July 2014 Retrospective Review Update

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
Modify, streamline, expand, or rescind existing rule to reduce regulatory and administration burdens						
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: 10/00/14	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: 10/00/14.

July 2014 Retrospective Review Update

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	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: 04/00/15	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: 4/00/15.
ACF	N/A	Removal of Child Abuse Prevention and Treatment Act (CAPTA) Regulations	This rule would remove the existing regulations for the Child Abuse Prevention and Treatment Act (CAPTA). There have been major and extensive legislative changes to CAPTA since the regulations were issued in 1983 and updated in 1990. Consequently, the existing regulations for CAPTA (at 45 CFR 1340) are outdated and no longer apply to the CAPTA programs they were designed to implement.	Rule is under discussion.	CAPTA is not a permanently authorized program and must be reauthorized every five years. The existing regulations for CAPTA (at 45 CFR 1340) are outdated and no longer apply to the CAPTA programs they were designed to implement. There are no budget implications associated with removing the CAPTA regulations from the Code of Federal Regulations.	Rule is under discussion.

July 2014 Retrospective Review Update

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
FDA	N/A	Revocation of the General Safety Test Requirements for Biological Products	This proposed rule would amend the biologics regulations by removing the general safety test (GST) requirements for biological products found in 21 CFR 610.11, 610.11a and 680.3(b). FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation.	Proposed Rule target: 1/00/15	FDA believes this action is appropriate because it will provide manufacturers of licensed biological products with flexibility, as appropriate, without diminishing public health protections.	Proposed Rule in development. Target: 1/00/15.
FDA	N/A	Amending the general biological product standards relating to dating periods, standard preparations and limits on potency	The proposed rule would provide additional flexibility to manufacturers of licensed biological products by amending the general biological products standards relating to dating periods and removing certain regulations for standard preparations and limits of potency. FDA is taking this action to provide additional flexibility to manufacturers of licensed products and to update obsolete or outdated requirements.	Proposed Rule target: 7/00/15	FDA believes this action is appropriate because it will provide manufacturers of licensed biological products with flexibility, as appropriate, without diminishing public health protections.	Proposed Rule in development. Target: 7/00/15.

July 2014 Retrospective Review Update

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
HRSA	0905-AB03	Improve Efficiency & Integrity of the National Health Service Corps (NHSC) Program	This proposed rule would update National Health Service Corps (NHSC) regulations (42 CFR 23 & 42 CFR 62) to enhance program operations and integrity. Provisions under consideration include: 1) clarifying that retroactive service credit may be allowed during a continuation contract process; 2) clarifying the definition of "unconscionable" and "primary health services" as they relate to the NHSC; 3) clarifying the contract termination process; and 4) other administrative changes to make regulations consistent with statute.	Proposed Rule target: 1/00/15	HRSA is developing the proposed rule to streamline NHSC business processes, improve program integrity, and better serve program participants. The proposed rule would also make conforming administrative changes to the regulation consistent with statute, specifically changes made to the program from the Affordable Care Act.	Proposed Rule target: 1/00/15
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: 12/00/14	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 under development Target: 12/00/14.

July 2014 Retrospective Review Update

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
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 under 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 under discussion.
SAMHSA	N/A	Oral Fluid Mandatory Guidelines for Federal Workplace Drug Testing Programs (OFMG)	The Mandatory Guidelines would establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, and the forensic acceptability of oral fluid testing. The use of an electronic chain-of-custody form to replace the current 5-page paper form is currently at the department-level clearance, to be reviewed by OMB.	Proposed Oral Fluid Mandatory Guidelines Target for public comments: 12/00/14	SAMHSA proposes to issue the Federal Workplace Drug Testing Oral Fluid Mandatory Guidelines (OFMG). The OFMG Guidelines will allow Executive Branch agencies and the regulated industry to implement an alternative testing process that is less intrusive and cost/time effective when compared to the current urine based testing program. The use of an electronic chain-of-custody form will also reduce the administrative burden of participating in this program.	Target for publication of the proposed Guidelines for public comment: 12/00/14.

