HHS Retrospective Review Update
May 2012

No.	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
1	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.	Proposed Rule Target: 7/00/12	These changes would partially offset the burden of meeting new performance standards required under the statute. The proposed rule would reduce confusion and streamline the application process using automation.	Proposed rule in development (Target: 7/00/12).
2	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: 8/00/12	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.	Proposed rule in development (Target: 8/00/12).
3	ACF	N/A	Award of Office of Refugee Resettlement Social Services Grants to States	This proposed rule would reduce the frequency of financial status reports required by Social Services grantees from quarterly to annually. The rule maintains flexibility for the Office of Refugee Resettlement to request financial status reports more frequently as needed.	Proposed Rule: In Discussion	This rule would reduce burden on states by decreasing the frequency of reporting unless a specific need surfaces.	Proposed rule in discussion.
4	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: In Discussion	This rule would clarify programmatic operating procedures.	Proposed rule in discussion.
5	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: In Discussion	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 discussion.
6	CDC	0920-AA21	Specifications for Medical Examination of Underground Coal Miners	This final rule would permit the use of digital radiography in the medical examination for medical screening of underground coal miners for pneumoconiosis (black lung).	Proposed Rule Published: 1/9/12 Final Rule Target: 10/00/12	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.	Proposed Rule Published: 1/9/12. Comment Period Closed: 3/9/12. Final rule in development (Target: 10/00/12).
7	CDC	0920-AA23	Control of Communicable Disease; Foreign - Nonhuman Primate (NHP)	This final rule would extend the existing non-human primate (NHP) importation requirements for three species of NHPs to the importation of all NHPs. This modification would reduce administrative burden for importers of NHPs. The rule would also reduce the frequency of registration renewal from every 180 days to every two years.	Proposed Rule Published: 1/5/11 Final Rule Target: 9/00/12	The rule would strengthen the public health benefits of current practices by extending existing importation requirements to additional non-human primates to better protect the public from communicable disease transmission. In addition, the rule would reduce administrative burden on the regulated community of importers by reducing the frequency of required registration.	Proposed Rule Published: 1/5/11. Comment period was scheduled to end 3/7/11 and was extended to 4/25/11. Final rule in development (Target: 9/00/12).
8	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 *Federal Register* 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.	Completed. CMS issued the Medicare-Medicaid Coordination Office Report to Congress on 2/10/12.

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9	CMS	0938-AO53	Home & Community Based Services State Plan Option Proposed & Final Rules (CMS-2249-F)	This reform would extend the period of approval of certain types of Medicaid waivers, making obsolete the 2-year renewal period and reducing the administrative burden on state Medicaid programs by reducing the number of times they must submit renewal applications for managed care programs.	Second Proposed Rule Published: 5/3/12 Final Rule Target: TBD	The regulatory impact statement in the proposed rule acknowledged but was not able to provide a quantifiable impact for the reduced reporting burden for states that elect this new option.	Second Proposed Rule Published: 5/3/12. Comment Period Ends: 7/2/12. Final rule will be in development.
10	CMS	0938-AP61	Medicaid Home & Community Based Services Waiver Final Rule (CMS-2296-F)	This final rule would eliminate a longstanding federal barrier to creating one Medicaid Home and Community Based Services (HCBS) waiver that serves multiple target groups instead of three separate and distinct waivers. It would enable states to design and operate fewer waiver programs by designing packages based on need rather than diagnosis. This would provide maximum flexibility for states to serve multiple target populations in a single HCBS waiver, regardless of diagnosis.	Proposed Rule Published: 4/15/11 Final Rule Target: 12/21/12	This reform would streamline an existing waiver process and provide maximum flexibility.	Proposed Rule Published: 4/15/11. Final rule in development (Target: 12/21/12).
11	CMS	0938-AQ32	Disallowance of Claims for Federal Financial Participation (FFP) and Technical Corrections Proposed & Final Rules (CMS-2292-F)	This final rule would revise 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 Target: 5/00/12	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.	Proposed Rule Published: 8/3/11. Final rule in development (Target: 5/00/12).
12	CMS	0938-AQ38	Patient Access to Laboratory Test Report Proposed & Final Rules (CMS-2319-F)	This final rule would revise portions of the Clinical Laboratory Improvement Amendments regulations to clarify existing policy and thereby promote patient access to laboratory test reports.	Proposed Rule Published: 9/14/11 Final Rule Target: TBD	This final rule would increase transparency. It would 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 would improve health care, especially for patients and providers who do not have access to electronic health records in the near term.	Proposed Rule Published: 9/14/11. Final rule in development.
13	CMS	N/A	Improving CMS Quality and Performance Measures	This reform 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 would come from the clinical record. For the Physician Quality Reporting System (PQRS), CMS would 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.	To be determined; some steps already taken. For example, on 3/7/12, CMS published an electronic health records proposed rule to integrate both physician reporting and incentive measures; the final rule is scheduled for summer 2012. As well, on 11/2/11, CMS published the Accountable Organization final rule with flexibility for ACOs to align measures.	This set of reforms would both increase the usefulness and reduce the burden of CMS requirements for using and reporting quality measures. Current measures have improved health care services, and CMS anticipates even better future performance.	Specific actions in development.
14	CMS	N/A	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction--Round Two (CMS-3267-P)	CMS is considering a set of reform proposals to address Conditions of Participation and other restrictions that CMS did not address in the round one final rule published this May. CMS is considering proposing a dozen or more reforms focusing on restrictions that limit the flexibility of hospitals, critical access hospitals, and other providers to provide efficient and effective services or those that require wasteful spending.	Proposed Rule: In Discussion	Because CMS is still considering specific reforms, an overall estimate is premature. CMS expects, however, annual savings generated by these reforms could be in the range of several hundred million dollars a year, or more.	Proposed rule in discussion.
15	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.	Completed. Proposed Rule Published: 10/11/11. Final Rule Published: 4/12/12.

