

Template for Agencies
July 2013 Retrospective Review Update and Two-Year Forecast

Modify, streamline, expand, or rescind existing rule to reduce regulatory and administration burdens						
Agency	RIN/OMB Control No.	Title of Initiative/Rule/Information Collection Request (ICR) under the PRA	Brief Description	Actual or Target Completion Date	Anticipated savings in costs and/or information collection burdens, together with any anticipated changes in benefits	Progress updates and anticipated accomplishments
ACF	0970-AB73	Child Support Enforcement for Indian Tribes	This proposed rule would update the Tribal Child Support regulations, published in 2004. The changes to the regulation will improve the operations of tribal programs. Tribal programs have been operating for over 8 years; this rule will strengthen the regulations and close the gaps in the current regulation.	Proposed Rule Target: 8/00/15	Prior to writing this NPRM, OCSE will consult with Tribal Governments. This proposed regulation will improve the budget process, saving time for the grantee and the federal government. This NPRM will propose case closure standards for tribal programs, a critical element that is currently missing from the regulation. This rule may impact child support distribution, providing a more family friendly distribution scenario.	Proposed rule in development. ACF plans to discuss anticipated action at ACF Tribal Consultation in July 2013.
ACF	0970-AC50	Flexibility, Efficiency, and Modernization of Child Support Enforcement Programs	This rule would: 1. improve document management by allowing states to submit and accept information electronically; 2. increase statutory state law exemption approval periods from three to five years; 3. update case closure criteria to increase state flexibility and facilitate effective transfer between states and tribes; and 4. discontinue the mandate for states to notify other states involved in enforcing a support order when they submit an interstate case for offset. States referring interstate child support cases for federal income tax refund offset to collect past-due child support would notify other states involved in enforcing the support orders when offset amounts are received from the U.S. Treasury.	Proposed Rule Target: 7/00/13	This proposed rule would: 1. provide flexibility in the use of cost-saving and efficient technologies, such as e-mail or electronic document storage, whenever possible; 2. provide relief to states by decreasing the frequency with which states have to request an extension of any approved state law exemption; 3. provide states greater flexibility to close unenforceable cases and redirect resources to more productive efforts and provide states a process to close and transfer cases to tribal child support programs; and 4. relieve states from being inundated with unnecessary information, ultimately saving both time and resources.	Under E.O. 12866 review. Proposed rule in development (Target: 7/00/13).
ACF	N/A	Statewide Automated Child Welfare System (SACWIS)	This proposed rule would grant greater flexibility to states and tribes to implement automation that supports their business models; reflect changing technology advances; and enable tribes to implement SACWIS-like systems.	Proposed Rule Target: 3/00/14	This proposed regulation would provide greater flexibility to states and tribes, and result in lower costs for the design, development, implementation, operation, and maintenance of state and tribal systems. Increased flexibility would also help foster care agencies place and keep track of children across jurisdictions.	Federal Register Notice for tribal consultations published on 1/5/12. Tribal consultation teleconferences were held on 2/15/12-2/16/12. The public comment period for tribal consultation concluded 4/6/12. Proposed rule in development (Target: 3/00/14)
CDC	0920-AA23	Control of Communicable Diseases; Foreign - Importation of Nonhuman Primates	This final rule extends the existing nonhuman primate importation requirements from three species to all nonhuman primates. This rule also reduces the frequency of registration renewal from every 180 days to every two years.	Proposed Rule Published: 1/5/11 Final Rule Published: 2/15/13	This rule strengthens the public health benefits of current practices by extending existing importation requirements to additional nonhuman primates to better protect the public from communicable disease transmission. In addition, the rule reduced the administrative burden on importers by reducing the frequency of required registration.	Completed Action. Proposed Rule Published: 1/5/11. Final Rule Published: 2/15/13.
CMS	0938-AR49	Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3267-F)	This set of reform proposals addresses conditions of participation and other restrictions that were not addressed in the 5/16/12 round one final rule. The reforms focus on restrictions that limit the flexibility of hospitals, Critical Access Hospitals, and other providers to provide efficient and effective services and avoid wasteful spending.	Proposed Rule Published: 2/7/13 Final Rule Target: Before the MMA section 902 deadline - 2/00/16	These reforms would result in a first year savings of approximately \$148 million to \$676 million, and annual recurring savings of \$126 million to \$654 million (or nearly \$652 million to \$3.3 billion over 5 years) for Medicare and Medicaid providers and suppliers.	Proposed Rule Published: 2/7/13 Final rule in development (Target: 2/00/16).

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CMS	0938-AR37	Part D Reporting Requirements (included in Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4159-P))	Efforts are underway to reduce burden in the Medicare Prescription Drug Program. These efforts include deleting unnecessary requirements and changing reporting frequency. This rule will result in an overall decrease in responses, burden hours, and annualized burden per respondent associated with the revised data collection for the Part D Reporting Requirements.	Proposed Rule Target: 9/00/13 Final Rule Target: 3/00/14	Streamlining reduces the amount of time sponsors and health plans spend related to reporting requirements for Medicare Prescription Drug Programs. CMS estimates that the annual burden reduction for the Part D Reporting Requirements is \$112,000.	Proposed rule in development (Target: 09/00/13).
CMS	0938-AP61	Medicaid Home & Community Based Services Waiver & State Plan Services Program (CMS-2296-F & CMS-2249-F)	This final rule revises the regulations implementing Medicaid Home & Community Based Services (HCBS) waivers. It provides states the option to combine the existing three waiver targeting groups. In addition, CMS is implementing other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are not home and community-based, to clarify the timing of amendments and public input requirements when states propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure state compliance with the Medicaid statute. Finally, this rule would also amend the Medicaid regulations to define and describe state plan HCBS under the Affordable Care Act. The rule would offer states flexibilities in providing necessary and appropriate services to elderly and disabled populations.	Proposed Rule Published: 4/15/11 Final Rule Target: 12/00/13	This reform would streamline an existing waiver process and provide maximum flexibility. For states that choose to implement this option it will reduce administrative resources staff time and costs for reporting, amendments, and renewal submissions.	Proposed Rule Published: 4/15/11. Final rule in development (Target: 12/00/13).
FDA	0910-AF86	Medical Device Reporting: Electronic Submission Requirements	FDA is considering amending its postmarket medical device reporting to require that manufacturers and importers submit mandatory reports of medical device adverse events in electronic format that FDA can process, review, and archive. FDA would take this action to improve its systems for collecting and analyzing postmarketing safety reports. This change would help FDA more quickly review safety reports and identify emerging public health issues.	Proposed Rule Published: 8/21/09 Final Rule Target: 12/00/13	This rule would save lives and decrease adverse events by allowing a more rapid response to adverse events by using a paperless reporting system. This rule will result in a significant decrease in burden of recordkeeping and reporting for industry.	Proposed Rule Published: 8/21/09. Final rule in development (Target: 12/00/13).
FDA	0910-AA49	Requirements for Foreign and Domestic Establishments Registration and Listing for Human Drugs including Drugs that are Regulated Under a Biologics License Application and Animal Drugs (e-DRLS)	This final rule would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations would describe when, how, and where to register drug establishments and list drugs in addition to information submission requirements for the initial registration and listing as well as for updates.	Proposed Rule Published: 8/29/06 Final Rule Target: 7/00/14	FDA anticipates cost savings and burden reductions by allowing drug makers to use the latest technology in submitting information. This would improve FDA's ability to inspect manufacturing establishments.	Proposed Rule Published: 8/29/06. Final rule in development (Target: 7/00/14).
FDA	0910-AG95	Veterinary Feed Directives (VFDs)	This initiative would improve efficiency of the process for veterinarians to issue feed directives.	Proposed Rule Target: 9/00/13	Streamlined VFDs would assist veterinarians and medicated feed manufacturers.	Draft text of proposed regulation published on 4/13/12. Comment period ended on 7/12/12. Proposed rule in development (Target: 9/00/13).

