HHS July 2016 Retrospective Report

Agency	Sub-agency	Title Of Initiative/Rule or ICR	RIN/OMB Control Number	Summary of Initiative	Status of Initiative -- New to this update, Ongoing, or Completed	Target Completion Date (if completed, please add the publication date and cite in Federal Register for example)	Does the Initiative include regulatory flexibilities such as pilot projects, safe harbor examptions, sunset provisions, trigger provisions, streamlined requirements, state flexibilities, or other similar strategies?	What methods will you engage in to Identify Improvements (public comment, analyses, third party assessments, etc). Please identify all that apply	If Available, anticipated or realized savings in costs &/or burdens and anticipated or realized changes in benefits
HHS	ACF	Flexibility, Efficiency, and Modernization of Child Support Enforcement Programs	0970-AC50	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.	Ongoing	Final Rule Target: September 2016	This 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.	Before drafting the proposed rules, OCSE consulted with States, Tribes, employers, and other stakeholders. The National Council of Child Support Directors voluntarily established a subcommittee that would provide OCSE with cost saving proposals. We also sought Tribal input in a formal fashion as discussed in the Tribal Impact Statement. These efforts helped OCSE to: Identify regulations where we could encourage noncustodial parents to assume more personal responsibility; increase State and employer flexibility to better serve families; improve program effectiveness, efficiency, and innovation; streamline intergovernmental case processing; improve customer service; and remove barriers identified by employers, States, and families that impede efficient and timely child support payments. We also identified obsolete and outmoded requirements and technical fixes that are needed. This proposed rule recognizes and incorporates policies and practices that reflect the progress and positive results that have resulted from successful program implementation by States and Tribes.	This final rule, along with proposed changes in recognition of technological advances, will improve the delivery of child support services, support the efforts of noncustodial parents to provide for their children, and improve the efficiency of operations.
HHS	ACF	Head Start Performance Standards	0970-AC63	This final rule would modify Head Start performance standards to implement provisions in the Improving Head Start for School Readiness Act of 2007. Head Start performance standards would be revised to take into account increased knowledge in the early childhood field since the standards were last updated more than 15 years ago. Changes would strengthen requirements on curriculum and assessment, supervision, health and safety, and governance.	Ongoing	Final Rule Target: August 2016	The final rule would streamline existing regulations to eliminate unnecessary or duplicative requirements.	This final rule builds upon extensive consultation with researchers, practitioners, recommendations from the Secretary's Advisory Committee Final Report on Head Start Research and Evaluation and other experts, as well as internal analysis of program data and years of program input on the regulations. In addition, program monitoring has also provided invaluable experience regarding the strengths and weaknesses of the current regulations. Moreover, research and practice in the field of early childhood education has expanded exponentially in the 15 years since the regulations governing service delivery were last revised, providing a multitude of new insights on how to support improved child outcomes.	We estimate the changes to have a net cost of approximately $1 billion, primarily driven by the increases in the length of the day and year. The president's 2016 budget request includes a $1 billion initiative to increase the length of the program day and year which would cover the bulk of the costs associated with these changes. However, without this additional appropriation, we estimate 128,000 fewer children – or a roughly 13 percent reduction – would be served due to the costs associated with increasing quality. We believe these quality improvements are critical to Head Start achieving and sustaining better child and family outcomes. Therefore despite potentially serving fewer children, having a larger, more sustainable impact on those we serve will result in greater societal benefits. Coupled with the proposal to improve Head Start's education standards, we believe increasing these minimums is essential to improving Head Start's effort to prepare children to succeed in school and beyond.
