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	SAMHSA	Notice of the Mandatory Guidelines proposed by the Secretary of Health and Human Services	0930-ZA06	The Department of Health and Human Services ("HHS" or "Department") is proposing to establish scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).	Ongoing	2/28/2016; Final rule 8/28/16	SAMHSA proposes to issue the Federal Workplace Drug Testing Oral Fluid Mandatory Guidelines (OFMG). The OFMG will allow Executive Branch agencies and the regulated industry to implement an alternative testing process that is less intrusive and more cost/time effective when compared to the current urine-based testing program. The use of an electronic chain-of-custody form will also reduce the administrative burden of participating in this program.	public comment	The OMFG will lessen the administrative and financial burden of workplace drug testing, since they will provide flexibility to use oral fluid testing in addition to existing urine testing procedures.

HHS	SAMHSA	Notice of the Mandatory Guidelines proposed by the Secretary of Health and Human Services		The Department of Health and Human Services (“HHS” or “Department”) is proposing to establish scientific and technical guidelines for the inclusion of hair specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).	New	1-Sep-16	SAMHSA proposes to issue the Federal Workplace Drug Testing Hair Mandatory Guidelines (HrMG). The HrMG will allow Executive Branch agencies and the regulated industry to implement an alternative testing process that is less intrusive and more cost/time effective when compared to the current urine and proposed oral fluid-based testing program. The use of an electronic chain-of-custody form will also reduce the administrative burden of participating in this program.	public comment	The HrMG will lessen the administrative and financial burden of workplace drug testing and detect drug use for a longer period of time for pre-employment testing. Hair testing will provide flexibility in addition to existing urine testing procedures and the proposed oral fluid testing procedures.
HHS	SAMHSA	Notice of Proposed Rulemaking (NPRM) to Increase the Highest Patient Limit for Qualified Physicians to Treat Opioid Use Disorder with Buprenorphine		The Department of Health and Human Services ("HHS" or "Department") is proposing a rule to increase the highest patient limit for qualified physicians to treat opioid use disorder under 21 U.S.C. 823(g)(2).	New	May-16	The NPRM allows practitioners with a waiver under 21 U.S.C. 823(g)(2) flexibility to treat more patients under certain circumstances.	public comment	This rule will expand access to medication assisted treatment (MAT) by allowing eligible practitioners to request a waiver to treat additional patients under 21 U.S.C 823(g)(2). In addition, it provides practitioners with needed flexibility to treat more patients in emergency circumstances. The rule also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk of misuse, addiction, and diversion.

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	Pilot projects; 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	Fire Safety (Life Safety Code) 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-patent 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 help ensure that care will be delivered in a safe setting.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 4/16/14 79 FR 21552 Final Rule Target: Before the MMA section 902 deadline - 4/00/17	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 $108 million in the first year of implementation, $102 million, annually, for years 2 and 3 of implementation, and $96 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	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	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.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 2/2/12 77 FR 5317 Final Rule Target: 12/00/15	Streamlined requirements; State flexibilities; Exceptions processes; Phase-ins	Public comment; Analyses	In 2012, CMS estimated that this rule would save approximately $17.7 billion for FY 2014, reflecting $13.7 billion in federal savings and $4 billion in state savings. These estimates represented the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid managed care organizations, and provides for adequate pharmacy reimbursement. We are not able at this time to provide updated cost and benefit estimates. As we move toward publication, estimates of the cost and benefits of these important initiatives will be included in the rule.

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: 4/00/16	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	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.	Ongoing--Proposed Rule Completed; Final Pending.	Proposed Rule Published: 6/1/15 80 FR 31097 Final Rule Target: 4/00/16	Streamlined requirements; Trigger provisions; State flexibilities; Exceptions processes	Public comment; Analyses; State feedback	The overall economic impact for this rule is estimated to be $112 million in the first year of implementation. Additionally, 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	CMS	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-P)	0938-AS21	This proposed rule would update the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. These proposals are intended to conform the requirements 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	Proposed Rule Target: 2/00/16	Streamlined requirements; Antibiotic Stewardship	Public comment; Analyses; Beneficiary Advocacy Group Feedback	This rule includes important health and safety initiatives to protect Medicare beneficiaries. The rule would create ongoing cost savings to hospitals and CAHs in many areas. 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	CDC	Administrative Functions, Practices, and Procedures	RIN 0920-AA55	Rescinded rule no longer needed	Completed	80 FR 73667 11/25/2015	No	N/A	N/A
HHS	CDC	Medical Examination of Aliens	RIN 0920-AA28	Removes 3 STDs as inadmissible conditions to the US	Ongoing	January, 2016	No	N/A	N/A

