

A.1 Department Wide Initiatives

CFR Cite	Reference	Agency	Purpose	Impact
Updating regulations in recognitions of changing technology				
45 CFR §§1355.50 – 56	Statewide Automated Child Welfare System (SACWIS)	ACF/ACYF/CB	Grant greater flexibility to States to implement automation that supports their business model; Reduce costs; Reflect changing technology advances; Enable Tribes to implement SACWIS-like systems	Increased flexibility at reduced costs for title IV-E agencies
45 CFR §1351.17	How is application made for a Runaway and Homeless Youth Program grant?	ACF/ACYF/FYSB	Update outdated procedures for obtaining announcements and submitting applications.	Reduce confusion and streamline application process using automation
45 CFR Parts 301, 302, 303, 304, 305, 307	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.	OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.
42 CFR Part 67	Health Services Research, Evaluation, Demonstration, and Dissemination Projects; Peer Review of Grants and Contracts	AHRQ	Update of Regulations [Federal Register Volume 62, Number 52 (Tuesday, March 18, 1997)], pages 12906 - 12914	Minimal impact; primary purpose is to revise and update this AHRQ Peer Review Regulation
42 CFR 37	Specifications for Medical Examinations of Underground Coal Miners (NPRM, RIN 0920-AA21)	CDC	Modification will allow the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current regulations require the use of film radiography which is being phased out of use at medical facilities in the U.S.	Use of current technology will increase accessibility of services to coal miners. Also anticipate decreased cost for mine operators to obtain modern digital chest images instead of outdated chest x-rays
21 CFR 310 21 CFR 414 21 CFR 600	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)	FDA/CDER	FDA is revising its regulations to allow mandatory safety reports to be transmitted electronically.	Would allow FDA to collect and analyze safety reports more quickly and to identify emerging problems faster and disseminate information.
21 CFR 314 21 CFR 601	Electronic Submission of Clinical Study Data (e-CSD)	FDA/CDER	FDA is revising its regulations to require submission of data in drug applications in electronic format that FDA can process, review and archive.	Use of modern technology would increase efficiency and allow for more comprehensive data review.
21 CFR 201	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (e-Labeling)	FDA/OP	This rule would require electronic "package inserts" for human drug and biological products.	Up-to-date prescribing information for healthcare professionals.
21 CFR 207	Electronic Registration and Listing for Drugs (e-DRLS)	FDA-CDER	Would convert the registration and listing process to a paperless system, while maintaining an avenue for companies that do not have access to the web.	Would allow for the utilization of latest technology in the collection of information and improve FDA's ability to inspect manufacturing establishments.

21 CFR 807	Electronic Registration and Listing for medical devices	FDA/CDRH	Would convert the registration and listing process to a paperless system, while maintain an avenue for companies that do not have access to the web.	Would allow for the utilization of latest technology in the collection of information.
42 CFR Part 485	Telemedicine Final Rule	CMS	Would allow practitioners in one Medicare participating hospital to provide consultation and services to a patient in another Medicare participating hospital without requiring certification in the second hospital.	Published May 11, 2011. Expected to increase access to health care providers and reduce costs. CMS estimates \$13.6 million in net annual savings to hospitals from this initiative.
21 CFR 4	Current Good Manufacturing Practices (CGMPs) for Combination Products	FDA/OC	Would clarify and codify CGMPs requirements for products that are combinations of drug, device and/or biological products.	Would provide regulatory clarity for manufacturers of combination products.
21 CFR 4	Postmarketing Safety Reporting for Combination Products	FDA/OC	Would clarify that a combination product is subject to the reporting requirements associated with the type of marketing application under which the product was approved.	Would provide regulatory clarity for manufacturers of combination products.

Review reporting and recordkeeping requirements to reduce burden

45 CFR Parts 1385-1388	Requirements applicable to the developmental disabilities program	ACF/ADD	The original NPRM from June 2008 (to establish long overdue regulations for full reauthorization of the DD Act of 2000) received negative comments. ADD plans to rewrite the package to reduce administrative burden; to reflect improvements in data collection, performance measurement and reporting; and to improve consistency with the statute.	Additional flexibility and reduced administrative burden. Reflect improvements in data collection, performance measurement and reporting. Improved consistency with the statute.
42 CFR 34	Medical Examination of Aliens	CDC	NPRM will propose streamlining regulations, updating vaccination requirements and definition changes for drug abuse and drug addiction, revise the scope of the medical examination, and update the list of a communicable disease of public health significance.	Rule reduces the burden and streamlines the immigration process for both the physicians conducting the medical examinations and the U.S. communities receiving immigrants and refugees.
42 CFR 71.53 71.53	Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primates (NPRM, RIN 0920-AA23).	CDC	NPRM proposes to modify and streamline existing regulations and guidance to reduce administrative burdens for importers of NHPs.	NPRM proposes to reduce the frequency at which importers of nonhuman primates are required to renew their registrations, and to eliminate quarantine costs for zoo-to-zoo and laboratory-to-laboratory facilities that maintain detailed records.
42 CFR Part 412	Inpatient Prospective Payment System Final Rule	CMS	Currently hospitals must provide actuarial determinations for pension costs and Medicare contractors must review those actuarial reports. Revised reporting could reduce burden by removing the need for an actuarial determination.	Published August 1, 2011. Expected to provide flexibility to reduce burdens and costs.

45 CFR 164.512	Disclosures of Student Immunization Records to Schools under the HIPAA Privacy Rule	OCR	Better facilitate the disclosure of student immunization records to schools in states that have school entry laws	Will facilitate these public health disclosures, reduce burden on parents and health care providers, and help avoid delays in children beginning school
45 CFR 164.528	HIPAA Privacy Rule Accounting of Disclosures Requirements	OCR	Improve the workability of current disclosure requirements and better balance the burden to regulated entities with the benefit to individuals	Will provide the individual with information about those disclosures that are most likely to have an impact on the individual's legal and personal interests, while reducing administrative burden on regulated entities
45 CFR 164.520	HIPAA Privacy Rule Requirements on Health Plans to Re-Distribute to Individuals Their Notices of Privacy Practices When Material Changes are Made	OCR	This rule will propose changes to reduce administrative burdens on health plans while still ensuring individuals are notified of material changes to privacy practices.	OCR estimates that this rule will achieve a one-time net savings of \$120 million with an associated reduction of 2 million burden hours. Savings are expected to accrue to both public and private health plans within 60 days of the compliance date of the regulation.

Reviewing regulations to "clean up" or eliminate outdated provisions.

45 CFR Part 1370	Family Violence Prevention and Services Programs	ACF/ACYF/FYSB	Rescind the requirement to publish quarterly funding opportunity announcements in the Federal Register and revise regulations to bring them into conformity with the reauthorized Family Violence Prevention and Services Act	Clarity of programmatic operating procedures
45 CFR § 400.11(c)	Award of Grants to States	ACF/ORR	Delete reference to financial status reports being required quarterly for Social Services grants; Add language to require annual reporting for Social Services grants with the flexibility for ORR to request financial status reports more frequently in accordance with Part 92.	Reduces burden on states by decreasing frequency of reporting unless a specific need surfaces.
42CFR8	Opioid Treatment Facilities	SAMHSA	Review requirements that methadone clinics are to follow and credentialing agencies are to follow in credentialing such programs.	Provide more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction. Such flexibility will expand the number of patients receiving this form of treatment and potentially reduce costs associated with drug related crime because more patients are receiving treatment.