HHS	ACF	Comprehensive Child Welfare Information System (CCWIS)	0970-AC59	This final rule grants 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.	Completed	6/2/2016; 2016-12509	We proposed a 24 month transition period of uninterrupted funding sufficient to allow title IV-E agencies to make a determination about how to proceed under the new rules and whether to transition their existing system to new system requirements.	We solicited comments from the public through a Federal Register notice in summer 2010, and conducted a series of conference calls with interested stakeholder groups to discuss the 2010 FR Notice, answer questions, and encourage the submission of comments. We engaged in a tribal consultation concerning the SACWIS regulations in Spring 2012. The proposed rule had a public comment period, and we considered those comments in drafting the final rule.	This final rule provides 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 will also help foster care agencies place and keep track of children across jurisdictions

HHS	ACF	Family Violence Prevention and Services Program	0970-AC62	This final 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.	Ongoing	Final rule target: October 2016	This rule would clarify programmatic operating procedures.	ACF/FYSB engaged in various meetings and consultations, among many other activities, that assisted in the development of the NPRM. To support our statutory responsibilities for administering the State and Coalition formula grants, we host either an annual or bi-annual, joint grantee meeting of the State FVPSA funding administrators and the State Domestic Violence Coalitions. These meetings provide important opportunities for Federal, State, and private staff to engage with each other to learn about and address issues of intersecting importance, including issues such as protecting victim/survivor confidentiality that are addressed in the proposed rule. The National Resource Centers, Special Issue Resource Centers, and Culturally-Specific Special Issue Resource Centers comprise what is known as the FVPSA Domestic Violence Resource Network (DVRN). The DVRN convenes every one to two years to share and promote evidence-informed and best practices about prevention and intervention services for victims of family, domestic, and dating violence. ACF funded Tribal administrators, advocates, and leaders also are convened annually. Issues addressed and best practices shared are most commonly related to service delivery; new initiatives; business needs; funding issues; information exchange; collaborations ranging from service delivery models to police	This rule would clarify programmatic operating procedures.
HHS	ACF	Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43	This final rule would implement section VIII of the Reconnecting Youth Act of 2008, requiring HHS to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program. The final rule also would harmonize the regulations with existing statute and administrative and managerial provisions already in use and make changes to reduce burden associated with the grant application process.	Ongoing	Final Rule target: July 2016	These changes would drive performance improvements and help assure accountability.	In keeping with the requirements of the statute, the Family and Youth Services Bureau (FYSB) sought input from grantees and other stakeholders prior to the development of the proposed rule. In April 2009, FYSB conducted a consultation forum that brought together forty-four individuals including subject experts, technical assistance providers, Runaway and Homeless Youth grantees, Federal staff, persons with extensive program monitoring experience, and national, regional and statewide youth servicing organization representatives. FYSB also obtained stakeholder perspectives and other information to inform the proposed rule in a number of additional ways. Since 2008, we have conducted national conferences bringing together all stakeholder groups and allowing for broad, informal exchanges of views. One such conference, the 2008 Runaway and Homeless Youth Grantee Conference, was attended by 442 participants, including representatives from 252 grantee organizations, to share ideas, promising approaches, and best practices. Participants met in over 30 different workshops addressing both universal issues and specific programmatic needs of the three major Runaway and Homeless Youth programs. Through the Runaway and Homeless Youth Training and Technical Assistance Centers, we have conducted an	The rule will increase transparency and streamline the grant application process using automation.
ASPR	OEM			Eagle Horizon 2016 Senior Leadership Tabletop	Completed	2-May-16			
ASPR	OEM			Eagle Horizon 2016 and Gradient Aspect 2016	Completed	May 16-17			
ASPR	OEM			Healthcare and Public Health Sector-Specific Plan for Critical Infrastructure Protection	Completed	May-16			
ASPR	OEM			NSSE Democratic National Concention					
ASPR	OEM			NSSE Republican National Concention					

ASPR	OEM			NSSE POTUS Inauguration					
HHS	CDC	National Healthcare Safety Network revisions	0920-0666	This collection is currently approved for 8,975,750 responses and 4,277,716 burden hours. This revision request includes adding 19 forms, removing one form and revisions to 22 previously approved forms. The reporting burden will increase by 489,174 hours, for a total estimated burden of 5,110,716 hours; annual cost of reporting would increase by $20,082,304.	Ongoing				The reporting burden will increase by 489,174 hours, for a total estimated burden of 5,110,716 hours; annual cost of reporting would increase by $20,082,304.