July 2014 Retrospective Review Update

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
Modify, streamline, expand, or rescind rule with unanticipated costs or benefits to achieve better results						
ACF	N/A	Family Violence Prevention and Services Program	This proposed rule would 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.	Proposed Rule target: 01/01/15	This rule would clarify programmatic operating procedures.	Proposed Rule target: 01/01/15
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 target: 02/00/15	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 target: 02/00/15

July 2014 Retrospective Review Update

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	N/A	Child and Family Services Quality Improvement (CFSQI) for States and the Child and Family Services Plan (CFSP) for States and Indian Tribes	The proposed rule for the CFSQI process is a revised monitoring protocol of titles IV-B and IV-E of the Social Security Act for State child welfare agencies as required in section 1123A of the Social Security Act (revise 45 CFR 1355.10 - 1355.39). The CFSQI process would allow states to use results from their internal quality assurance processes to meet federal monitoring requirements and would be integrated into current comprehensive child and family services planning under the CFSP. The current regulated monitoring protocol for state child welfare agencies is known as the Child and Family Services Reviews (CFSR). For Indian tribes, the proposed rule will also update and streamline requirements for the title IV-B plans for Indian tribes (revise 45 CFR 1357).	Proposed rule under discussion.	The proposed rule would streamline the child and family services reporting and monitoring for states and Indian tribes. It will also reduce the amount of duplicate effort and information created; align federal and state quality assurance activities; and provide flexibility for states to craft quality assurance procedures that line up with state child welfare practices.	Proposed rule under discussion.

July 2014 Retrospective Review Update

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-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: 12/00/14	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: 12/00/14.
ACF	N/A	Sharing Child Support Data with State Marketplaces	This proposed rule would assist in the implementation of the Affordable Care Act.	Proposed Rule under discussion.	This proposed rule would assist in the implementation of the Affordable Care Act.	Proposed Rule under discussion.

July 2014 Retrospective Review Update

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
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: 12/00/2014	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: 12/00/2014

July 2014 Retrospective Review Update

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-AO91	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-F)	This final 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 Published: 12/27/13 Final Rule Target: Before the MMA section 902 deadline - 12/00/2016	This rule includes important health and safety initiatives to protect Medicare beneficiaries. Although CMS is unable to specifically quantify the number of lives saved as a result of this proposed rule, all of the data CMS has read regarding emergency preparedness indicate that implementing the requirements in this proposed rule could have a significant impact on protecting the health and safety of individuals served by providers and suppliers that participate in the Medicare and Medicaid programs.	Proposed Rule Published: 12/27/13 Final Rule target: 12/00/2016

July 2014 Retrospective Review Update

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-AQ38	Patients' 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: 01/00/15	This specific reform increases transparency and will facilitate the ability of patients to compare test results over time, as well as 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. The estimated cost to laboratories to provide patients with a copy of their test reports upon request is between $3 million and $63 million in 2013; however, these costs will diminish in subsequent years. In addition, laboratory provision of test reports to patients may provide information that could benefit the patient by reducing the chance of the patient not being informed of a laboratory test result, reducing the number of patients lost to follow-up, and benefiting health care providers by reducing their workload in providing	Proposed Rule Published: 9/14/11 Final Rule in development. Target: 01/00/15.

July 2014 Retrospective Review Update

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-AR72	Fire Safety (Life Safety Code) Requirements for Certain Health Care Facilities (CMS-3277-F)	This final rule 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 rule adopts 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 published 12/27/2013 Final Rule target: Before the MMA section 902 deadline - 12/00/2016	The overall economic impact for this ruleis estimated to be $41,437, 279 for the first year of implementation, and $7,109,914 after the first year of implementation annually thereafter for an 11-year period. Additiomally, although we are not quantifying the numer of lives tha would be saved upopn im;ementation of this rule, due tothe lack of data that could provide a reliable estimate, we believ there is potential for such a result.	Final Rule in development.
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: 8/00/14	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 target: 8/00/14

