HHS Retrospective Regulatory Review

Update – January 2012

Since the President's Executive Order on Improving Regulation and Regulatory Review, HHS has made significant progress in its retrospective review activities. To date, we published eight proposed rules and nine final rules on the list of regulations identified for retrospective regulatory review. An additional four proposed rules and three final rules are targeted for publication during the first quarter of 2012.

Two of the proposed rules we published are expected to result in significant savings to the health industry. The first, a major revision to the *Medicare Conditions of Participation for Hospitals*, is likely to result in an estimated savings of close to $5 billion over five years. The second, *Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction*, may result in cost savings that approach $200 million during the first year. HHS is working to finalize these rules.

Some of the key cost savers of these proposed rules include:

- Permit laboratory services to operate on-site at critical access hospitals, *saving roughly $15.8 million per yea*r.
- Allow hospitals to determine the total number of directors needed for the various outpatient services that a hospital offers, *saving $300 million per year*.
- Allow hospitals to set their own policies regarding the duties and privileges of Advanced Practice Registered Nurses, Physician Assistants, and other licensed nonphysician practitioners in accordance with their state laws and scope-of-practice acts. This reform *should save hospitals roughly $330 million per year*.
- Permit hospital nursing service care plans to be integrated into the hospital's overall interdisciplinary care plan, thereby eliminating the requirement that nursing staff develop two care plans. *Estimated savings are roughly $110 million per year.*
- Allow hospitals to use standing medical orders approved by the hospital's clinical leadership to advance the practice of evidence-based medicine and ensure more consistent care for all patients. *This reform should save $90 million per year.*
- Remove certain Medicare reenrollment bars and revocations for incidental failures to comply with Medicare requirements such as a failure of a provider or supplier to respond timely to a re-validation request or failure to submit a Medicare claim for a consecutive 12-month period. *Expected savings are $10 million per year.*

Other rules recently published as final will make provider practice more efficient and less burdensome. One rule, the Home Health Prospective Payment System Rate Update for Calendar Year 2012 (0938-AQ30), removes the previous regulatory requirement that the physician who conducts the face-to-face visit with a Medicare home health patient prior to recertification must be the same physician who completes the recertification. Yet another final rule, Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and

Practitioners (0938-AQ05), allows hospitals to more easily credential and provide privileges for physicians and other practitioners who provide telemedicine services.

Still other rules give patients easier access to information about their health care. One such final rule, Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage (0938-AP93), removes the requirement that an ambulatory surgery center provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to the date of the procedure. Now those centers can give patients that information on the day of the procedure, thereby saving time and travel costs for the patient. Another proposed rule, Patients' Access to Laboratory Test Reports (0938–AQ38), permits patients to more easily access their clinical lab test results. This rule, coupled with the Fiscal Year 2012 Physician Fee Schedule final rule (0938-AR06) that removes the requirement for the physician to sign every order for a clinical lab test, will save costs and increase efficiency in the system.

Additional rules propose to provide much needed relief to states. For example, the Disallowance of Claims for Federal Financial Participation (FFP) and Technical Corrections (0938-AQ32) rule proposed to revise the repayment schedule for states that received more Medicaid funds than they were entitled to receive. The proposal provides three options for states to elect a repayment schedule that recognizes the unique fiscal pressures states are experiencing and allows for a longer repayment period. A second rule, the Medicaid Home & Community Based Services Waiver final rule (0938-AP61) will permit states greater flexibility to design and operate fewer Medicaid waiver programs for home and community based services by designing packages based on need rather than diagnosis.

In a rule providing greater flexibility, efficiency, and modernization in the child support enforcement programs (970-AC50), states will be able to submit and accept information electronically, maintain electronic records, and accept electronic signatures in these programs. States will also have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible. Finally, states will have greater flexibility to close unenforceable cases and redirect resources to more productive efforts and, in some cases, close and transfer appropriate cases to a tribal child support program.

In another major undertaking, retrospective review will result in major modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's requirements for distribution of Notices of Privacy Practices (0991-AB80).

Finally, the Department is undertaking a major review of FDA's Bar Code Rule for Drugs. Under the current rule, drug manufacturers must use a certain type of bar code to identify the drug, but recent changes in technology have resulted in the availability of multiple types of bar codes and bar code readers on the market. FDA will conduct an extensive economic review to determine if the rule should be modified to permit a wider range of bar code uses in light of these changes in technology that have occurred since the rule went into effect. To that end, FDA published a notice in the Federal Register requesting comment on this matter by February 23, 2012. Those comments will help FDA determine whether and how to proceed with a major revision to this rule.