HHS	CMS	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-F)	0938-AO91	This final rule establishes national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems to ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. These regulations will help to ensure the safety of those receiving care in any setting if an emergency situation occurs.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 12/27/13 78 FR 79082 Final Rule Target: Before the MMA section 902 deadline - 12/00/16	Exceptions processes; Phase-ins	Public comment; Analyses; Industry Feedback	This rule includes important health and safety initiatives to protect Medicare beneficiaries. Although CMS is unable to specifically quantify the number of lives saved as a result of this rule, all of the data CMS has read regarding emergency preparedness indicates that implementing the requirements in this rule could have a significant impact on protecting the health and safety of individuals served by providers and suppliers that participate in the Medicare and Medicaid programs.
HHS	CMS	Home Health Agency Conditions of Participation (CMS-3819-F)	0938-AG81	This final rule revises the current conditions of participation that home health agencies must meet. The requirements focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These revised regulations will help to ensure patients receive efficient, quality care and services.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 10/9/14 79 FR 61163 Final Rule Target: Before the MMA section 902 deadline - 10/00/17	Exceptions processes; Phase-ins	Public comment; Analyses; Industry Feedback	This rule includes important health and safety initiatives to protect Medicare beneficiaries. The potential for significant benefits, ranging from improved patient outcomes to increased staff productivity, which may be realized by HHAs as a result of improved practices and a higher quality patient care outweighs any costs incurred.
HHS	CMS	Reform of Requirements for Long-Term Care (LTC) Facilities (CMS-3260-F)	0938-AR61	This proposed rule would revise the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These proposals are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers. These changes will allow more flexibility in how care is delivered in the LTC setting which will enhance the lives of residents who reside in LTC facilities.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 7/16/15 80 FR 42167 Final Rule Target: Before the MMA section 902 deadline - 7/00/18	Exceptions processes; Phase-ins	Public comment; Analyses; Industry Feedback	This proposed rule would implement comprehensive changes intended to update the current requirements for long-term care facilities and create new efficiencies and flexibilities for facilities. In addition, these changes will support improved resident quality of life and quality of care. Quality of life in particular can be difficult to translate into dollars saved. However, there is a body of evidence suggesting the factors that improve quality of life may also increase the rate of improvement in quality and can have positive business benefits for facilities.
HHS	CMS	Programs of All-Inclusive Care for the Elderly (PACE) Update (CMS-4168-P)	0938-AR60	This proposed rule would update the PACE regulations published on December 8, 2006. The rule would improve the quality of the existing regulations, provide operational flexibility and modifications, and remove redundancies and outdated information. These updates are intended to ensure the health and safety of PACE participants.	Ongoing--Proposed Rule Pending.	Proposed Rule Target: 7/00/16	Streamlined requirements; Exceptions processes	Public comment; Analyses	This rule includes important health and safety initiatives to protect Medicare beneficiaries. We are not able at this time to provide specific cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.
HHS	CMS	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-F)	0938-AS21	This final rule updates the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. These requirements are intended to conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 6/16/16 81 FR 39448 Final Rule Target: Before the MMA section 902 deadline - 06/00/19	Streamlined requirements; Antibiotic Stewardship	Public comment; Analyses; Beneficiary Advocacy Group Feedback	This rule includes important health and safety initiatives to protect Medicare beneficiaries. The impact of the rule as proposed lies primarily with the estimated costs (approximately $773 million to $1.1 billion) of revising the hospital and CAH infection control CoPs, including the new requirements for antibiotic stewardship programs. However, these costs may be more than offset by the savings, and the overall benefits to patients, that would be achieved with these changes (net savings to society of up to $284 million).