July 2014 Retrospective Review Update

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-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: 12/00/14	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 target: 12/00/14

July 2014 Retrospective Review Update

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-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: 4/00/15	In 2012, CMS estimated that this rule would save approximately $17.7 billion for FY 2014, reflecting $13.7 billion in federal savings and $4 billion in state savings. These estimates represented 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. We are not able at this time to provide updated 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: 2/2/12 Final Rule target: 4/00/15

July 2014 Retrospective Review Update

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-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's 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).
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 published: 03/03/14 Final Rule target: TBD	Improving nutrition information would help consumers make better dietary choices, thereby reducing costs associated with obesity and chronic diabetes.	Proposed Rule published: 03/03/14 Final Rule target: TBD

July 2014 Retrospective Review Update

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
FDA	0910-AF23	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; Updating and Modifying the Reference Amounts Customarily Consumed	FDA is proposing to amend its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. If finalized, this rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating certain RACCs, FDA is also considering amending the definition of single-serving containers; amending the definition of serving size for breath mints; and providing for dual-column labeling, which would provide nutrition information per serving and per container or units, as applicable, under certain circumstances	Proposed Rule Published: 3/3/14 Final Rule Target: TBD	Improving nutrition information would help consumers make better dietary choices, thereby reducing costs associated with obesity and chronic diabetes.	Proposed Rule published: 3/3/14 Final Rule in development.

July 2014 Retrospective Review Update

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
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: 12/00/14	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: 12/00/14.
FDA	0910-AF96	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e- SADR)	This final rule will allow mandatory safety reports to be transmitted electronically.	Proposed Rule published: 8/21/09 Final Rule target: 12/00/14	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.	Final Rule Target: 12/00/14

July 2014 Retrospective Review Update

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
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: 12/00/14	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: 12/00/14.
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 under 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 under discussion.
FDA	0910-AG36	Hazard Analysis and Risk-Based Preventive Controls	This final 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 11/22/13 Final Rule target: 8/00/15	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 11/22/13. Final Rule in development. Target: 8/00/15.

July 2014 Retrospective Review Update

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
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 under 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 under discussion.

July 2014 Retrospective Review Update

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
Other reasons for regulatory review (harmonize with other regulations or international standards, cross-cutting collaboration with other federal agencies to reduce administration or regulatory						
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 Final rule under discussion (post-market safety	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 under discussion (post-market safety reporting).
FDA	0910-AF87	Laser Products; Amendment to Performance Standards	This 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 ended 9/23/13 Final Rule Target:	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 ended 9/23/13. Final rule in development.Target: 8/00/15.
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 under discussion.	This rule would provide flexibility and harmonization for the pharmaceutical industry.	Proposed rule under discussion.

July 2014 Retrospective Review Update

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
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 under discussion.	This rule would provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.	Proposed rule under discussion.
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: 02/00/15	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: 02/00/15.
FDA	needs RIN	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	needs RIN	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 development.	This would update standards for the regulation of nonclinical laboratory studies.	Review ongoing.

July 2014 Retrospective Review Update

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
FDA	needs RIN	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: 12/00/14	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: 12/00/14.
FDA	0910-AG95	Veterinary Feed Directives (VFDs)	This initiative would improve efficiency of the process for veterinarians to issue feed directives.	Proposed Rule published: 12/12/13 Final Rule target: 4/00/15	Streamlined VFDs would assist veterinarians and medicated feed manufacturers.	Proposed Rule published: 12/12/13 Final Rule in development. Target: 4/00/15.

July 2014 Retrospective Review Update

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
NIH	N/A	NIH Construction Grants	NIH is revising the NIH construction grants regulations, at 42 CFR 52b, to reflect the current standards, laws, policies, and practices of NIH construction grant program and update the documents incorporated by reference in the existing construction grants regulations.	Proposed rule under discussion.	Updating the regulations to reflect policy and other changes will provide more transparency of current program procedures and practices. 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.	Proposed rule under discussion.