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HRSA	0906-AA87	Elimination of Duplication Between the Healthcare Integrity and Protection Data Bank (HIPDB) into the National Practitioner Data Bank (NPDB)	This final rule, required by the Affordable Care Act, eliminates the redundant reporting requirements for two closely related national health care data banks. The rule would terminate the Healthcare Integrity and Protection Databank (HIPDB) and transfer all data collected in the HIPDB to the National Practitioner Data Bank (NPDB) established pursuant to the Health Care Quality Improvement Act of 1986. It would also provide for the disclosure of information, fee collection, and establishment of dispute procedures.	Proposed Rule Published: 2/15/12 Final Rule Published: 4/5/13	This regulation streamlines two similar regulations to reduce duplicative administrative burden. Consumers and others who use these systems would realize monthly savings.	Completed Action. Proposed Rule Published: 2/15/12. Comment Period Closed: 4/16/12. Final Rule Published: 4/5/13.
NIH	0925-AA43	National Institutes of Health Loan Repayment Programs	NIH issued a single set of regulations to govern all of its loan repayment (LRP) authorities. This action rescinded the regulations at 42 CFR part 68a and at 42 CFR part 68c, and replaced them with the new consolidated set of LRP regulations. A single set of regulations governing all eight NIH loan repayment programs, rather having a separate set of regulations for each program, streamlines program regulations and enhances program participants' understanding of and compliance with program requirements.	Proposed Rule Published: 2/22/12 Public comment period expired: 4/23/12 Final Rule Published: 4/5/13	Establishing a single set of regulations to govern all eight of the current NIH loan repayment programs would streamline regulatory requirements for the programs and enhance program participants' understanding of and compliance with program requirements.	Completed Action. Proposed Rule Published: 2/22/12. Comment Period Closed: 4/23/12. Final Rule Published: 4/5/13
OASH	0937-AA02	Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators (Common Rule)	The proposed rule would revise current human subjects regulations in order to strengthen protections for research subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.	Advance Notice of Proposed Rulemaking Published: 7/26/11 Proposed Rule Target: 10/00/13	The proposed rule could eliminate unnecessary Institutional Review Board (IRB) reviews and enable IRBs to better focus their resources on review of research protocols that pose greater than minimal risks to subjects. The rule could also better protect human subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators and research subjects.	Advance Notice of Proposed Rulemaking Published: 7/26/11. Proposed rule in development (Target: 10/00/13).
OCR	0945-AA00	Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Accounting of Disclosures	The final rule would revise the current accounting for disclosures requirements in the HIPAA Privacy Rule to improve workability and to better balance the burden to regulated entities with the benefit to individuals.	Proposed Rule Published: 5/31/11 Final Rule in discussion.	The modifications would 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.	Proposed Rule Published: 5/31/11. Final rule in discussion.

Modify, streamline, expand, or rescind rule with unanticipated costs or benefits to achieve better results

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ASFR	0991-AB86	Health and Human Services Acquisition Regulations (HHSAR)	HHS is amending its Federal Acquisition Regulation (FAR) supplement - the HHS Acquisition Regulation (HHSAR) - in its entirety to remove internal procedural matters which are non-regulatory and to update to incorporate new policy and correct or clarify existing policy. This proposed rule will revise the Department's Federal Acquisition Regulation (FAR) Supplement -the HHS Acquisition Regulation (HHSAR)--in its entirety to reflect statutory, FAR, and Government-wide and HHS policy changes since the last revision to the HHSAR in November 2010. HHS published a revision of the entire HHSAR (48 CFR parts 301 through 370) in the Federal Register on November 27, 2009, and additional technical corrections on April 26, 2010. No adverse comments were received.	Proposed Rule Target: 08/00/13	This rule will increase efficiency through effective use of guidance and appropriate application of policy.	Proposed rule in development (Target: 08/00/13).
CMS	0938-AP51	Conditions of Participation (CoPs) for Community Mental Health Centers (CMHCs) (CMS-3202-F)	This final rule establishes, for the first time, conditions of participation that community mental health centers must meet in order to participate in the Medicare program. The rule focuses on the care provided to the client, establishes requirements for staff and provider operations, and encourages clients to participate in their care plan and treatment. These regulations will provide for consistent, appropriate care delivery so clients will receive the optimum quality services they need.	Proposed Rule Published: 6/17/11 Final Rule Target: Before the MMA section 902 deadline - 06/00/14)	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed Rule Published: 6/17/11 Final rule in development (06/00/14).
CMS	0938-AO91	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-P)	This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems to ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. These regulations will help to ensure the safety of those receiving care in any setting if an emergency situation occurs.	Proposed rule Target: 09/00/13	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed rule in development (Target: 09/00/13).
CMS	0938-AQ38	Patient's Access to Laboratory Test Report (CMS-2319-F)	Under this reform, portions of the Clinical Laboratory Improvement Amendments regulations (CLIA) will be revised to clarify existing policy to promote patient access to laboratory test reports.	Proposed Rule Published: 9/14/11 Final Rule Target: 10/00/13	This specific reform increases transparency. It will facilitate the ability of patients to compare test results over time and to share this information with future physicians or multiple physicians. This improved information sharing is likely to improve health care, especially for patients and providers who do not have access to electronic health records in the near term. This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed Rule Published: 9/14/11 Final rule in development (Target: 10/00/13).