In addition to these regulatory changes, the Department established an Analytics Team based in the Office of the Assistant Secretary for Planning and Evaluation to share information, make the quality of analysis more consistent across the Department, and ensure the integration of such analysis into regulatory decision-making to improve the quality of regulation. The Analytics Team has already had a significant impact on several of the regulations developed as a result of the retrospective review activity.

The Department also established a webpage on its HHS.gov/Open website devoted to retrospective review activities: http://www.hhs.gov/open/execorders/13563/index.html. This is the first step in the long-term development of a single portal access point for all regulatory information across the Department.

Finally, the Department is moving forward with a Public Participation Task Force to develop innovative ideas for involving the public in the regulatory process. In two major efforts to involve the public thus far, the Department published an Advance Notice of Proposed Rulemaking to solicit public comment on revising the Common Rule, the signature rule on protection of human subjects that has not been revised for more than 20 years, and a second Notice inviting comment on whether and how the pharmaceutical bar code rule should be revised.

A full list of the regulations for which a review is complete or which are currently under development follows. HHS is committed to the President's vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The Department conducted its initial inventory of significant regulations that have been in effect for at least five years without revision when it developed the initial list of candidate rules targeted for review. HHS is continuing to take inventory of its existing, significant regulations to identify potentially outdated regulations, which can be integrated into the retrospective regulatory review plan on an ongoing basis.

No.	Agency	RIN/OMB Control No.	Title of Initiative/Rule/ICR	Brief Description	Actual or Target Completion Date	Anticipated savings in costs and/or information burdens, together with any anticipated changes in benefits	Progress updates and anticipated accomplishments
1	CMS	0938-AQ89	Hospital Conditions of Participation (CoPs) Proposed & Final Rules (3244-P & F)	Currently critical access hospitals (CAH) are required to provide laboratory services as direct services, which is inconsistent with the requirement for lab services in hospitals. Revise the regulation to state that lab services should be offered on-site.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $15.8 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
2	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Exclude reporting for deaths of patients for whom only soft 2-point wrist restraints were used (e.g., people post-operatively who are in soft wrist restraints designed to prevent patients from pulling out IV tubes as they recover from anesthesia).	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $9.9 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
3	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Remove the requirement that verbal orders must be authenticated within 48 hours when there is no state law that designates a specific timeframe for the authentication of verbal orders.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $80 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
4	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Reduce regulatory and financial burden on hospitals by revising the Outpatient Services CoP (at §482.54(b)(1)) to allow hospitals to establish their own policies regarding the total number of directors needed for the various outpatient services that a hospital offers.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $300 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.) The need to provide hospitals with flexibility on this issue was brought to our attention by The Joint Commission and the American Hospital Association.	Final rule under development.
5	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Allow hospitals to set their own policies regarding the duties and privileges of Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), and other licensed nonphysician practitioners in accordance with their State laws and scope-of-practice acts. Proposed revisions (at §482.22) would allow for a licensed doctor of podiatric medicine to serve as the President (or its equivalent) of a hospital's medical staff.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $330 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.) The proposed revisions to the Medical Staff CoP would be seen as responsive to an issue flagged by partners and stakeholders in the hospital community, specifically the American Podiatric Medical Association.	Final rule under development.
6	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Remove the requirement for the transplant hospital that recovers its own organs (using its own team) to have to conduct and document the ABO blood type verification again once the team arrives at the transplant hospital.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces burden on hospitals by 1305 hours per year or $200,000 per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
7	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Revise the hospital nursing service requirements for those hospitals that use an integrated plan of care in providing patient care. We proposed that the care plan for nursing services be developed and kept current as part of the hospital's overall interdisciplinary care plan. This would decrease the burden of the nursing staff having to develop two care plans.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $110 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
8	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Revise the requirements under the medical record services CoPs that specifically pertain to verbal orders, their authentication, and the timeframe by which they must be authenticated. The proposed changes would allow for the use of standing orders approved by the hospital's clinical leadership, advance the practice of evidence-based medicine, and ensure more consistent care for all patients.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $90 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.