July 2014 Retrospective Review Update

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
Completed Actions Listed on Previous Retrospective Review Updates						
CDC	0920-AA51	Occupational Safety and Health Investigations of Places of Employment; Technical Amendments	The purpose of this rule is to update the current regulation to remove outdated terminology and obsolete agency names.	Direct Final Rule published 01/16/14	This rulemaking clarifies the current regulation for the public.	Direct Final Rule published 01/16/14
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 published 7/22/13	This rulemaking clarifies the current regulation for the public.	Direct Final Rule published 7/22/13
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.	Listed on July 2013 update.
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	Listed on September 2012 update.

July 2014 Retrospective Review Update

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-AQ38	Patients' 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 published: 2/6/14	This specific reform increases transparency and will facilitate the ability of patients to compare test results over time, as well as 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. The estimated cost to laboratories to provide patients with a copy of their test reports upon request is between $3 million and $63 million in 2013; however, these costs will diminish in subsequent years. In addition, the laboratory provision of test reports to patients may provide information that could benefit the patient by reducing the chance of the patient not being informed of a laboratory test result, reducing the number of patients lost to follow-up, and benefiting health care providers by reducing their workload in providing	Listed on January 2014 update.

July 2014 Retrospective Review Update

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-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 published: 10/29/13	We estimate that this final rule will cost CMHCs approximately $3 million in the first year of implementation and approximately $2.2 million annually thereafter; however, we believe that the burden and reforms associated with this rule are reasonable and necessary to ensure the health and safety of all CMHC clients.	Listed on January 2014 update.

July 2014 Retrospective Review Update

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-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 published: 1/16/14	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. While States may incur costs in coming into compliance with the provisions in this rule, given the variability in State programs, and the varying extent to which some are already complying, it is difficult to estimate these costs.	Final Rule published: 1/16/14

July 2014 Retrospective Review Update

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-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-F))	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 published: 1/10/14 Final Rule published: 5/23/14	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.	Listed on January 2014 update.
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 published: 5/12/14	These reforms would result in a one-time savings of $22 million and an annual recurring savings of $910 million for Medicare and Medicaid providers and suppliers.	Final Rule published: 5/12/14
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.

July 2014 Retrospective Review Update

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-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.

July 2014 Retrospective Review Update

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-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.

July 2014 Retrospective Review Update

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-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.	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	Listed on January 2012 update.

July 2014 Retrospective Review Update

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-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.

July 2014 Retrospective Review Update

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-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.

July 2014 Retrospective Review Update

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-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.

July 2014 Retrospective Review Update

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-AQ22; 0938 AQ84; 0938-AR12	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 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.

July 2014 Retrospective Review Update

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-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. There is no burden associated with this reform as it provides assistance to cash strapped states who 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 *Federal Register* 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.
FDA	0910-AF86	Electronic Submission for Medical Device Reporting of Adverse Events ("eSubmissions")	This final rule revises the Medical Device Reporting (MDR) regulation to require manufacturers and importers to submit electronic reports of individual medical device adverse events (MDRs) to the FDA. Electronic submission of MDRs will improve the agency's systems for collecting and analyzing post market MDRs and will reduce the burden of reporting on the device industry.	Proposed Rule published: 8/21/09 Final Rule published: 2/14/14	FDA anticipates that medical device manufacturers and importers will save approximately $7.6 million and reduce the time to prepare and submit reports by 345,081 hours annually.	Proposed Rule published: 8/21/09. Final Rule published 2/14/14.

July 2014 Retrospective Review Update

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
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 completed: 11/30/13	This review fulfills requirements of Regulatory Flexibility Act.	Review completed 11/30/13.
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.

July 2014 Retrospective Review Update

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
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	Docket Number FDA-1997-N-0040	Medical Devices; Neurological Devices; Clarification of Classification for Human Dura Mater; Technical Amendment	This final rule revised 21 CFR 882.5975 to clarify that dura mater would now be regulated as human cell & tissue product.	Final Rule published: 6/24/11	This final rule streamlined and clarified regulatory requirements.	Listed on January 2012 update.