HHS	CMS	Covered Outpatient Drug (CMS-2345-F)	0938-AQ41	This final rule implements several provisions of the Affordable Care Act that pertain to prescription drugs under the Medicaid program. It revises the rebate formulas for covered outpatient drugs, revises the definition of average manufacturer price, and revises the Federal Upper Payment Limits for multiple source drugs.	Complete	Proposed Rule Published: 2/2/12 77 FR 5317 Final Rule Published: 2/1/16 81 FR 5170	Streamlined requirements; State flexibilities; Exceptions processes; Phase-ins	Public comment; Analyses	We estimate the savings from the implementation of the FULs as revised in this final rule of $2.735 billion over 5 years (2016 through 2020), $1.61 billion to the federal government and $1.125 billion to the states. Lastly, we estimate costs to drug manufacturers and states of $431.96 million for FFYs 2016 through 2020.
HHS	CMS	Fire Safety Requirements for Certain Health Care Facilities (CMS-3277-F)	0938-AR72	This final rule amends the fire safety standards for hospitals, critical access hospitals, long-term care facilities, intermediate care facilities for the intellectually disabled, ambulatory surgery centers, hospices which provide in-patient services, religious non-medical health care institutions, and Programs of All-Inclusive Care for the Elderly facilities. Further, this rule adopts the 2012 edition of the Life Safety Code and eliminates references in our regulations to all earlier editions. These regulations will ensure that care will be delivered in a safe setting.	Complete	Proposed Rule Published: 4/16/14 79 FR 21552 Final Rule Published: 5/4/16 81 FR 26871	State flexiblities; Exceptions processes; Phase-ins	Public comment	This rule includes important health and safety initiatives to protect Medicare beneficiaries. The overall economic impact for this rule is estimated to be $18 million in the first year of implementation, $12 million, annually, for years 2 and 3 of implementation, and $6 million, annually, for years 4-12 of implementation. Additionally, although we are not quantifying the number of lives that would be saved upon implementation of this rule due to the lack of data that could provide a reliable estimate, we believe that there is potential for such a result.

HHS	CMS	Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions related to Third Party Liability (CMS-2390-F)	0938-AS25	This final rule modernizes the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The rule aligns the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implements statutory provisions; strengthens actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; ensures appropriate beneficiary protections; and, enhances expectations for program integrity. This rule also implements provisions of CHIPRA and addresses third party liability for trauma codes.	Complete	Proposed Rule Published: 6/1/15 80 FR 31097 Final Rule Published: 5/6/16 81 FR 27901	Streamlined requirements; Trigger provisions; State flexibilities; Exceptions processes	Public comment; Analyses; State feedback	The total projected cost associated with this final rule is $113.8 million for all revisions in the first year. However, non-quantifiable benefits include improved health outcomes, reduced unnecessary services, improved beneficiary experience, improved access, and improved program transparency, which facilitates better decision making.
HHS	FDA	Hearing Aid Access and Innovation	N/A	Through this initiative FDA is exploring areas where regulatory action can improve hearing aid access and spur innovation and development.	Ongoing	FR notice to reopen comment period on draft guidance published 1/7/2016. Comment period ended 5/6/2016.	Yes. This initiative explores whether there are regulatory barriers to access and possible improvement.	Public comments	N/A
HHS	FDA	Postmarketing Safety Reporting for Combination Products	0910-AF82	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.	Ongoing	NPRM published 10/1/09 Final Rule Target date TBD	Streamlined requirements	Public comments	N/A
HHS	FDA	Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets	0910-AG26	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 and the Food and Drug Administration Safety and Innovation Act.	Ongoing	Target Publication 10/00/2016	The regulation contains both trigger and certification / verification provisions. A related guidance document has also been published.	Public comments	N/A
HHS	FDA	Patient Labeling for Drugs (Patient Package Inserts and Medguides)	No RIN yet	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.	Ongoing	TBD	TBD	TBD	TBD
HHS	FDA	Laser Products; Amendment to Performance Standards	0910-AF87	This proposed rule would amend the performance standards for laser products to achieve closer harmonization with the International Electrotechnical Commission (IEC) standards.	Ongoing	NPRM Published: 6/24/13. Comment Period ended 9/23/13	Streamlined requirements	Public comments	We anticipate a burden reduction because we will achieve closer harmonization with international standards.