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CMS	0938-AR72	Fire Safety (Life Safety Code) Requirements for Certain Health Care Facilities (CMS-3277-P)	This proposed rule would amend the fire safety standards for hospitals, critical access hospitals, long-term care facilities, intermediate care facilities for the intellectually disabled, ambulatory surgery centers, hospices which provide in-patient services, religious non-medical health care institutions, and Programs of All-Inclusive Care for the Elderly facilities. Further, this proposed rule would adopt the 2012 edition of the Life Safety Code and eliminate references in our regulations to all earlier editions. These regulations will ensure that care will be delivered in a safe setting.	Proposed Rule Target: 11/00/13	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed rule in development (Target: 11/00/13).
CMS	0938-AG81	Home Health Agency Conditions of Participation (CMS-3819-P)	This proposed rule would revise the current conditions of participation that home health agencies must meet. The proposed requirements would focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These revised regulations will help to ensure patients receive efficient, quality care and services.	Proposed Rule Target: 11/00/13	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed rule in development (Target: 11/00/13).
CMS	0938-AR61	Requirements for Long Term Care Facilities & Quality Assurance and Performance Improvement (QAPI) (CMS-3260-P)	This proposed rule would revise the requirements that Long-Term Care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. These proposed changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These proposals are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers. These changes will allow more flexibility in how care is delivered in the LTC setting which will enhance the lives of residents who reside in LTC facilities.	Proposed Rule Target: 12/00/13	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.	Proposed rule in development (Target: 12/00/13).
CMS	0938-AQ41	Covered Outpatient Drug (CMS-2345-F)	This final rule implements several provisions of the Affordable Care Act that pertain to prescription drugs under the Medicaid program. It revises the rebate formulas for covered outpatient drugs, revises the definition of average manufacturer price, and revises the Federal Upper Payment Limits for multiple source drugs.	Proposed Rule Published: 2/2/12 Final Rule Target: 01/00/14	CMS estimates this rule will save approximately \$17.7 billion for FY 2014, reflecting \$13.7 billion in federal savings and \$4 billion in state savings. These estimates represent the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid managed care organizations, and provides for adequate pharmacy reimbursement.	Proposed Rule Published: 2/2/12. Final rule in development (Target: 01/00/14).
CMS	0938-AP01	Requirements for the Medicare Incentive Reward Program and Provider Enrollment (CMS-6045-F)	This final rule revises the Incentive Reward Program and strengthens certain provider enrollment requirements. This rule increases the incentive for individuals to report fraud; improves CMS' ability to detect new fraud schemes; and, helps to ensure that potentially fraudulent entities and individuals do not enroll in or maintain their enrollment in the Medicare program.	Proposed Rule Published: 4/29/13 Final Rule Target: Before the MMA section 902 deadline - 4/00/16	CMS estimates the changes to the incentive reward program could result in an annual net increase in recoveries of \$24.5 million. CMS has estimated that making the effective date of billing privileges for ambulance providers consistent with other provider types would result in an annual savings of \$327.4 million.	Proposed Rule Published: 4/29/13. Final rule in development (Target: 04/00/16).

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FDA	0910-AF22	Food Labeling (Nutrition Initiative)	This proposed rule would revise and update food labeling regulations to make nutrition information on packaged food more useful to consumers. This rulemaking would modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label, to help consumers maintain healthy dietary practices.	Proposed Rule Target: 11/00/13	Improving nutrition information would help consumers make better dietary choices, thereby reducing costs associated with obesity and chronic diabetes.	Proposed rule in development (Target: 11/00/13).
FDA	0910-AF82	Postmarketing Safety Reporting for Combination Products	This rule would describe the postmarket safety reporting requirements for combination products (i.e., combinations of drug, device, and/or biological products). The rule would clarify that a combination product is subject to the reporting requirements associated with the type of marketing application under which the product receives approval, licensure, or clearance and to certain additional specified reporting requirements depending on the types of constituent parts. This regulation would ensure consistency and appropriateness of postmarket safety reporting for combination products while minimizing duplicative reporting requirements.	Proposed Rule Published: 10/1/09 Final Rule Target: 9/00/13	This rule would provide regulatory clarity for manufacturers of combination products. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while minimizing duplicative reporting requirements.	Proposed Rule Published: 10/1/09 Final rule in development (Target: 9/00/13).
FDA	0910-AF96	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)	FDA is considering revising its regulations to allow mandatory safety reports to be transmitted electronically.	Proposed Rule Published: 8/21/09 Final Rule Target: 12/00/13	This final rule would allow FDA to collect and analyze safety reports more quickly, identify emerging problems faster, and disseminate safety information to the public more quickly.	Proposed Rule Published: 8/21/09 Final rule in development (Target: 12/00/13).
FDA	0910-AG14	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act to determine whether to modify or eliminate it to reduce the impact on small businesses while still achieving the regulatory objective.	Review extended to 11/30/13.	This review fulfills requirements of Regulatory Flexibility Act.	Review ongoing. Since the May 2012 Retrospective Review update, FDA decided to extend review for an additional year.
FDA	0910-AG18	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (eDL)	This proposed rule would require electronic package inserts for human drug and biological prescription products with limited exceptions, in lieu of paper, which is currently used. These inserts contain prescribing information intended for health care practitioners. This rule would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.	Proposed Rule Target: 10/00/13	The expected long-term benefit is the ability to provide up-to-date prescribing information for health care professionals. Clarification of labeling would improve provider understanding of drugs and biologics and drug interactions and dosages, thereby reducing the risk of improper prescribing.	Proposed rule in development (Target: 10/00/13).
FDA	0910-AG26	Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets	This final rule would amend certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to the agency. These changes would implement provisions of the FDA Amendment Act.	Proposed Rule Published: 1/3/12 Final rule in discussion.	This regulation would clarify the required certifications when individuals file Citizen Petitions related to generic drug applications.	Proposed Rule Published: 1/3/12. Comment Period Closed: 4/2/12. Final rule in discussion.

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FDA	0910-AG36	Hazard Analysis and Risk-Based Preventive Controls	This proposed rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent or, at a minimum, quickly identify food-borne pathogens before they get into the food supply.	Proposed Rule Published: 1/16/13 Comment period extended to 9/16/13 Final Rule Target: 6/00/14	FDA anticipates that this rule would benefit the public by significantly minimizing or preventing the occurrence of hazards in food manufacturing that could cause foodborne illnesses. It would also help FDA more quickly identify specific pathogens and potential causes.	Proposed Rule Published: 1/16/13. Comment period extended to 9/16/13. Final rule in development (Target: 6/00/14).
FDA	0910-AG54	General Hospital and Personal Use Devices; Issuance of Draft Special Controls for Infusion Pumps	Based on an analysis of death and serious injury reports submitted to FDA, FDA is proposing establishing special controls to provide reasonable assurance of safety and effectiveness of these devices. The proposed rule would amend the classification of infusion pumps from class II (performance standards) to class II (special controls). FDA is pursuing this action to provide reasonable assurance of the safety and effectiveness of these devices.	Proposed rule in discussion.	The proposed rule would provide cost savings in morbidity and mortality reductions by increasing safety for patients and to industry in reduced liability exposure.	Proposed rule in discussion.
FDA	N/A	Patient Labeling for Drugs (Patient Package Inserts and Medguides)	FDA is considering a proposed rule to require a one-page, single-sided Patient Medication Information document to replace the current forms of medication information distributed to consumers such as medication guides and patient package inserts.	Proposed rule in discussion.	FDA expects long-term benefits to be the ability to provide consistent, easily understood prescription medication information for patients. Streamlining patient labeling into a one-page, single-sided document would provide patients with the essential medication information needed to aid them in using their prescription medications in a safe manner.	Proposed rule in discussion.