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9	CMS	0938-AQ89	Hospital CoPs Proposed & Final Rules (3244-P & F)	Update the infection control CoP to add a new standard for influenza vaccination. Update regulations to reflect current state of the art practices and terminology.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves hospitals $6.6 million per year. (This reform is part of the hospital conditions rule that saves approximately $940 million per year in savings or $5 billion over 5 years.)	Final rule under development.
10	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove regulations issued prior to the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), applicable to initial determinations and appeals for Medicare Parts A and B, respectively.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces confusion. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
11	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove the outdated current language in the Medicaid regulations and replace it with the updated Medicare personnel qualifications for physical therapists and occupational therapists under 42 CFR §484.4.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform updates obsolete information. This was also a recommendation received from The American Occupational Therapy Associations, Inc. (AOTA). (This reform is part of the rule to promote program efficiency, transparency, & burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
12	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Current regulations limit the Intermediate Care Facilities for the Mentally Retarded (ICF/MR) provider agreements under Medicaid to annual time limits. We proposed eliminating the time limited agreement for ICFs and replacing it with the similar requirement for skilled nursing facilities and nursing facilities (i.e., statewide average of 12 months with no more than a 15-month interval between surveys).	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces confusion and the extent of paperwork for states related to the current process. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
13	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Eliminate the enrollment bar which precludes re-enrollment of providers and suppliers who have not responded timely to re-validation or other requests for information. Revise the regulation that provides for revocation of Medicare billing privileges to expressly provide that the re-enrollment bar will not apply if the revocation is based upon the failure of a provider or supplier to respond timely to a re-validation request.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform increases flexibility for providers and suppliers. The overall paperwork burden would not change. This specific reform produces a savings of approximately $10 million per year. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
14	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove the regulation that requires Medicare billing privileges to be revoked if Medicare claims are not submitted for a consecutive 12-month period.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform saves collection of information costs for Medicare-enrolled physicians and non-physician practitioners totaling approximately $26.7 million per year. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
15	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Modify 42 CFR 494.60(e) with an additional provision that exempts certain End Stage Renal Disease (ESRD) facilities from specific requirements in the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA), as long as they demonstrate substantial compliance with the other applicable LSC requirements of NFPA 101, 2000 edition.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform results in a one time cost savings of approximately $108.7 million to ESRD facilities. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.

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16	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove the obsolete requirement that Ambulatory Surgical Centers (ASCs) establish an infection control program.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces red tape for ASCs. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
17	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove the duplicate provision that states that the governing body of an Organ Procurement Organizations (OPO) has full legal responsibility and authority for the management and provision of all OPO services and must develop and oversee the implementation of the policies and procedures necessary to ensure the effective administration of the OPO.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces red tape for OPOs. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
18	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Revise certain definitions for OPOs to be consistent with current definitions used in the OPO and transplant communities.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform updates obsolete information. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
19	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove the list of emergency equipment that must be available in an ASC's operating room. Substitute a requirement for the ASC's medical staff and governing body to develop written policies and procedures, following accepted standards of practice, specifying the type, quantity, etc., of emergency equipment, medications, and supplies that must be immediately available to handle inter- or post-operative emergencies.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform reduces red tape for ASCs and results in a one time savings of $18.5 million to ASCs. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.)	Final rule under development.
20	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	New Health Insurance Portability and Accountability Act of 1996 (HIPAA) modifications to the HIPAA transactions National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard version D.0 and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 Health Care Eligibility Benefit Inquiry and Response (270/271)) went into effect on January 1, 2012. Current e-prescribing standards use the outdated versions of these transactions. We would retire the older versions of e-prescribing transactions and adopt the newer versions to be in compliance with the current e-prescribing standards for Medicare Part D.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform updates outdated regulations. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.) Based on available information, we believe there will be support for this change from industry because they have already shown support for adopting the changes to these two HIPAA transactions.	Final rule under development.
21	CMS	0938-AQ96	Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction (9070-P & F)	Remove from the Code of Federal Regulations (CFR) the Office of Management and Budget (OMB) control numbers, approval numbers, and information collections since they are obsolete and can be accessed on the OMB website.	Proposed rule published 10/24/11 Final Rule TBD	This specific reform removes unnecessary information from the CFR. (This reform is part of the rule to promote program efficiency, transparency, and burden reduction that will save as much as $200 million in the first year.) There likely would be no opposition to removing the chart from the CFR as we have had no inquiries about the chart since it was added many years ago.	Final rule under development.
22	CMS	0938-AQ86	Contract Year 2013 Part C & D Proposed & Final Rules (4157-P & F)	Remove 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 10/11/2011 Target for final rule publication: 3/2012	This specific reform reduces red tape for HMOs and CMPs.	Final rule under development.