HHS	OASH	Federal Policy for the Protection of Human Subjects	0937-AA02	The proposed rule would revise current human subjects regulations in order to strengthen protections for research subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.	Ongoing	TBD	No	Public Comment	Present costs, 13,342 Million; Presnt benefits, 2,662 Million
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	FDA	Food Labeling (Nutrition Initiative)	0910-AF22	This proposed rule would revise and update food labeling regulations to make nutrition information on packaged food more useful to consumers. This rulemaking would modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label, to help consumers maintain healthy dietary practices.	Ongoing	NPRM published 3/3/14 ; comment period closed 8/1/14. Final rule TBD	No	Public comments	The NPRM Annualized over 20 years, the labeling cost associated with the proposed rules is $122 million per year at a 3 percent discount rate and $165 million per year at a 7 percent discount rate. We estimate benefits annulized over 20 years $2.0 billion per year assuming a 3 percent discount rate and $1.9 billion per year assuming a 7 percent discount rate. The benefits are based on consumers willingness to pay for the label information
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	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (eDL)	0910-AG18	This proposed rule would amend the prescription drug and biological product labeling regulations to require that the prescribing information intended for health care professionals be distributed electronically to ensure that the most up-to-date information regarding safety and efficacy will be available and readily accessible to health care professionals at the time of clinical decisionmaking and dispensing.	Ongoing	NPRM published 12/18/14. Comment period ended 5/18/15	Yes. The proposed rule, if finalized, would allow FDA to exempt a product from electronic distribution requirements where electronic distribution could adversely affect the safety, effectiveness, purity, or potency of the drug; is not technologically feasible; or is otherwise inappropriate. FDA has proposed an effective date of 6 months after publication of the final rule with a 2-year period of enforcement discretion to permit maximum flexibility for implementation of required labeling changes.	Public comment. Internal and external analyses were performed in development of the NPRM.	The NPRM includes an analysis of costs and benefits and predicts annualized net savings ranging from $5 million to $74 million. The public health benefits of users having access to the most up-to-date version of the prescribing information have not been quantified, but are anticipated.
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 Adminstration Safety and Innovation Act.	Ongoing	Target Publication 1/31/2016	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.	Proposed Rule in Developme nt.	TBD	TBD	TBD	TBD
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.	Ongoing [Under Centers Final Clearance]	TBD	No Reg Flex	Public Comment	Reduces certain regulatory burdens
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.	NPRM Published: 6/24/13. Comment Period ended 9/23/13	TBD	Streamlined requirements	Public comments	We anticipate a burden reduction because we will achieve closer harmonization with international standards.

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.	NPRM Published: 4/19/13. Comment period ended 6/18/13	TBD	Streamlined requirements	Public comments	Regulation would reduce burden of labeling requirements by harmonizing 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.	Notice requesting info published 10/26/11. Comment period ended 6/18/13.	TBD	TBD	TBD	TBD
HHS	FDA	Good Laboratory Practices for NonClinical Laboratory Studies	No RIN yet	FDA is reviewing regulations for nonclinical laboratory studies to determine how best to update them.	Ongoing	TBD	Streamlined requirements	Public comments	TBD
HHS	FDA	New Animal Drugs--Records and Reports concerning experience with approved drugs and medicated feeds	No RIN yet	FDA is reviewing regulations to determine how to clarify, streamline, and harmonize with international standards.	Ongoing	TBD	Streamlined requirements	Public comments; Harmonization with Veterinary International Conference on Harmonization (VICH)	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.	NPRM published 2/25/13. Comment period ended 5/28/13.	TBD	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 Harmonisation 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	Harmonize with international requirements		Ongoing

HHS	NIH	NIH Construction Grants		NIH is revising the current NIH construction grants regulations at 42 FR 52b, Last updated in November 1999, to reflectupdated standards, laws, policies, and pratices of the NIH construction grants program and update the documents incorporated by reference in the current regulations.	Proposed rule is still in developmen t stage.	16-Dec	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.
HHS	ASPA	Freedom of Information Act Regulations		Assistant Secretary for Public Affairs (ASPA) plans to issue proposed revisions to, and republication of, its regulations implementing the Freedom of Information Act (FOIA). The regulations are being revised in order to incorporate changes made to the FOIA by the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) and the Electronic FOIA Act of 1996 (E-FOIA Act).	New	Proposed: Spring 2016	The regulations are being updated to reflect changes to the organization, to make the FOIA process easier for the public to navigate, to update HHS's fee schedule, and to make provisions clearer.		
HHS	FDA	Hazard Analysis and Risk-Based Preventive Controls	0910-AG36	This rule modernizes current good manufacturing practices for food and requires 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.	Published	11/18/2015 (80 FR 71934)	The rule allows very small businesses to comply with modified requirements, exempts small and very small farms that only conduct specified low-risk activities, and provides 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.	TBD

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		This proposed rule would: 1) provide flexibility in the use of cost-saving and efficient technologies, such as e-mail or electronic document storage, whenever possible; 2) provide relief to states by decreasing the frequency with which states have to request an extension of any approved state law exemption; 3) provide states greater flexibility to close unenforceable cases and redirect resources to more productive efforts and provide states a process to close and transfer cases to tribal child support programs; and 4) relieve states from being inundated with unnecessary information, ultimately saving both time and resources.	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	These proposed regulations, 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	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. Comments due 5/6/2016.	Yes. This initiative explores whether there are regulatory barriers to access and possible improvement.	Public comments	N/A