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16	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.	Completed. Proposed Rule Published: 10/24/11. Final Rule Published: 5/16/12.
17	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.	Completed. Proposed Rule Published: 10/24/11. Final Rule Published: 5/16/12.
18	CMS	N/A	Streamlining and Reducing Burden for the Certification of Federally-Qualified Health Center “Look-Alikes”: Delegation of Authority Change	The Secretary previously delegated the formal Secretarial authority for all programmatic actions related to Title XVIII and XIX of the Social Security Act to CMS. This includes the authority for the qualification process for Federally Qualified Health Center (FQHC) “look-alikes.” Health centers fall under the domain of the Health Resources and Services Administration (HRSA), but because of the Medicare and Medicaid funding that supports FQHCs, CMS has historically been involved in the qualification process for the "look-alike" facilities. To make the approval process for FQHC look-alikes more efficient for states, CMS, and HRSA, the Secretary plans to re-delegate the authority to make FQHC “look-alike” designations to HRSA alone.	Redelegation Target: 6/1/12	This reform would reduce the amount of time that FQHCs would have to wait for approval by streamlining the process for review and approval of FQHC look-alike designations. The reform would provide efficiencies by reducing the amount of time that health centers must wait to begin receiving federal Medicare and Medicaid funding. It would also assist in expanding provider capacity to serve uninsured and low-income populations.	Redelegation in development (Target: 6/1/12).
19	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: In discussion	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 discussion.
20	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 (post-market safety reporting): In Discussion	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 (post-market safety reporting) in discussion.

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21	FDA	0910-AC52	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	This proposed rule would revise FDA's regulations to require submission of clinical study data and bioequivalence data in drug applications in electronic format that FDA can process, review, and archive.	Proposed Rule Target: 9/00/12	The use of modern technology would increase efficiency and allow for more comprehensive data review. The long term benefits would be enhanced patient safety.	Proposed rule in development (Target: 9/00/12).
22	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: 12/00/12	Improving nutrition information would help consumers make better dietary choices, thereby reducing costs associated with obesity and chronic diabetes.	Proposed rule in development (Target: 12/00/12).
23	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 Target: 7/00/12	This rule would provide regulatory clarity for manufacturers of combination products.	Proposed Rule Published: 9/23/09. Final rule in development (Target: 7/00/12).
24	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: 9/00/12	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: 9/00/12).
25	FDA	0910-AF86	Medical Device Reporting: Electronic Submission Requirements	FDA is considering amending its postmarket medical device reporting to require that manufacturers, importers, and user facilities 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: In Discussion	This rule would save lives and decrease adverse events by allowing a more rapid response to adverse events by using a paperless reporting system.	Proposed Rule Published: 8/21/09. Final rule in discussion.
26	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 Target: 6/00/12	This regulation would harmonize FDA laser product standards with the IEC and reflect current advances in science.	Proposed rule received by OMB for E.O. 12866 review on 5/24/11. Proposed Rule Target: 6/00/12.
27	FDA	0910-AF88	Electronic Registration and Listing for Medical Devices	This final rule would set 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 Target: 7/00/12.	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.	Proposed Rule Published: 3/26/10. Final rule in development (Target: 7/00/12).
28	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: In Discussion	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 Discussion.
29	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. Due to litigation, FDA is extending this review for 1 year.	Review will be completed by 12/31/12.	This review fulfills requirements of Regulatory Flexibility Act.	Review ongoing. Since the January 2012 Retrospective Review update, FDA decided to extend review for an additional year.