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23	CMS	0938-AP61	Medicaid Home & Community Based Services Waiver Final Rule (2296-F)	Eliminate a longstanding Federal barrier to creating one Medicaid Home and Community-based waiver that serves multiple target groups instead of three separate/distinct waivers. Enable states to design and operate fewer waiver programs by designing packages based on need rather than diagnosis. This will allow maximum flexibility for states to serve multiple target populations in a single Home and Community Based Services (HCBS) waiver, regardless of diagnosis.	Proposed rule published 4/15/2011 Target for final rule publication: TBD	There are no significant economic effects associated with this reform; it streamlines an existing waiver process and provides for maximum flexibility.	Final rule under development.
24	CMS	0938-AQ32	Disallowance of Claims for Federal Financial Participation (FFP) and Technical Corrections Proposed & Final Rules (2292-P & F)	Revise the repayment schedule providing 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 8/3/2011 Target for final rule publication: 7/2012	This specific reform increases flexibility for states and provides for a more extended repayment schedule by allowing states to select among three options for repaying federal overpayments. Cash strapped states will benefit from a longer term repayment option.	Final rule under development.
25	CMS	0938-AQ36	Home Health Face-to-Face Proposed & Final Rules (2348-P & F)	Revise the Medicaid home health service definition as required by section 6407 of the Affordable Care Act to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible individual within specified timeframes.	Proposed rule published 7/12/2011 Target for final rule publication: 9/2012	There will be an estimated $350 million savings from 2010 to 2014 to Medicare and an estimated $870 million savings from 2010 to 2019.	Final rule under development.
26	CMS	0938-AO53	Home & Community Based State Plan Option Proposed & Final Rules (2249-P2 & F)	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 targeted for early 2012 Target for final rule publication: TBD	This specific reform reduces red tape for states.	Proposed rule under development.
27	CMS	0938-AQ38	Patient's Access to Laboratory Test Report Proposed & Final Rules (2319-P & F)	Revise portions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to clarify existing policy and promote patient access to laboratory test reports.	Proposed rule published 9/14/11 Target for final rule publication: TBD	This specific reform increases transparency.	Final rule under development.
28	CMS	0938-AQ21	DME Face-to-Face Encounter Proposed & Final Rules (6033-P & F)	Establish a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items and align it with similar Medicare and Medicaid requirements.	Target for proposed rule publication as part of the Physician Fee Schedule proposed rule: 6/2012	The requirement is designed to reduce fraud, waste, and abuse and will ensure that DME is directed to those patients whose care requires it.	Under development.
29	CMS	0938-AG81	Home Health Agency (HHA) CoPs Proposed & Final Rules (3819-P & F)	Removes unnecessary prescriptive and burdensome requirements to reflect current practice and streamline operations.	Target for proposed rule publication: 6/2012	CMS is making extensive updates to coincide with current practice. This specific reform will streamline operations and reduce burden.	Proposed rule under development.

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30	CMS	0938-AQ31	Hospice Wage Index PPS Final Rule (1355-F)	Remove 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.	Complete.
31	CMS	0938-AQ00	Contract Year 2012 Part C & D Final Rule (4144-F)	For 2012, CMS will translate two model marketing material documents (Annual Notice of Change (ANOC)/Evidence of Change (EOC) and an enrollment form) into Spanish and Chinese. CMS is investigating translating other Part C and D materials into other languages, so that plans need not undertake the translation themselves.	Final rule published 4/15/11	CMS estimates savings to plan sponsors for this specific reform to be $4.6 million for 2012, and $230,000 for subsequent years. Part C & D Sponsors will support this initiative as it will result in a significant reduction in administrative, compliance, and oversight resources and cost.	Complete.
32	CMS	0938-AQ00	Contract Year 2012 Part C & D Final Rule (4144-F)	CMS began a voluntary process of annual rulemaking for the Parts C, D and cost contract programs. Annual rulemaking allows the Agency to fine-tune policy, enhance beneficiary protections, improve CMS' 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.	Final rule published 4/15/11	This specific 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' policy development process. The industry has expressed a desire that the annual regulations be published as early as possible in the year to allow maximum time to implement policy changes prior to the bid submission deadline for the following contract year (first Monday in June). The industry is very supportive of the rulemaking process. The annual regulation process has given all stakeholders (including industry, provider, and advocacy groups) the ability to influence CMS policy and our implementation of new statutory requirements.	Complete.
33	CMS	0938-AQ28	Inpatient Rehabilitation Facility PPS Final Rule (1349-F)	Revise change in ownership regulations for new inpatient rehabilitation facilities (IRFs), expanding IRFs, and IRF mergers/acquisitions.	Final rule published 8/5/11	This specific reform reduces red tape and increases flexibility for inpatient rehabilitation facilities. IRFs support this because it reduces the burden on providers.	Complete.
34	CMS	0938-AQ24	Inpatient Prospective Payment System Final Rule (1518-F)	Hospital Inpatient Prospective Payment System--Reporting Pension Costs: Revise cost report requirements to conform to Employee Retirement Income Security Act (ERISA) under Pension Protection Act of 2006.	Final rule published 8/18/11	This specific reform reduces paperwork for hospitals and provides flexibility. CMS estimates that hospitals will save $375,000 per year. Hospitals support this initiative.	Complete.
35	CMS	0938-AR06 0938-AQ25	CY 2012 Physician Fee Schedule Final Rule (1524-FC/1436-P)	Clinical Labs: Remove the new lab signature requirement that the physician sign orders for a clinical lab test.	Final rule published 11/28/11	This specific reform reduces red tape for physicians. There are approximately 21,088,145 burden hours associated with the physician signature requirement. This requirement was codified in CY 2011, but has been debated for several years; the overall paperwork burden would not change since this provision was not implemented. Physicians, clinical laboratories, and providers would support removing this requirement.	Complete.
36	CMS	0938-AQ53	"90/10" Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (2346-F)	Provide enhanced Federal Financial Participation (FFP) at the 90 percent rate for design, development, installation, or enhancement of eligibility determination systems to be available for state expenditures through CY 2015.	Final rule published 4/15/11	This specific reform reduces operation costs by enhancing development of new systems.	Complete.