HHS	FDA	Bar Code Rule for Drugs	No RIN yet	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.	Ongoing	Notice requesting info published 10/26/11. Comment period ended 6/18/13.	TBD	TBD	TBD
HHS	FDA	Good Laboratory Practices for NonClinical Laboratory Studies	0910-0119	FDA is reviewing regulations for nonclinical laboratory studies to determine how best to update them.	Ongoing	TBD	Streamlined requirements	Public comments	TBD

HHS	FDA	Human Subject Protection; Acceptance of Clinical Investigations for Medical Devices	0910-AG48	This rule will amend FDA's regulations on acceptance of data from clinical investigations conducted in support of a medical device premarket approval submission to allow data from foreign clinical investigations as long as those investigations are conducted in accordance with good clinical practices.	Ongoing	NPRM published 2/25/13. Comment period ended 5/28/13.	The rule will include a waiver provision that, upon request , will allow any applicable requirement to be waived. Waivers may be granted if an explanation is provided for why compliance with the requirement is unnecessary or cannot be achieved, if an alternative is provided that satisfies the purpose of the requirement, or if adequate justification can be provided.	Public comments	The rule will clarify FDA's requirements for using clinical data collected domestically and collected outside the United States to support medical device applications submitted to FDA. Clarifying these requirements will help to ensure the integrity of the data and the protection of human subjects; thereby, facilitating the use of such data in support of new device applications.
HHS	FDA	Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products	0910-AA97	FDA is considering whether to revise certain definitions and reporting requirements based on recommendations of the International Conference on Harmonization of Technical Requirements. This is intended to enhance the quality of the safety reports and facilitate harmonization.	Ongoing	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) target is 3/00/2017	Harmonize with international requirements		Ongoing
HHS	FDA	Labeling Requirements for Approved and Conditionally Approved New Animal Drugs	0910-AH27	FDA is proposing updated regulations for the labeling of new animal drugs and new regulations that specify the format and content of labeling for prescription new animal products, new animal drug products for use in feed, and over-the-counter new animal drug products. The objective of the proposed rule is to protect the health of animals by providing more drug information in a more uniform format on the animal drug label.	Ongoing	Target Publication 12/00/16	Streamlined Requirements	Public comments	TBD
HHS	FDA	Regulations on Fixed-Dose Combinations and Co-Packaged and/or Biological Products	0910-AF89	The proposed rule would amend FDA regulations on fixed-combination prescription and over-the-counter (OTC) drugs.	Ongoing	Proposed rule Published: 12/23/15	Streamlined requirements by using the same language to explain the Rx and OTC requirements and allows a waiver from the required data.	Public Comments	Ongoing
HHS	FDA	Patient Medication Information	0910-AH33	Amends FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development, consumer testing, and distribution. The proposed rule would require clear and concise written prescription drug product information in a consistent and easily understood format to help patient use their prescription drug products safely and effectively	Ongoing	Proposed Rule 12/00/2016	TBD	Public Comments	TBD
HHS	FDA	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910-AC53	FDA issued a proposed rule to amend the CGMP regulations and other regulations to, among other things, clarify and strengthen requirements for the labeling, color, and design of medical gas containers and closures. For example, FDA proposed requiring that all gas-specific use outlet connections on portable cryogenic medical gas containers be securely attached to the valve body.	New	Proposed Rule (4/10/2006); Final Rule (TBD)	Streamlined requirements	Public Comments	TBD
HHS	FDA	FDA Review and Action on Over-the-Counter Time and Extent Applications	0910-AH30	The rule would supplement the time and extent applications (TEA) process for over-the-counter drug products by establishing timelines and measurable metrics for FDA's review of non-sunscreen TEAs as required by the Sunscreen Innovation Act (SIA). On our own initiative, we are also proposing other changes to make the TEA process more efficient.	New	NPRM (2/26/2017) Final rule (2/00/2017)	Streamlined requirements	Public Comments	Ongoing
HHS	FDA	Responsibilities for the Initiation and Conduct of Clinical Investigations	0910-AH32	The rule would update the investigational new drug application (IND) regulations to define and clarify the roles and responsibilities of the various persons engaged in the initation, conduct and oversight of clinical investigations subject to IND requirements. The proposed changes would better protect the rights, safety and welfare of subjects and help ensure the integrity of clinical trial data.	New	Proposed Rule (4/00/2017)	TBD	Public Comments	TBD

HHS	FDA	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	0910-AG14	FDA reviewed 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.	Completed	Review completed 11/30/13.			
