Action	Date	FR Cite
NPRM	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses, Governmental Jurisdictions

Government Levels Affected: State, Tribal

Federalism: Undetermined

Agency Contact: Edwin Walker, Deputy Assistant Secretary for Policy and Programs, Department of Health and Human Services, Administration on Aging, Washington, DC 20201
Phone: 202 401–4634

RIN: 0985–AA00

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