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37	CMS	0938-AQ05	Telemedicine Final Rule (3227-F)	Revise the conditions of participation (CoPs) for hospitals and critical access hospitals (CAHs). Implement a new credentialing and privileging process for physicians and practitioners providing 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 will support this 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.	Complete.
38	CMS	0938-AP93	ASC Same-Day Services Final Rule (3217-F)	Remove 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 specific reform saves $50 million per year.	Complete.
39	CMS	9063-N & 9066-NC	Quarterly Issuance Notice (9063-N) & (9066-NC)	CMS compiles quarterly, in a Federal Register notice, information that is previously published or publicly displayed on a website. We have reformatted the notice and have saved $459,000 to date. We want to begin the process to revise the statute so that we can issue the notice with weblinks to where the information can be found on the internet, which we estimate would result in a total savings of over $720,000 per year.	Published 3/31/11 and 8/8/11	There is no burden associated with this reform. It will save $720,000 for CMS in publication costs per year. Publishing this notice has become very mechanical. We could possibly miss publishing the notice and no one may even notice.	Complete.
40	CMS	[N/A]	Notice Pursuing Alignment Opportunities (5507-NC)	Review all Medicare/Medicaid requirements that are misaligned for dual eligible individuals to identify those that should be revised based on conflicting or contradictory requirements. Issued an FR notice to solicit recommendations for aligning Medicare and Medicaid requirements for dual eligibles.	Notice published 5/16/11 Report to Congress under development.	There is no economic impact or burden associated with this reform. We expect most providers, states, beneficiaries, and advocates for dual eligible individuals to support this review and pay close attention to any resulting recommendations.	Report to Congress under development.
41	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 amends the federal opioid treatment program regulations by modifying the dispensing requirements for buprenorphine and buprenorphine combination products approved by FDA for opioid dependence and used in federally certified and registered opioid treatment programs. Opioid treatment programs that use these products in the treatment of opioid dependence will adhere to all other federal treatment standards established for methadone.	Target Final Rule Publication Date: 4/2012	The final rule will provide more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction. Such flexibility will expand the number of patients receiving this form of treatment and potentially reduce costs associated with drug related crime because more patients are receiving treatment.	Pending review from HHS/OS.
42	OCR	0991-AB80	Modifications to HIPAA Privacy Rule Requirements for Distribution of Notices of Privacy Practices	The modifications would reduce the administrative burden and cost on health plans associated with re-distributing their Notices of Privacy Practices when material changes are made to the privacy practices, while still ensuring individuals are notified in a timely manner of such material changes.	Target Final Rule Publication Date: 3/2012	Retrospective review will result in major modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's requirements for distribution of Notices of Privacy Practices.	Final Rule to OMB for review by early January 2012.
43	OCR	0991-AB80	Modifications to the HIPAA Privacy Rule Public Health Provisions for Disclosures of Student Immunization Records to Schools	The modifications would better facilitate the disclosure of student immunization records to schools in states that have school entry laws.	Target Final Rule Publication Date: 3/2012	The modifications would reduce burden on parents and health care providers and help avoid delays in children beginning school.	Final Rule to OMB for review by early January 2012.