HHS	FDA	Current Good Manufacturing Practices (CGMPs) for Combination Products	0910-AF81	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.	Completed	Proposed Rule Published: 9/23/09 Final Rule Published: 1/22/13			
HHS	FDA	Electronic Registration and Listing for Medical Devices	0910-AF88	This final rule sets forth requirements for electronic registration and listing for medical devices, while continuing to offer an avenue of registration and listing for those companies without web access. This rule would allow industry greater flexibility and encourage the use of the latest technology for information collection.	Completed	Proposed Rule Published: 3/26/10 Final Rule Published: 8/2/12			
HHS	FDA	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	0910-AG62	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.	Completed	FDA completed its review of this regulation by 12/31/11.			
HHS	FDA	Amendments to Sterility Testing Requirements for Biological Products	0910-AG16	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.	Completed	Proposed Rule Published: 6/21/11 Final Rule Published: 5/03/12			
HHS	FDA	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e- SADR)	0910-AF96	FDA is considering revising its regulations to allow mandatory safety reports to be transmitted electronically.	Completed	Final Rule published 6/10/2014			
HHS	FDA	Veterinary Feed Directives	0910-AG95	This initiative would improve efficiency of the process for veterinarians to issue feed directives.	Completed	Final Rule published 6/2/2015	Streamlined requirements	Public comments	FDA estimates the annualized cost savings associated with the more efficient requirements of the VFD process to be $13,000 over 10 years at a 7 percent discount rate (annualized at $11,000 over 10 years at a 3 percent discount rate). Additionally, the reduction in veterinarian labor costs due to this rule is expected to result in a cost savings of about $7.87 million annually.
HHS	FDA	Revocation of the General Safety Test Requirements for Biological Products	N/A	This final rule would amend the biologics regulations by removing the general safety test (GST) requirements for biological products found in 21 CFR 610.11, 610.11a and 680.3(b). FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation.	Completed	NPRM published 8/22/14. Comment period ended 11/20/14. Final Rule published 7/2/15.	No Reg Flex	Public Comment	Reduces certain regulatory burdens
HHS	FDA	Hazard Analysis and Risk-Based Preventive Controls	0910-AG36	This proposed rule would modernize current good manufacturing practices for food and 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.	Completed	NPRM published 1/13/12. Supplement published 9/29/14. Comment period ended 12/15/14. Final rule published 9/17/15.	Yes. The rule allows very small businesses to comply with modified requirements, would exempt small and very small farms that only conduct specified low-risk activities, and would provide an extended compliance date for small and very small businesses.	Public comments and a contract for a Food Processing Sector Study to determine food processing activities conducted on farms.	
HHS	FDA	Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972	N/A	The final rule removes §§ 601.25 and 601.26 which prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972.	Completed	Final Rule; 02/12/16	No Reg Flex	Public Comment	Removes certain regulatory burdens

HHS	FDA	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910-AF11	This final rule will amend the content and format of the "Pregnancy," "Labor and delivery," and "Nursing mothers" subsections of the "Use in Specific Populations" section of regulations regarding the labeling for human prescription drug and biological products to better communicate risks.	Completed	Final Rule: 12/04/15 (79 FR 72064)			
HHS	FDA	Use of Symbols in Device Labeling	0910-AG74	FDA is considering whether to allow validated symbols in certain device labeling without the need for accompanying English text.	Completed	NPRM Published: 4/19/13. Comment period ended 6/18/13. Final rule published 6/15/16	Streamlined requirements	Public comments	Regulation would reduce burden of labeling requirements by harmonizing with international standards.