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30	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).	Completed. Proposed Rule Published: 6/21/11. Final Rule Published: 5/03/12.
31	FDA	0910-AG18	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (e-Labeling)	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: 12/00/12	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: 12/00/12).
32	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: In Discussion	This rule would provide flexibility and harmonization for the pharmaceutical industry.	Proposed rule in discussion.
33	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.
34	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 Target: 5/00/12	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 received by OMB for E.O. 12866 review on 11/22/11. Proposed Rule Target: 5/00/12.
35	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 Target: 8/00/12	The proposed rule would provide cost savings in morbidly and mortality reductions by increasing safety for patients and to industry in reduced liability exposure.	Proposed rule in development (Target: 8/00/12).
36	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.	Completed. Since the January 2012 Retrospective Review update, FDA decided not to make any modifications to the existing regulation.
37	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: 8/00/12	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: 8/00/12).
38	FDA	0910-AG72	Orphan Drug Regulations	FDA is considering amending these regulations to clarify issues that have arisen since they were first issued in 1992. These revisions would provide sponsors with better information about program requirements and streamline the orphan-drug designation process.	Proposed Rule Published: 10/19/11 Final Rule: In Discussion	This revision would benefit sponsors who might otherwise be discouraged from submitting requests for designation of orphan drug status. It would reduce uncertainty and costs by ensuring that the requests submitted are complete and sufficient to meet the requirements of orphan designation. It would also help reduce costs for FDA by reducing the need for the agency to respond to deficient and non-designatable requests.	Proposed Rule Published: 10/19/11. Final rule in discussion.

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May 2012

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39	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: In Discussion	A regulation would reduce burden of labeling requirements by permitting harmonization with labeling for international markets.	Proposed rule in discussion.
40	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.	Request for Information Published: 10/26/11 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.
41	FDA	N/A	Down-classifications of Medical Devices (various under Federal Food, Drug, and Cosmetic Act sec. 515(i))	FDA is reviewing classifications of certain medical devices to determine if down-classification (i.e., move to a classification with less stringent requirements) is appropriate.	TBD	FDA anticipates streamlining and a reduction in regulatory burden.	FDA has completed some reviews and additional reviews are in development and ongoing.
42	FDA	N/A	Good Laboratory Practice for Nonclinical Investigations	FDA is reviewing regulations for nonclinical laboratory studies to determine how best to update them.	TBD	This would update standards for nonclinical investigations to streamline processes.	Review ongoing.
43	FDA	N/A	Medical Devices; Classification and Exemption from Premarket Notification for Certain Classified Devices	This initiative would provide less regulation to certain low risk devices that have sufficiently established safety and effectiveness.	TBD	These down classifications would reduce regulatory burden.	Review ongoing.
44	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.
45	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.
46	FDA	N/A	Veterinary Feed Directives (VFDs)	This initiative would improve efficiency of the process for veterinarians to issue feed directives.	Notice, Availability of Draft Regulation Text Published: 4/13/12	Streamlined VFDs would assist veterinarians and medicated feed manufacturers.	Draft text of proposed regulation published on 4/13/12. Comment period ends 7/12/12.
47	HRSA	0906-AA44	Negotiated Rulemaking Process for Designating Medically Underserved Areas (MUAs) and Health Professional Shortage Areas (HPSAs)	The Affordable Care Act required the Secretary to establish a rulemaking committee to draft an interim final rule for designation of Medically Underserved Populations (MUPs) and Primary Care Health Professions Shortage Areas (HPSAs). The rulemaking committee was unable to reach a consensus to produce an interim final rule for the Secretary's review and approval. However, the Affordable Care Act still requires the Secretary to issue an interim final rule at some point in the future.	Interim Final Rule Target: TBD	The current processes for designating Health Profession Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs) rely heavily on more precise data collected at the local level to supplement data available at the national level. This interim final rule would use national data sources to designate HPSAs and MUAs, which would reduce financial and administrative burdens on local communities previously responsible for pursuing this designation.	Interim final rule in development.
48	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, would eliminate 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 Target: 12/00/12	This regulation would streamline two similar regulations to reduce duplicative administrative burden. Consumers and others who use these systems would realize monthly savings.	Proposed Rule Published: 2/15/12. Comment Period Closed: 4/16/12. Final rule in development (Target: 12/00/12).