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44	OCR	0991-AB80	Modifications to the HIPAA Privacy Rule Authorization Requirements for Research	The modifications would streamline the process for obtaining HIPAA authorizations for research purposes and harmonize with the Common Rule's informed consent requirements.	Target Final Rule Publication Date: 3/2012	The modifications would provide increased flexibility for researchers, reduce paperwork and burden, and harmonize with other research rules.	Final Rule to OMB for review by early January 2012.
45	OCR	0991–AB62	HIPAA Privacy Rule Accounting of Disclosures Requirements	The modifications would improve the workability of the current requirements in the HIPAA Privacy Rule to account for disclosures and would better balance the burden to regulated entities with the benefit to individuals.	Target Final Rule Publication Date: Mid- to Late- 2012	The modifications would provide an individual with information about those disclosures that are most likely to impact the individual's legal and personal interests, while reducing administrative burden on regulated entities.	In the process of reviewing the comments received during the public comment period on the NPRM, which closed on August 1.
46	HRSA	0906-AA87	Merger of the Healthcare Integrity and Protection Data Bank (HIPDB) into the National Practitioner Data Bank (NPDB)	The NPDB and the HIPDB are primarily alert or flagging systems intended to facilitate a comprehensive review of health care practitioners' professional credentials as well as instances of fraud and abuse. Section 6403 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires the elimination of duplicative data reporting and access requirements between the NPDB and the HIPDB. The Secretary of Health and Human Services is required to establish a transition period to transfer all data in the HIPDB to the NPDB, and, once completed, to cease operations of the HIPDB.	Target NPRM publication: by 2/2012	HRSA is confident that the streamlining of these regulations will reduce duplicative administrative burdens.	This NPRM is currently under EO 12866 review.
47	CDC	0920-AA21	Specifications for Medical Examinations of Underground Coal Miners	Proposes to allow the use of digital radiography in medical screening of underground coal miners for pneumoconiosis (black lung). Modification will allow the use of digital radiography in medical screening of coal miners for pneumoconiosis.	NPRM published 1/9/12	This rule allows medical providers to voluntarily adopt digital radiography to screen coal miners for pneumoconiosis. There are no imposed additional costs.	Public comments close 3/9/2012.
48	CDC	0920-AA23	Control of Communicable Diseases: Foreign - Non-human Primate (NHP)	Rule will extend current requirements for three species of NHPs to all NHPs and will reduce the frequency at which importers must renew their registrations. Modification will reduce administrative burdens for importers of NHPs	Target Final Rule Publication Date: 7/2012	The rule strengthens the public health benefits of current practices by extending existing requirements to additional non-human primates to better protect the public from communicable disease transmission. In addition, the rule reduces administrative burden on the regulated community of importers by reducing the frequency of required registration.	NPRM published 1/5/2011. Final rule is under development.
49	FDA	0910-AA97	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)	FDA is revising its regulations to allow mandatory safety reports to be transmitted electronically.	TBD	This provides expected cost savings for industry by eliminating paper burdens and by allowing FDA to collect and analyze safety reports more quickly and to identify emerging problems faster and disseminate information to the public.	Proposed rule published in 8/21/09. Final rule in development.
50	FDA	0910-AC52	Electronic Submission of Clinical Study Data (e-CSD)	FDA is revising its regulations to require submission of data in drug applications in electronic format that FDA can process, review, and archive.	TBD	The use of modern technology would increase efficiency and allow for more comprehensive data review, thereby streamlining the application process for industry and reducing processing time.	Review ongoing.