Other reasons for regulatory review (harmonize with other regulations or international standards, cross-cutting collaboration with other federal agencies to reduce administration or regulatory burdens, etc.)						
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ACF	N/A	Family Violence Prevention and Services Program	This proposed rule would rescind the requirement to publish quarterly funding opportunity announcements in the <i>Federal Register</i> , and revise regulations to bring them into conformity with the reauthorized Family Violence Prevention and Services Act.	Proposed rule in discussion.	This rule would clarify programmatic operating procedures.	Proposed rule in discussion.
ACF	N/A	Revision of Refugee Medical Assistance Regulations	Revise 45 CFR 400.90 - 400.107 regarding refugee medical assistance (RMA) to harmonize with the Affordable Care Act, specifically the eligibility determination methodology	Proposed rule in discussion.	By updating the regulations to use the same income methodology specified in the Affordable Care Act, the process for determining eligibility of refugees for medical insurance is streamlined into one application and one system. The rule also will permit full-time college students to access health insurance and explicitly requiring states to get written approval to get Refugee Medical Assistance funding for medical screening without prior determination of eligibility.	Proposed rule in discussion.
ACF	0970-AC43	Performance Standards for Runaway and Homeless Youth Grantees	This proposed rule would implement section VIII of the Reconnecting Youth Act of 2008, requiring HHS to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program. The proposed rule also would harmonize the regulations with existing statute and administrative and managerial provisions already in use and make changes to reduce burden associated with the grant application process.	Proposed Rule Target: 09/00/13	These changes would drive performance improvements and help assure accountability. The proposed rule also would increase transparency and streamline the grant application process using automation.	Proposed rule in development (Target: 09/00/13).
CDC	0920-AA53	Distribution of Reference Biological Standards and Biological Preparations	The purpose of this rule is to update the current regulation to reflect the agency's current name, mailing address, and instructions to obtain the current fee structure.	Direct Final Rule Target: 8/00/13	This rulemaking clarifies the current regulation for the public.	Direct final rule in development (Target: 08/00/13).
CDC	0920-AA51	Amendments to Occupational Safety and Health Investigations of Places of Employment	The purpose of this rule is to update outdated terminology.	Direct Final Rule Target: 10/00/13	This rulemaking clarifies the current regulation for the public.	Direct final rule in development (Target: 10/00/13).
FDA	0910-AA97	Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products	FDA is considering whether to revise certain definitions and reporting requirements based on recommendations of the International Conference on Harmonisation of Technical Requirements. This is intended to enhance the quality of the safety reports and facilitate harmonization.	Proposed Rule Published (pre and post market safety reporting): 3/14/03 Final Rule Published (pre-market safety reporting): 9/29/10	FDA anticipates that this rule would revise reporting requirements and times to enhance the quality and quantity of safety reports received by FDA.	Proposed Rule Published (pre and post market safety reporting): 3/14/03 Final Rule Published (pre-market safety reporting): 9/29/10 Final rule in discussion (post- market safety reporting): 9/29/10
FDA	0910-AF87	Laser Products; Amendment to Performance Standards	This proposed rule would amend the performance standards for laser products to achieve closer harmonization with the International Electrotechnical Commission (IEC) standards.	Proposed Rule Published: 6/24/13 Comment Period ends 9/23/13 Final Rule Target: 06/00/14	This regulation would harmonize FDA laser product standards with the IEC and reflect current advances in science.	Proposed Rule Published: 6/24/13. Comment Period ends 9/23/13. Final rule in development (Target: 06/00/14).

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FDA	0910-AG20	Amendment to Current Good Manufacturing Practice regulations for Finished Pharmaceuticals (Pharmaceutical CGMP for the 21st Century--Phase 2)	FDA is considering revising its Current Good Manufacturing Practices (CGMP) regulations to accommodate advances in technology and to harmonize with other international standards.	Proposed Rule Target: 1/00/14	This rule would provide flexibility and harmonization for the pharmaceutical industry.	Proposed rule in development (Target: 1/00/14).
FDA	0910-AG70	Amendment to Current Good Manufacturing Practices regulations—Components	This proposed rule would amend Current Good Manufacturing Practices regulations regarding the control over drug components used in manufacturing finished pharmaceuticals.	Proposed Rule Target: 7/00/13	This rule would provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.	Proposed rule in development (Target: 7/00/13).
FDA	0910-AG74	Use of Symbols in Device Labeling	FDA is considering whether to allow validated symbols in certain device labeling without the need for accompanying English text.	Proposed Rule Published: 4/19/13 Comment period ended 6/18/13 Final Rule Target: 04/00/14	This regulation would reduce burden of labeling requirements by permitting harmonization with labeling for international markets.	Proposed Rule Published 4/19/13. Comment period ended 6/18/13. Final rule in development (Target: 04/00/14).
FDA	N/A	Bar Code Rule for Drugs	FDA is conducting a retrospective economic review of this economically significant regulation, originally issued in 2004. The rule requires the inclusion of linear bar codes -- such as are used on millions of packages of consumer goods -- on the label of most prescription drugs and on certain over-the-counter drugs. Each bar code must contain, at a minimum, the drug's National Drug Code number and may include information about lot number and product expiration dates.	Federal Register Request for Information Published: 10/26/11. Comment period closed: 2/23/12. Comments under review.	FDA is assessing the costs and benefits to determine whether it should modify the rule to take into account changes in technology that have occurred since the rule went into effect.	Federal Register Request for Information Published: 10/26/11. Comment period closed: 2/23/12. Comments under review.
FDA	N/A	Good Laboratory Practice for Nonclinical Laboratory Studies	FDA is reviewing regulations for nonclinical laboratory studies to determine how best to update them.	Proposed rule in discussion.	This would update standards for the regulation of nonclinical laboratory studies.	Review ongoing.
FDA	N/A	New Animal Drugs—Records and Reports concerning experience with approved drugs and medicated feeds	FDA is reviewing regulations to determine how to clarify, streamline, and harmonize with international standards.	TBD	Alignment with international standards and a clarification of requirements would improve reporting by sponsors.	Review ongoing.
FDA	0910-AG48	Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices	This rule will amend FDA's regulations on acceptance of data from clinical studies conducted in support of a medical device premarket approval submission to allow data from foreign clinical studies as long as those studies are conducted in accordance with good clinical practices.	Proposed Rule Published: 2/25/13 Comment period ended 5/28/13 Final Rule Target: 9/00/14	This rule will provide consistency in FDA requirements for both foreign and domestic requirements for acceptance of clinical studies data.	Proposed Rule Published: 2/25/13. Comment period ended 5/28/13. Final rule in development (Target: 9/00/14).