HHS Retrospective Review Update
May 2012

No.	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
49	NIH	0925-AA43	National Institutes of Health Loan Repayment Programs	This final rule would consolidate regulations to govern all of NIH's loan repayment (LRP) authorities by replacing the current regulations at 42 CFR part 68a and 42 CFR part 68c with a new consolidated set of LRP regulations. Establishing a single set of regulations to govern all eight of the current NIH loan repayment programs rather than issuing a separate set of regulations for each program would streamline regulatory requirements for the programs and enhance program participants' understanding of and compliance with program requirements.	Proposed Rule Published: 2/22/12 Final Rule: In Discussion	Establishing a single set of regulations to govern all eight of the current NIH loan repayment programs rather than issuing a separate set of regulations for each program would streamline regulatory requirements for the programs and enhance program participants' understanding of and compliance with program requirements.	Proposed Rule Published: 2/22/12. Comment Period Closed: 4/23/12. Final rule in discussion.
50	OASH	0937-AA02	Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators (Common Rule)	The Department of Health and Human Services, in coordination with the Office of Science and Technology Policy, issued an advance notice of proposed rulemaking (ANPRM) to request comment on how to modernize and to increase the effectiveness of current regulations for protecting human subjects who participate in research. This ANPRM solicited comment on how to better protect human subjects who are involved in research while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The proposed rule would revise current human subjects regulations in order to strengthen protections for research subjects.	Advance Notice of Proposed Rulemaking Published: 7/26/11 Proposed Rule Target: 9/00/12	The proposed rule could eliminate unnecessary Institutional Review Board reviews and enable them 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: 9/00/12).
51	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 would make 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 in a timely manner.	Proposed Rule Published: 7/14/10 Final Rule Target: 7/00/12	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 savings of $90 million and an associated 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.	Proposed Rule Published: 7/14/10. Final rule received by OMB for E.O. 12866 review on 3/24/12. Final Rule Target: 7/00/12.
52	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 Target: TBD	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 development.
53	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 Target: 8/00/12	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.	Proposed Rule Published: 3/07/12. Comment Period Closed 5/07/12. Final rule in development (Target: 8/00/12).

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54	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 would increase 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 would adhere to all other federal treatment standards established for methadone.	Proposed Rule Published: 6/19/09 Final Rule Target: 6/00/12	The final rule would provide more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction. This flexibility would expand the number of patients receiving this form of treatment consistently and potentially reduce 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.	Proposed Rule Published: 6/19/09. Final rule received by OMB for E.O. 12866 review on 3/08/12. Final Rule Target: 6/00/12.
Completed Actions Previously Listed on January 2012 Update							
1	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, to enhance beneficiary protections, to improve CMS's ability to provide effective oversight of our contracts, and to 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. Both the industry and the advocacy community have been supportive of annual rulemaking as a way of increasing transparency in CMS's policy development process. Early (April) publication gives plans time to implement policy changes prior to annual bid submissions in June. The annual regulation process gives all stakeholders (including industry, provider, and advocacy groups) the ability to influence CMS policy, including implementation of new statutory requirements. 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.	Completed.
2	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.	Completed.
3	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.	Completed.
4	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.	Completed.
5	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.	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.	Completed.

HHS Retrospective Review Update
May 2012

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6	CMS	0938-AQ53	"90/10" Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS-2346-F)	This final rule provides enhanced Federal Financial Participation (FFP) at the 90 percent rate for design, development, installation, or enhancement of state Medicaid eligibility determination systems through calendar year 2015 and in later years provides a continuing enhanced match rate if states continue to meet regulatory obligations. The higher match rate applies even if work on approved advanced planning documents (APDs) continues after 2015. Enhanced FFP at the 75 percent rate to maintain and operate systems that previously qualified for 90 percent FFP will be available after 2015 if these systems continue to meet the requirements specified in regulations.	Final Rule Published: 4/15/11	This specific reform reduces state operation costs by enhancing development of new systems. The total net federal cost impact of the regulation is approximately $2.3 billion for FY2011-2020. States will see a corresponding decrease in net state share due to enhanced match for eligibility systems they will receive through CY2015 and benefits accrued because of more efficient systems. States are expected to see approximately $1.9 billion in savings for FY2011-2020.	Completed.
7	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, telemedicine may be a cost effective alternative to traditional service delivery approaches and, most importantly, may improve patient outcomes and satisfaction.	Completed.
8	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.	Completed.
9	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.	Completed.
10	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.	Completed.