July 2014 Retrospective Review Update

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
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	Proposed Rule published: 2/15/12 Final Rule published: 4/5/13	This regulation streamlines two similar regulations to reduce duplicative administrative burden. The overall savings to consumers and others who use these systems is estimated to be $336,000 per month.	Listed on July 2013 update.
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.	Listed on July 2013 update.

July 2014 Retrospective Review Update

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
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	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: (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; (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 (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	Proposed Rule published: 7/14/10 Final Rule published: 1/25/13	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.	Listed on January 2013 update.

July 2014 Retrospective Review Update

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
ONC	0991-AB82	Health Information Technology: New and Revised Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology ("2014 Edition")	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.	Proposed Rule published: 3/07/12 Final Rule published: 9/4/12	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.	Listed on September 2012 update.

July 2014 Retrospective Review Update

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
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	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.	Proposed Rule Published: 6/19/09 Final Rule Published: 12/6/2012	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.	Listed on January 2013 update.

July 2014 Retrospective Review Update

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
Ongoing Reporting and Paperwork Burden Reduction Initiatives						
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.	Complete.
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.	Complete.

July 2014 Retrospective Review Update

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
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 and approved by OMB 10/30/13. This revision request includes removing one form, adding nine forms, and revisions to 32 previously approved forms. The reporting burden will increase by 542,123 hours, for a total estimated burden of 4,104,775 hours; annual cost of reporting would increase by $10,782,604.	Burden reduction effective: N/A	This action is expected to result in a burden increase of approximately 542,123 hours.	Complete. ICR approval date of 10/30/2013. Realized increase of 542,123 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: 6/01/2012.		Because of the increased emphasis on Quality Bonus Payments which utilize Medicare Advantage and Prescription Drug Plan CAHPS survey measures, we were unable to reduce the number of items in the survey and subsequently reduce the burden. The burden reduction will be delayed due to CMS' need to add the Section 4302 items to the survey as required by the Affordable Care Act.

July 2014 Retrospective Review Update

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	0938-0936	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: 1/15/14.	No major change.	Complete. Although the revisions made to improve and streamline the application were originally expected to reduce burden hours, the total annual burden slightly increased rather than decreased (from 2,132 hours to 2,319).
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: 9/20/13		Complete.
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	Burden reduction effective: 1/00/14	Medicare Advantage plans will save approximately 40,000 (39,362) hours annually due to this reform.	Complete.

July 2014 Retrospective Review Update

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: 1/00/14	Part C & D plan sponsors will save approximately 58,000 (57,826) hours annually due to this reform.	Complete.
FDA	0910–AH04	Mammography Quality Standards Act; Regulatory Amendments	FDA is proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes, such as breast density reporting, that have occurred since the regulations were published in 1997.	Proposed rule in development.	FDA anticipates burden reductions from this rule by updating the regulations to reflect the current mammography technology. This proposed rule could potentially improve the accuracy of mammography by decreasing the number of false positives and false negatives.	Proposed rule in development.

July 2014 Retrospective Review Update

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
FDA	0910-0437	Electronic Submission for Medical Device Reporting of Adverse Events ("eSubmissions")	FDA drafted a final rule to revise the Medical Device Reporting (MDR) regulation to require manufacturers and importers to submit electronic reports of individual medical device adverse events (MDRs) to the FDA. Electronic submission of MDRs will improve the agency's systems for collecting and analyzing post market MDRs and will reduce the burden of reporting on the device industry. By amending its regulations to require electronic submissions instead of paper submissions, FDA expects to reduce the total burden hours for medical device manufacturers and importers from 391,526 hours to 46,445 hours, for a net reduction of 345,081 hours.	Burden reduction effective: One year after publication of the final rule. Final Rule published: 2/14/14	Medical device manufacturers and importers will save approximately $7.6 million and reduce the time to prepare and submit reports by 345,081 hours annually.	Complete. Final rule published 2/14/14.