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NIH	N/A	NIH Construction Grants	NIH is considering revising the NIH construction grants regulations to update the documents incorporated by reference and the grants program information to reflect the current standards, laws, policies, and practices of NIH construction grant projects.	Proposed rule in discussion.	Updating the documents incorporated by reference will make it much easier for the public to access information concerning minimum construction standards that apply to all NIH construction grants projects. Providing web addresses will ensure that the most up to date information is available to grantees, instead of doing their own search or visiting the NIH campus to view the documents. In addition, other updates may be needed to reflect policy and other changes that may have evolved in the years since the regulations were originally published.	Proposed rule in discussion.

Completed Actions Listed on Previous Retrospective Review Updates

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CDC	0920-AA21	Specifications for Medical Examination of Underground Coal Miners	This final rule would permit the use of digital radiography for medical screening of underground coal miners for pneumoconiosis (black lung).	Proposed Rule Published: 1/9/12 Final Rule Published: 09/13/12	The final rule would allow medical providers to voluntarily use a new technology, digital radiography, to screen coal miners for pneumoconiosis (black lung) rather than requiring the use of x-ray film only. There are no imposed additional costs.	Listed on September 2012 update.
CMS	N/A	Identification of Alignment Opportunities for Beneficiaries Who are Dual Eligibles for Medicare and Medicaid (CMS-5507-NC)	CMS reviewed all Medicare/Medicaid requirements that are misaligned for dual eligible individuals to identify those it should revise based on conflicting or contradictory requirements. CMS issued a <i>Federal Register</i> notice to solicit recommendations from stakeholders for aligning Medicare and Medicaid requirements for dual eligibles.	Notice Published: 5/16/11 Medicare-Medicaid Coordination Office Report to Congress issued on 2/10/12	There is no economic impact or burden associated with this reform. CMS expects that most providers, states, beneficiaries, and advocates for dual eligible individuals support this review. Potential further reforms would create streamlined care for dual eligibles and increase quality and care coordination.	Listed on May 2012 update.
CMS	0938-AQ86	Publication Reform in Contract Year 2013 Part C & D Proposed & Final Rules (CMS-4157-FC)	This final rule removed a requirement that a health maintenance organization (HMO) or competitive medical plan (CMP) that does not intend to renew its contract must notify the general public at least 30 days before the end of the contract period by publishing a notice in one or more newspapers of general circulation in each community or county located in the HMO's or CMP's geographic area.	Proposed Rule Published: 10/11/11 Final Rule Published: 4/12/12	This final rule reduces red tape for HMOs and CMPs by removing this unnecessary, burdensome public notice requirement.	Listed on May 2012 update.
CMS	0938-AQ89	Hospital Conditions of Participation (CoPs) Reform (CMS-3244-F)	This final rule updated the rules for hospitals that treat Medicare and Medicaid patients -- the Conditions of Participation. These changes reflect substantial advances in health care delivery and in patient safety knowledge and practices. They are also an integral part of CMS's efforts to achieve broad-based improvements in the quality of health care furnished through federal programs and in patient safety, while at the same time reducing procedural burdens on providers. The final rule revised many provisions, such as allowing hospitals to consolidate duplicative patient care plans, eliminating outdated requirements for hospital management, and allowing hospitals to determine the extent to which professional staff acting within the scope of their license and training would need additional physician supervision.	Proposed Rule Published: 10/24/11 Final Rule Published: 5/16/12	These reforms are estimated to save hospitals about \$940 million per year (nearly \$5 billion over the first five years) and perhaps grow to much more over time as hospitals increasingly use their new flexibility.	Listed on May 2012 update.
CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction--Round One (CMS-9070-F)	This final rule addressed regulatory requirements for providers other than hospitals and identified reforms in Medicare and Medicaid regulations that CMS found to be unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries. It eliminated duplicative, overlapping, outdated, and conflicting regulatory requirements for health care providers and suppliers such as end-stage renal disease (ESRD) facilities and durable medical equipment suppliers. Examples of these reforms include eliminating unnecessary building modifications in ESRD facilities, eliminating unnecessary delays in reinstating providers who make paperwork errors in their Medicare participation renewals, and updating obsolete e-prescribing technical requirements to meet current standards.	Proposed Rule Published: 10/24/11 Final Rule Published: 5/16/12	These reforms are estimated to save about \$200 million in the first year and \$100 million a year thereafter. This rule increases the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care.	Listed on May 2012 update.

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CMS	0938-AQ05	Telemedicine Final Rule (CMS-3227-F)	This final rule revises the conditions of participation (CoPs) for hospitals and critical access hospitals (CAHs) to implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. This removes a major barrier to telemedicine services.	Final Rule Published: 5/5/11	This specific reform is estimated to result in \$13.6 million savings to hospitals per year. These revisions will provide more flexibility to small hospitals and CAHs in rural areas and regions with a limited supply of primary care and specialized providers. Hospitals and CAHs support this reform as it reduces the burden associated with the credentialing and privileging process. In certain instances, <u>telemedicine may be a cost effective alternative to traditional service</u>	Listed on January 2012 update.
CMS	0938-AQ24	Hospital Pension Cost Reporting in Inpatient Prospective Payment System Final Rule (CMS-1518-F)	This change to the Hospital Inpatient Prospective Payment System revises the reporting of pension costs. It both simplifies reporting and revises cost report requirements to conform to the Employee Retirement Income Security Act (ERISA) under the Pension Protection Act of 2006.	Final Rule Published: 8/18/11	This reform reduces paperwork for hospitals and provides flexibility. CMS estimates that hospitals will save \$375,000 per year. Hospitals support this initiative.	Listed on January 2012 update.
CMS	0938-AP93	Ambulatory Surgical Center Same-Day Services Final Rule (CMS-3217-F)	This final rule removes the ambulatory surgical centers (ASC) condition for coverage that requires an ASC to provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure.	Final Rule Published: 10/24/11	This reform saves ASCs \$50 million per year by providing flexibility for when ASCs can give the patient right's notice to the patient. It also saves patients time and travel expenses by removing the need to return to the ASC for a second visit.	Listed on January 2012 update.
CMS	0938-AQ00	Contract Year 2012 Part C & D Final Rule (CMS-4144-F)	CMS began a voluntary process of annual rulemaking for the Parts C, D, and cost contract programs. This provides a formal basis for the many stakeholders in these programs to provide ideas for improving the operation of these programs. Annual rulemaking allows the agency to fine-tune policy, enhance beneficiary protections, improve CMS's ability to provide effective oversight of our contracts, and eliminate duplicative and outdated regulations. In addition, this process improves transparency by introducing a formal notice-and-comment process for annual policy changes. In addition, for 2012, CMS improved enrollee access to information and reduced cost to plans by translating two model marketing material documents (specifically, the Annual Notice of Changes/Evidence of Coverage documents and enrollment forms) into Spanish and Chinese.	Final Rule Published: 4/15/11	This reform increases transparency and improves service for Part C & D sponsors. With respect to language translation, CMS estimates savings to plan sponsors for this specific reform to be \$4.6 million for 2012 and \$230,000 for subsequent years.	Listed on January 2012 update.
CMS	0938-AQ31	Reforming the Hospice Face-to-Face Requirement through Hospice Wage Index Prospective Payment System Final Rule (CMS-1355-F)	This final rule removes a regulatory requirement that the physician who conducts the face-to-face visit with a Medicare hospice patient prior to recertification must be the same physician who completes the recertification.	Final Rule Published: 8/4/11	This specific reform reduces burden and improves service for hospices and will result in \$870 million savings over 10 years for Medicare. Hospices and physicians support this recommendation.	Listed on January 2012 update.
CMS	0938-AQ28	Inpatient Rehabilitation Facility Ownership Reporting in the Inpatient Rehabilitation Facility Prospective Payment System Final Rule (CMS-1349-F)	This final rule changes ownership regulations for new and expanding inpatient rehabilitation facilities (IRFs) and for IRF mergers and acquisitions.	Final Rule Published: 8/5/11	This reform reduces red tape and increases flexibility for inpatient rehabilitation facilities. IRFs support this because it reduces the burden on providers.	Listed on January 2012 update.