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51	FDA	0910-AG18	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (e-Labeling)	This rule would require electronic "package inserts" for human drug and biological products.	TBD	Clarification of labeling will improve provider understanding of drugs and biologics and drug interactions and dosages, thereby reducing the risk of improper prescribing.	Proposed rule under development.
52	FDA	0910-AA49	Electronic Registration and Listing for Drugs (e-DRLS)	This rule would convert the registration and listing process to a paperless system, while maintaining an avenue for companies that do not have access to the web.	TBD	FDA anticipates cost savings and burden reductions by allowing drug makers to use the latest technology in submitting information. This will improve FDA's ability to inspect manufacturing establishments.	Final rule in development.
53	FDA	0910-AF88	Electronic Registration and Listing for medical devices	This rule would convert the registration and listing process to a paperless system, while maintaining an avenue for companies that do not have access to the web.	TBD	FDA anticipate cost savings and burden reductions from this rule by allowing medical device makers to use the latest technology in submitting information. This will improve FDA's ability to inspect manufacturing establishments.	Review ongoing.
54	FDA	0910-AF81	Current Good Manufacturing Practices (CGMPs) for Combination Products	This rule would clarify and codify CGMPs requirements for products that are combinations of drug, device, and/or biological products.	TBD	This rule would provide regulatory clarity for manufacturers of combination products.	Proposed rule published 9/23/09. Final rule in development.
55	FDA	0910-AF82	Postmarketing Safety Reporting for Combination Products	This rule would clarify that a combination product is subject to the reporting requirements associated with the type of marketing application under which the product was approved.	TBD	This rule would provide regulatory clarity for manufacturers of combination products.	Proposed rule published 10/1/09. Final rule in development.
56	FDA	0910-AF86	Electronic Medical Device Reporting	This rule would convert adverse events reporting of medical devices to a paperless system.	TBD	This rule will save lives and decrease adverse events by allowing a more rapid response to adverse events from a paperless reporting system.	Final rule in development.
57	FDA	N/A	Down-classifications of Medical Devices (various)	This rule would review classifications of 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.	Review ongoing.
58	FDA	0910-AG76	Revision of Device Premarket Approval Regulations (21 CFR 814.39); Special PMA Supplement Changes Being Effected	This rule would remove duplicative requirements.	TBD	This rule would streamline and clarify regulatory requirements.	Review ongoing.
59	FDA	N/A	Revise 21 CFR 882.5975 referencing device classification for dura mater, now regulated as an HCT/P	This rule would clarify classification of dura mater.	Final rule published 6/24/11	This rule would streamline and clarify regulatory requirements.	Complete.
60	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 establishing special controls to provide reasonable assurance of safety and effectiveness of these devices.	TBD	This would provide cost savings in morbidly and mortality reductions by increasing safety for patients and to industry in reduced liability exposure.	Review ongoing.

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61	FDA	0910-AG74	Use of Symbols in Device Labeling	This rule would allow validated symbols in certain device labeling without the need for accompanying English text.	TBD	This rule would reduce burden of labeling requirements by permitted harmonization with labeling for international markets.	Review ongoing.
62	FDA	0910-AG18	Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products	FDA is revising certain definitions and reporting requirements based on recommendation of the International Conference on Harmonisation (ICH).	TBD	This would revise reporting requirements and times to enhance the quality of safety reports received by FDA.	Final rule in development.
63	FDA	N/A	Bar Code Rule for Drugs	FDA is conducting a retrospective economic review of this economically significant regulation.	TBD	FDA is assessing costs and benefits to determine if the rule should be modified to take into account changes in technology that have occurred since the rule went into effect.	FR notice requesting information published 10/26/11. Comment period ends 2/23/12.
64	FDA	0910-AG20	Amendment to Current Good Manufacturing Practices (CGMP) regulations for Finished Pharmaceuticals (Pharmaceutical CGMP for the 21st Century--Phase 2)	FDA is revising its CGMP regulations to accommodate advances in technology and to harmonize with the other international standards.	TBD	This would provide flexibility and harmonization for the pharmaceutical industry.	Proposed rule in development.
65	FDA	0910-AG70	Amendment to CGMP regulations—Components	FDA is revising its CGMP regulations to address control of drug components.	TBD	This would provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.	Proposed rule in development.
66	FDA	0910-AG26	Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets	FDA is revising its existing regulations to implement provisions of the FDA Amendment Act.	Proposed rule published 1/3/12	This would clarify the required certifications when individuals file Citizen Petitions related to generic drug applications.	Comment period ends 4/1/12.
67	FDA	0910-AF22	Food Labeling (Nutrition Initiative)	This rule would revise and update food labeling regulations to make nutrition information on packaged food labels more useful to consumers.	FDA drafting proposed rule	Improving nutrition information will help consumers make better dietary choices, thereby reducing costs associated with obesity and chronic diabetes.	Proposed rule in development.
68	FDA	0910-AG36	Preventive Controls (Modernization of Current Food Good Manufacturing Practice (GMP) Regulations)	In recognition that existing food GMP rules are inadequate, the Food Safety Modernization Act requires FDA to establish preventive controls for food facilities.	NPRM Target: 1/2012	This rule would provide significant cost savings from reduced illness and death from food-borne illness and reduced liability exposure of food industry.	Proposed rule in development.
69	FDA	0910-AG62	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act to determine whether it should be modified or eliminated to reduce the impact on small businesses while still achieving the regulatory objective.	FDA completed its review of this regulation by 12/31/11	If FDA determines that the regulation requires modification or elimination, this would reduce burdens and costs to small business.	Currently making a determination on whether to make any modifications to the existing regulation.