HHS	FDA	Amending the general biological product standards relating to dating periods, standard preparations and limits on potency [Title change: Standard preparations, limits of potency, and dating period limitations for biological products]	N/A	The direct final/companion proposed rule would provide additional flexibility to manufacturers of licensed biological products by amending the general biological products standards relating to dating periods and removing certain regulations for standard preparations and limits of potency. FDA is taking this action to provide additional flexibility to manufacturers of licensed products and to update obsolete or outdated requirements.	Completed	Direct Final Rule published 5/4/16; comments close 7/18/16	No	Public Comment	Reduces certain regulatory burdens
HHS	FDA	Food Labeling: Revision of the Nutrition and Supplement Facts Labels	0910-AF22	This rule revises and updates food labeling regulations to make nutrition information on packaged food more useful to consumers. This rulemaking will 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.	Completed	Final rule published 5/27/16	No	Public comments	
HHS	FDA	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments	0910-AF23	This rule contains provisions to define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish several reference amounts customarily consumed (RACCs); amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations.	Completed	Final rule published 5/27/16	No	Public comments	
HHS	FDA	Individual Patient Expanded Access Applications: Form FDA 3926	NA	The guidance describes Form FDA 3926 (Individual Patient Expanded Access--Investigational New Drug Application (IND)), which is available for licensed physicians to use for expanded access requests for individual patient INDs. Individual patient expanded access allows for the use of an investigational new drug outside of a clinical investigation, or the use of an approved drug where availability is limited by a risk evaluation and mitigation strategy (REMS), for an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. Form FDA 3926 provides a streamlined alternative for submitting an IND for use in cases of individual patient expanded access, including for emergency use. This guidance finalizes the draft guidance issued in February 2015	Completed	6/3/2016	Streamlined the submission process for individual expanded access INDs.	It is anticipated that the use of Form FDA 3926 will reduce the current information collection burden by 15,797 hours.	NA
HHS	HRSA	Termination of the Smallpox Vaccine Injury Compensation Program	0906-AA84	This direct final rule terminates the obsolete Smallpox Vaccine Injury Compensation Program and removes its implementing regulation.	New action added to an existing, ongoing rulemaking.	Target publication date: 8/1/2016	This metric is not applicable to this regulatory action because we are eliminating an obsolete program.	This metric is not applicable to this regulatory action because we are eliminating an obsolete program.	This metric is not applicable to this regulatory action because we are eliminating an obsolete program.

HHS	HRSA	Maternal and Child Health Services Block Grant Application and Annual Report Guidance	0915-0172	This PRA action involved revising the Application and Annual Report Guidance used by the 50 states and nine jurisdictions eligible for state formula grants under the Maternal and Child Health Services Block Grant.	Completed	Notice of Action Date: 12/23/2014. 60-day notice published 6/27/14; 79 FR 36537-9	This PRA action streamlines the reporting process through the use of electronic data reporting assuring that data represented in multiple tables are entered only once. In addition, a new Web-based data entry and Web-reports system is being implemented.	In addition to the public comments received during the 60-day public comment period, the draft Application/Annual Report Guidance was discussed with appropriate State Directors at the face-to-face Application/Annual Report review in August 2014.	The previous inventory for this activity was 14,514 hours. Following this action, the current inventory is 9,213 hours, for a reduction of burden of 5,301 hours.
HHS	HRSA	Performance Report for Grants and Cooperative Agreements	0915-0061	This PRA action involved the annual performance and progress report required from each health professions' and nursing education grantee with an approved, funded project with a project period of one year or more. The report is used to determine the extent to which the project's objectives have been met and are used to consider continued funding.	Completed	Notice of Action Date: 6/10/2016. 60-day notice published 12/17/15; 80 FR 78748-9	This PRA action streamlines the electronic reporting process by providing user-friendly templates on certain forms as well as pre-populated data fields on forms that do not utilize templates.	Scientists from HRSA's National Center for Workforce Analysis met with government project officers to discuss updates to the measures. Also, technical assistance sessions with grantees were held to discuss the performance reporting change to annual reporting.	The previous inventory for this activity was 7,737 hours. Following this action, the current approval is 5,992 burden hours, for a reduction of burden of 1,745 hours.