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CMS	0938-AR06 0938-AQ25	Revisions to Payment Policies and Clinical Laboratory Signature Reform Under the Physician Fee Schedule and Part B for CY 2012 Final Rule (CMS-1524-FC/CMS-1436-P)	The 2012 Physician Fee Schedule Final Rule removed the requirement that physicians sign orders for all clinical laboratory tests. In addition, based on a recommendation by the Association of American Medical Colleges (AAMC), CMS reviewed whether current evaluation and management (E&M) visit guidelines accurately reflect the providers' work and are consistently understood and used. CMS reviewed the codes as part of the misvalued coding initiative announced in the CY 2012 Physician Fee Schedule final rule.	Proposed Rule Published: 7/19/11 Final Rule Published: 11/28/11	The physician signature reform reduces red tape for physicians. There are approximately 21,088,145 burden hours associated with the physician signature requirement. The CY 2011 rule codified this requirement in 2010 for the CY 2011 rule, but it has been debated for several years. Physicians, clinical laboratories, and providers support removing this requirement. Because CMS decided not to implement the signature requirement, the overall paperwork burden did not change. Based on Bureau of Labor Statistics data showing hourly physician wages average about \$124, the avoided cost would have been approximately \$270 million a year. Although this retrospective review reform does not provide savings due to budget neutrality requirements, this illustrates CMS's commitment to retrospective review of economically significant regulations, as required by section 610(c) of the Regulatory Flexibility Act.	Listed on January 2012 update.
CMS	0938-AQ13	Administrative Simplification: Standard Unique Identifier for Health Plans & ICD-10 Delay (CMS-0040-F)	This reform requires health plans to go online to determine which health plan identifier they qualify for and to receive a Health Plan ID. Data entry will be streamlined by leveraging an existing system (CMS's Health Information Oversight System (HIOS)).	Proposed Rule Published: 4/17/12 Final Rule Published: 9/5/12	This reform significantly streamlines data entry by including pre-populated information for each plan in the common portal used by health plans. Delaying the compliance date of ICD-10 provides more time for covered entities to prepare for the transition to ICD-10 and to conduct thorough testing. By allowing more time to prepare, covered entities may be able to avoid costly obstacles that would otherwise emerge while in production. CMS estimates savings of approximately \$3.6 billion to nearly \$8 billion by avoiding costs that would have occurred from a significant number of providers being unprepared for the transition to ICD-10.	Listed on September 2012 update.
CMS	0938-AQ84	Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (EHR Stage 2) (CMS-0044-F)	This reform requires all clinical quality measures to move to electronic reporting in 2014. This reform also offers the option to batch report all meaningful use attestations; there will no longer be the need to manually enter data. Providers will no longer have to pull together paperwork; they will be able to generate a file from the EHR system. For providers who choose to manually attest to their reports in the system, CMS will be certifying the accuracy of their records, and they will no longer need to reconcile the values and their records.	Proposed Rule Published: 3/7/12 Final Rule Published: 9/4/12	CMS believes that eligible hospitals and eligible professionals can obtain substantial benefits by participating in the Medicare and Medicaid EHR Incentive Programs, including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, increased patient safety, and reduced medical errors.	Listed on September 2012 update.
CMS	0938-AR01	Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfers (EFT) and Remittance Advice (RA) Transactions (CMS-0028-IFC)	This reform improves upon the January 10, 2012 interim final rule with comment by allowing health plans to provide electronic bank information and change their companion guides and EFT enrollment forms. Through the use of EFT for health care claim payments and the use of electronic remittance advice that describes adjustments to the payments, providers will have decreased administrative costs. This rule builds upon earlier Administrative Simplification rules; the publication of each new rule further reduces burden.	Interim Final Rule With Comment Published: 8/10/12	This reform reduces burden by streamlining enrollment via an online enrollment process.	Listed on September 2012 update.