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70	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 it should be modified or eliminated to reduce the impact on small businesses while still achieving the regulatory objective.	FDA completed its review of this regulation by 12/31/11	If FDA determines that the regulation requires modification or elimination, this would reduce burdens and costs to small business.	Currently making a determination on whether to make any modifications to the existing regulation.
71	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.	NPRM Target: 1/2012	This rule would harmonize standards with the IEC and reflect current advances in science.	Proposed rule in development.
72	FDA	N/A	Veterinary Feed Directives (VFDs)	This would improve efficiency of the process for veterinarians to issue feed directives.	TBD	Streamlined VFDs will assist veterinarians and medicated feed manufacturers.	Review ongoing.
73	FDA	N/A	New Animal Drugs—Records and Reports concerning experience with approved drugs and medicated feeds	This review of regulations will determine how to clarify, streamline, and harmonize.	TBD	Alignment with international standards and a clarification of requirements will improve reporting by sponsors.	Review ongoing.
74	FDA	N/A	Good Laboratory Practice for Nonclinical Investigations	FDA is reviewing regulations for nonclinical investigations to determine how best to update them.	TBD	This would update standards for nonclinical investigations to streamline processes.	Review ongoing.
75	ACF	N/A	Statewide Automated Child Welfare System (SACWIS)	This rule grants greater flexibility to states to implement automation that supports their business model; reduces costs; reflects changing technology advances; and enables tribes to implement SACWIS-like systems.	In progress	The regulation will provide greater flexibility to states, thereby reducing their cost burdens, and will enable states to more easily and effectively place children across jurisdictions, especially with respect to Indian tribes.	A Federal Register Notice for tribal consultation was published January 5, 2012, with tribal consultation to follow in February. The draft NPRM is being developed. The goal is to have the NPRM published in 2013 and the final rule published in early 2014.
76	ACF	0970-AC43	Applications for Runaway and Homeless Youth Program Grants	This rule would update outdated procedures for obtaining announcements and submitting applications.	In progress	The rule would reduce confusion and streamline the application process using automation.	NPRM is currently going through clearance with the goal of a final rule being published in 2013.
77	ACF	N/A	Family Violence Prevention and Services Programs	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.	TBD	This would increase the clarity of programmatic operating procedures.	In progress.

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78	ACF	0970-AB11 was RIN for NPRM	Requirements applicable to the developmental disabilities program	The original NPRM from June 2008 to implement the Developmental Disabilities Act of 2000 received negative comments. ACF plans to rewrite the package to reduce administrative burden; to reflect improvements in data collection, performance measurement, and reporting; and to improve consistency with the statute.	TBD	This rule would provide additional flexibility and reduce administrative burden; provide improvements in data collection, performance measurement, and reporting; and improve consistency with the statute.	In progress.
79	ACF	0970-AC50	Efficiency in child support	The Office of Child Support Enforcement (OCSE) is drafting an NPRM which improves document management by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.	NPRM Target: 4/2012	This NPRM would provide OCSE, states, and others the flexibility to use cost-saving and efficient technologies, such as e-mail or electronic document storage, wherever possible.	In progress.
80	ACF	0970-AC50	Efficiency in child support	The Office of Child Support Enforcement (OCSE) is drafting an NPRM which increases statutory state law exemption approval periods from three to five years.	NPRM Target: 4/2012	This NPRM would provide relief to states by decreasing the frequency with which states have to request an extension of an approved state law exemption.	In progress.
81	ACF	0970-AC50	Efficiency in child support	The Office of Child Support Enforcement (OCSE) is drafting an NPRM which updates case closure criteria to increase state flexibility and facilitate effective case transfer between states and tribes.	NPRM Target: 4/2012	This NPRM would provide states greater flexibility to close unenforceable cases and redirect resources to more productive efforts. States will also have a process by which cases can be closed and transferred to a tribal child support program.	In progress.
82	ACF	0970-AC50	Efficiency in child support	OCSE is drafting an NPRM which discontinues the mandate for states to notify other states involved in enforcing a support order when they submit an interstate case for offset. States referring past-due support for offset will notify any such other state involved in enforcing the debt only when they receive the offset amount from the United States Treasury.	NPRM Target: 4/2012	Under this NPRM, states would no longer be inundated with unnecessary information, and the rule will ultimately save both time and resources.	In progress.
83	ACF	NA	Award of grants to states	Delete reference to financial status reports being required quarterly for Social Services grants and add language to require annual reporting for Social Services grants with the flexibility for the Office of Refugee Resettlement to request financial status reports more frequently in accordance with Part 92.	TBD	This would reduce the burden on states by decreasing the frequency of reporting unless a specific need surfaces.	In progress.