HHS	HRSA	Medical Rural Flexibility Grant Program (Flex) Performance Measures	0915-0363	This PRA action involves the Flex program, which supports state designated entities that assist critical access hospitals improve across Flex initiatives. These initiatives help ensure residents in rural communities have access to high quality health care.	Ongoing	TBD	This PRA action streamlines the reporting process by lowering the measures to be reported.	Flex program performance measures were drafted and approved with stakeholder feedback to aggregate program data required by Congress under the Government Performance and Results Act of 2010.	The current inventory provides for 9,720 hours. This request is for 3,150 hours, for a reduction of burden of 6,570 hours. This decrease is due to the lower number of measures that will be reported on by grantees.
HHS	HRSA	Discretionary Grants Information System	0915-0298	This PRA initiative seeks to revise the collection of information from public and private agencies or organizations engaged in demonstrations, research, training, or other projects that receive funding from the Special Projects of Regional and National Significance and Community Integrated Service Systems federal discretionary grant programs, and other categorical discretionary grant programs.	Ongoing	TBD	This PRA initiative streamlines the reporting process by reducing the number of measures to be reported on by most programs.	To obtain feedback on the proposed changes, HRSA held four virtual town hall meetings: one for HRSA staff and three for all stakeholders, including individual grantees.	The current inventory for this activity is 37,062 hours. This request is for 21,600 hours, for a reduction of burden of 15,462 hours. This decrease is due to an anticipated lower number of rograms reporting than it has been historically and most programs will report on fewer measures.
HHS	NIH	NIH Construction Grants		NIH is revising the current NIH construction grants regulations at 42 FR 52b , last updated in November 1999, to reflect updated standards, laws, policies, and practices of the NIH construction grants program and update the documents incorporated by reference in the current regulations.	Ongoing	3/1/17	No	Public comment	Updating the regulations to reflect policy and other changes will increase transparency of current program procedures and practices. Updating the documents that are incorporated by reference in the regulations will make it much easier for the public to access information regarding minimum construction standards that apply to all NIH construction grants projects. Providing web addresses will ensure that the most current information is readily available to grantees , thereby eliminating the need to conduct searches and/or make campus visits to view the documents.
OASH	OHRP	Federal Policy for the Protection of Human Subjects: Final Rules	0937-AA02	The final rules would revise current human subjects regulations in order to strengthen protections for research subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.	Ongoing	9/1/2016	Yes	Public Comment	Currently Not Available
HHS	OCR	HIPAA Privacy Rule Accounting of Disclosures under the HITECH Act	0945-AA00	The Final Rule would revise the current accounting of disclosures requirements in the HIPAA Privacy Rule to improve workability and to better balance the burden to regulated entities with the benefit to individuals.	Ongoing	Proposed Rule Published: 5/31/11 The workability changes to the accounting of disclosures provisions are currently attached to a long term action on OCR's regulatory agenda to implement other changes to the provisions under the HITECH Act.	No	Public comment was obtained on the Proposed Rule. OCR also engaged in meetings with stakeholders on matters relating to this initiative.	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.
HHS	SAMHSA	Medication Assisted Treatment for Opioid Use Disorders	0930-AA22	The proposed rule will increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA) from 100 to 200, giving providers the flexibility to serve more consumers if they choose to.	Ongoing	7/6/2016	No	The proposed rule was released for public comment.	
HHS	SAMHSA	Mandatory Guidelines for Federal Workplace Drug Testing Programs (Oral Fluid)	0930-ZA06	By expanding the guidelines to include a broader range of testing options, SAMHSA is providing more options for organizations implementing drug testing programs compliant with the SAMHSA guidelines.	Ongoing	8/25/2016	No	The Guidelines were released for public comment.	
HHS	SAMHSA	Mandatory Guidelines for Federal Workplace Drug Testing Programs (Hair)	NA	By expanding the guidelines to include a broader range of testing options, SAMHSA is providing more options for organizations implementing drug testing programs compliant with the SAMHSA guidelines.	Ongoing	3/15/2017	No	The Guidelines were released for public comment.	