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CMS	0938-AR10	CY 2013 OPPS Proposed & Final Rules (CMS-1589-F)	These reforms would revise the Quality Improvement Organizations (QIOs) regulations by giving QIOs the authority to send and receive secure transmissions of electronic versions of health information and include a new alternative dispute resolution option (immediate advocacy). These reforms would reduce the costs associated with copying and mailing medical records, improve the QIO program, give beneficiaries more timely information regarding review activities, and reduce burden for both providers and practitioners.	Proposed Rule Published: 7/6/12 Final Rule Published: 11/15/12	These reforms would result in an estimated savings of \$305,550 each year as a result of QIOs using immediate advocacy instead of the traditional peer review process, and an estimated savings of \$2,388,622 per year as a result of giving QIOs the authority to transmit information electronically. This is a total savings of \$2,694,172 per year for Medicare providers as a result of the proposed changes to the QIO regulations.	Listed on September 2012 update.
CMS	To be determined	Improving CMS Quality and Performance Measures	This set of reforms would simplify the measures required for reporting across all CMS programs, eliminate outdated/redundant current and future quality measures, improve standardization in the reporting methods and measure sets across different programs, and align the quality measures reported across programs. For example, CMS plans to phase out manual chart abstraction by 2015 for the Hospital Inpatient Quality Reporting program. In place of the chart-abstracted measures, this would mean a single set of electronic health record (EHR) measures that would come from the clinical record. For the Physician Quality Reporting System (PQRS), CMS will align the measures that are reported from EHRs with the Medicare EHR Incentive Program, and also set consistent electronic prescribing requirements for the Medicare e-prescribing and EHR incentive programs. These reforms will reduce the number of quality measures required for the Hospital Inpatient Quality Reporting Program from 72-59 beginning in 2013.	Aligning Measures for Accountable Care Organizations Proposed Rule Published: 4/7/11 Final Rule Published: 11/2/11 Meaningful Use Stage 2 Rule for Electronic Health Records Proposed Rule Published: 3/7/12 Final Rule Published: 9/4/12 Hospital Inpatient Quality Reporting Program (HIQR) Proposed Rule Published: 5/11/12 Final Rule Published: 8/31/12	This set of reforms will both increase the usefulness and reduce the burden of CMS requirements for using and reporting quality measures. Current measures have been shown to improve health care services, and we anticipate even better future performance. We estimate the burden will decrease by 860,000 hours per year due to eliminating paper medical record abstraction. The decrease is due to eliminating paper medical record abstraction to collect information. We anticipate that hospitals will have EHRs with readily available quality measure information for collection and transmission through their EHR. The principal source of burden reduction is that hospital staff would not be forced to find quality measure information by manually reviewing paper medical records and entering this information into electronic format.	Listed on September 2012 update.
CMS	0938-AQ32	Disallowance of Claims for Federal Financial Participation (FFP) and Technical Corrections Proposed & Final Rules (CMS-2292-F)	This final rule revises the repayment schedule for states that must reimburse overpayments to Medicaid. The rule would provide three options for states electing a repayment schedule, including schedules that recognize the unique fiscal pressures of states that are experiencing economic distress.	Proposed Rule Published: 8/3/11 Final Rule Published: 5/29/12	This final rule would increase flexibility for states and provide for a more extended repayment schedule by allowing states to select among three options for repaying federal overpayments. Cash strapped states would benefit from a longer term repayment option.	Listed on September 2012 update.
CMS	N/A	Quarterly Issuance Notice (CMS-9063-N) & (CMS-9066-NC)	CMS compiles a quarterly <i>Federal Register</i> notice containing information that is previously published or publicly displayed on a website. CMS reformatted the notice to refer the public to weblinks where the information can be found on the internet, which CMS estimates is resulting in a total savings of over \$720,000 per year.	Notices Published: 3/31/11 and 8/8/11	There is no burden associated with this reform. It saves \$720,000 for CMS in publication costs per year.	Listed on January 2012 update.

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FDA	0910-AF81	Current Good Manufacturing Practices (CGMPs) for Combination Products	The final rule would clarify and codify the current good manufacturing practice (CGMP) requirements for combination products (combinations of a drug, device, and/or biological product). The final rule would ensure consistency and appropriateness in the regulation of combination products. When manufacturing combination products, it would avoid the necessity to fully implement both drug CGMP regulations and device quality system regulations.	Proposed Rule Published: 9/23/09 Final Rule Published: 1/22/13	This rule would provide regulatory clarity for manufacturers of combination products.	Listed on January 2013 update.
FDA	0910-AF88	Electronic Registration and Listing for Medical Devices	This final rule sets forth requirements for electronic registration and listing for medical devices, while continuing to offer an avenue of registration and listing for those companies without web access. This rule would allow industry greater flexibility and encourage the use of the latest technology for information collection.	Proposed Rule Published: 3/26/10 Final Rule Published: 8/2/12	FDA anticipates cost savings and burden reductions from this rule by allowing medical device makers to use the latest technology in submitting information. This would improve FDA's ability to inspect manufacturing establishments.	Listed on September 2012 update.
FDA	0910-AG62	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	FDA completed the periodic review of this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act to determine whether it should modify or eliminate it to reduce the impact on small businesses while still achieving the regulatory objective.	FDA completed its review of this regulation by 12/31/11.	This review fulfills requirements of Regulatory Flexibility Act.	Listed on May 2012 update.
FDA	0910-AG16	Amendments to Sterility Testing Requirements for Biological Products	This final rule removes references to specific test method requirements for sterility testing. This rule will provide manufacturers of biological products greater flexibility and encourage use of the most appropriate and state-of-the-art methodologies to ensure the safety of biological products.	Proposed Rule Published: 6/21/11 Final Rule Published: 5/03/12	This final rule will allow greater flexibility and promote advances in technology. It also makes FDA's requirements consistent with the US Pharmacopeia (USP).	Listed on May 2012 update.
FDA	N/A	Revise 21 CFR 882.5975 referencing device classification for dura mater, now regulated as a human cell & tissue product.	This final rule clarified the classification of dura mater.	Final Rule Published: 6/24/11	This final rule streamlined and clarified regulatory requirements.	Listed on January 2012 update.

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OCR	0945-AA03	Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules	<p>This omnibus final rule makes a number of changes to improve and strengthen the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, including the following changes expected to result in increased flexibility for and reduced burdens on regulated entities:</p> <p>(1) modifications to streamline the Privacy Rule process for obtaining HIPAA authorizations for research purposes and to harmonize the authorization requirements with the Common Rule's informed consent requirements;</p> <p>(2) modifications to the Privacy Rule's public health provisions to better facilitate the disclosure of student immunization records to schools in states that have school entry laws; and</p> <p>(3) modifications to reduce the administrative burden and cost on health plans associated with re-distributing their Notices of Privacy Practices when material changes are made to privacy practices, while still ensuring the notification of material changes to individuals in a timely manner.</p>	<p>Proposed Rule Published: 7/14/10</p> <p>Final Rule Published: 1/25/13</p>	<p>The identified modifications, in the order they were described, are expected to: (1) increase flexibility for researchers, reduce paperwork and burden for researchers, and harmonize the requirements with other research regulations; (2) reduce burden on parents and health care providers and help avoid delays in children beginning school; and (3) result in a one-time reduction of 1,800,000 burden hours with respect to re-distribution of Notices of Privacy Practices. Savings attributed to the changes in Notice distribution requirements would accrue to both public and private health plans within 60 days of the compliance date of the regulation.</p>	<p>Listed on January 2013 update.</p>
ONC	0991-AB82	Health Information Technology: New and Revised Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology ("2014 Edition")	<p>This final rule would establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year and calendar year 2014. The final rule would also revise the permanent certification program for health information technology, including changing the program's name.</p>	<p>Proposed Rule Published: 3/07/12</p> <p>Final Rule Published: 9/4/12</p>	<p>Consistent with stakeholder feedback and recommendations received from the Health Information Technology Standards Committee, the final rule is expected to address the definition of Certified EHR Technology established in the 2010 Standards and Certification Criteria final rule in ways that provide more flexibility for eligible professionals, eligible hospitals, and critical access hospitals participating in the Medicare and Medicaid EHR Incentive Programs. The final rule would also address the current regulatory processes of the permanent certification program in an effort to reduce burden and make certification of EHR technology more efficient.</p>	<p>Listed on September 2012 update.</p>
SAMHSA	0930-AA14	Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Proposed Modification of Dispensing Restrictions for Buprenorphine and Buprenorphine Combination as Used in Approved Opioid Treatment Medications	<p>This final rule increases provider flexibility by modifying the dispensing requirements for FDA-approved buprenorphine and buprenorphine combination products used in federally certified and registered opioid treatment programs. Opioid treatment programs that use these products in the treatment of opioid dependence may now adhere to all other federal treatment standards established for methadone.</p>	<p>Proposed Rule Published: 6/19/09</p> <p>Final Rule Published: 12/6/2012</p>	<p>The final rule provides more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction. This flexibility expands the number of patients receiving this form of treatment consistently and potentially reduces costs associated with drug-related crime because more patients would be receiving treatment at federally certified opioid treatment programs (OTPs). Increased opioid addiction treatment at OTPs could also reduce the health costs associated with opioid use.</p>	<p>Listed on January 2013 update.</p> <p>Proposed Rule Published: 6/19/09.</p> <p>Final Rule Published: 12/6/12.</p>

Ongoing Reporting and Paperwork Burden Reduction Initiatives

Agency	RIN/OMB Control No.	Title of Initiative/Rule/Information Collection Request (ICR) under the PRA	Brief Description	Actual or Target Completion Date	Anticipated savings in costs and/or information collection burdens, together with any anticipated changes in benefits	Progress updates and anticipated accomplishments
ACF	0970-0154	Income Withholding for Support Form (IWO)	ACF will allow electronic submission of the Income Withholding for Support Form, which provides a standardized and efficient mechanism to direct employers/income withholders to calculate and withhold child support. Paperwork burden will be reduced by 50,000 hours annually.	Burden reduction effective: 5/00/14.	Employers and private collection agencies will save approximately 50,000 hours annually.	No change since January 2013 update.
ACF	0970-0166	National Directory of New Hires	The National Directory of New Hires serves as a repository of information on newly hired employees and on the earnings and unemployment compensation claims data of employees. This information is used to locate individuals for child support and other specified purposes in Title IV-D of the Act. The Administration for Children and Families (ACF) plans to reduce paperwork burden hours by reviewing and updating the methodology used to collect the information and by updating numbers of respondents using automated reporting based on recent automation efforts. This effort will reduce paperwork burden by 200,000 hours annually.	Burden reduction effective: 1/00/14.	Private sector companies and states will save 200,000 hours of annual burden reduction.	This initiative is now expected to be completed by January 2014.
CDC	0920-0666	National Healthcare Safety Network revisions	The forms processed by the National Healthcare Safety Network were revised by the Centers for Disease Control and Prevention in this burden reduction initiative. Minor revisions, updates and clarifications were made to 29 of the forms, reducing overall burden. Additionally, 6 forms for collecting information about individual Healthcare Workers were removed altogether. The information previously collected at the individual level is now collected at the summary level only. Paperwork burden was reduced by approximately 295,000 hours annually for Healthcare providers by no longer needing to submit the forms eliminated and by reducing the time to complete the forms improved.	Burden reduction effective: 12/00/12.	This action is expected to result in a burden reduction of approximately 294,500 hours.	ICR approval date of 1/4/2013. Realized reduction of 294,500 burden hours.
CMS	0938-0732	Medicare Managed Care CAHPS Survey and Supporting Regulations	CMS will modify several different beneficiary perception surveys (i.e., CAHPS) by reducing the number of questions included. The initiative will use the 2014 Final Call Letter as the policy vehicle to effect the change. Medicare beneficiaries will reduce paperwork burden by 10,300 hours annually due to this reform.	Burden reduction effective: 6/00/14.	Medicare beneficiaries will save approximately 10,300 hours saved annually due to this reform.	No change since January 2013 update.
CMS	0938-0936	Applications for Medicare Part D Plans: PDP Plans, MA-PD Plans, Cost Plans, PACE Organization, SAE and EPOG	CMS will reduce the burden associated with completing the 2014 prescription drug benefit application by removing redundant information in the applications provided to CMS and reducing the number of attestations required by the applicants. Part D plan sponsors will reduce paperwork burden by 2,100 hours annually.	Burden reduction effective: 1/00/14.	Part D plan sponsors will save approximately 2,100 hours annually.	No change since January 2013 update.
CMS	0938-0992	Medicare Part D Reporting Requirements	CMS will reduce the frequency and level of reporting for Medicare Part D. For example, this could entail a change in the unit at which data are reported (contract versus plan level) and a change in the frequency of reporting (from quarterly to bi-annual). Part D plan sponsors will reduce paperwork burden by 59,000 hours annually due to this reform.	Burden reduction effective: 2/00/14.	Part D plan sponsors will save approximately 59,000 hours annually due to this reform.	No change since January 2013 update.
CMS	0938-1054	Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 C.F.R. 422.516(a)	The Centers for Medicaid and Medicare Services (CMS) will decrease the number of measures that Medicare Advantage plans are required to report as part of their Part C Reporting Requirements. Medicare Advantage plans will realize a paperwork burden reduction of 88,730 hours annually due to this reform.	Burden reduction effective: 1/00/13.	Medicare Advantage plans will save approximately 88,730 hours annually due to this reform.	This initiative is now expected to be completed by January 2014.

Agency	RIN/OMB Control No.	Title of Initiative/Rule/Information Collection Request (ICR) under the PRA	Brief Description	Actual or Target Completion Date	Anticipated savings in costs and/or information collection burdens, together with any anticipated changes in benefits	Progress updates and anticipated accomplishments
CMS	0938-1115	Medicare Part C and Part D Data Validation (42 C.F.R 422.516g and 423.514g)	CMS will reduce the burden of Part C and Part D data validation by deleting items that need to be validated. Part C & D plan sponsors will reduce paperwork burden by 57,000 hours due to this reform.	Burden reduction effective: 1/00/13.	Part C & D plan sponsors will save approximately 57,000 hours annually due to this reform.	This initiative is now expected to be completed by January 2014.
OCR	0990-0294 Transferred to 0945-0003	HIPAA Privacy Rule - Updated Notice of Privacy Practices Requirements	Updated Notice of Privacy Practices Requirements An omnibus final rule made a number of changes to reduce the administrative burden and cost on health plans associated with distributing revised Notices of Privacy Practices (NPP) when material changes are made to those privacy practices. Under the previous regulations, health plans were required to provide a printed copy of any material change of a plan's privacy practices to all plan participants within 60 days of the change, which would have imposed a burden of 2 million hours due to other changes in the regulations necessitated by the HITECH Act. The HIPAA omnibus regulation revised the notification requirements so that health plans may instead publish the changed NPP on their websites. An estimated 90% of health plans benefited from the simplified notification requirement resulting in 1,800,000 hours of burden avoided. This notification revision also relieves burden to health plans on any future out-of-cycle changes to the NPP. The OMB control number associated with this paperwork burden reduction initiative was transferred to OMB control number 0945-0003.	Burden reduction effective: Upon publication of the Final Rule, expected by the end of December 2012.	Health plans will save approximately 1.8 million burden hours.	The final rule affecting the initiative for 0945-0003 (formerly 0990-0294) was published on 1/16/2013. Realized reduction of 1.8 million burden hours.