# HHS July 2015 Retrospective Review

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| 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: December 2015 | 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 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. | 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. |
| ACF | Head Start Performance Standards -- 0970-AC63 | This proposed 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 | NPRM Published June 19, 2015; 80 FR 35429. Final Rule target: July 2016 | The notice of proposed rulemaking would streamline existing regulations to eliminate unnecessary or duplicative requirements. | This NPRM 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 FY 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% 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. |

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| ACF | Removal of Child Abuse Prevention and Treatment Act (CAPTA) Regulations -- 0970-AC65 | This rule would remove the existing regulations for the Child Abuse Prevention and Treatment Act (CAPTA). There have been major and extensive legislative changes to CAPTA since the regulations were issued in 1983 and updated in 1990. Consequently, the existing regulations for CAPTA (45 CFR 1340) are outdated and no longer apply to the CAPTA programs they were designed to implement. | Completed | Published: March 30, 2015; 80 FR 16577 | N/A- This is a final rule to remove outdated regulations. | N/A- This is a final rule to remove outdated regulations | CAPTA is not a permanently authorized program and must be reauthorized every five years. The existing regulations for CAPTA (45 CFR 1340) are outdated and no longer apply to the CAPTA programs they were designed to implement. There are no budget implications associated with removing the CAPTA regulations from the Code of Federal Regulations. |
| ACF | Comprehensive Child Welfare Information System (CCWIS) -- 0970-AC59 | This proposed rule would grant greater flexibility to states and tribes to implement automation that supports their business models; reflect changing technology advances; and enable tribes to implement SACWIS-like systems. | Ongoing | Proposed Rule target: July 2015 | We are proposing 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 will have a public comment period, and we will consider those comments in drafting the final rule. | This proposed regulation would provide greater flexibility to states and tribes, and result in lower costs for the design, development, implementation, operation, and maintenance of state and tribal systems. Increased flexibility would also help foster care agencies place and keep track of children across jurisdictions |
| ACF | Child and Family Services Quality Improvement (CFSQI) for States and the Child and Family Services Plan (CFSP) for States and Indian Tribes -- 0970-ACXX | The proposed rule for the CFSQI process is a revised monitoring protocol of titles IV-B and IV-E of the Social Security Act for State child welfare agencies as required in section 1123A of the Social Security Act (revise 45 CFR 1355.10 - 1355.39). The CFSQI process would allow states to use results from their internal quality assurance processes to meet federal monitoring requirements and would be integrated into current comprehensive child and family services planning under the CFSP. The current regulated monitoring protocol for state child welfare agencies is known as the Child and Family Services Reviews (CFSR). For Indian tribes, the proposed rule will also update and streamline requirements for the title IV-B plans for Indian tribes (revise 45 CFR 1357). | Ongoing | Proposed Rule target: June 2015 | In spring 2013, we completed a four state pilot of a process to assess the continuous quality improvement systems of states. We are waiting to complete the 2014-2015 CFSR review cycle before finalizing the proposed rule. We are making several adjustments to the 2014-2015 CFSR reviews, including changes to data measures, the review process, and integration of the CFSP process. Conducting a cycle of reviews with these changes will inform our rulemaking. | During the second round of CFSRs, we continued to evaluate the process by gathering informal feedback from administrators and others involved in the CFSRs on an ongoing basis. In Spring 2011,we issued a Federal Register request for public comment about improvements the CFSRs. We conducted a series of in-person meetings and tribal roundtables to solicit comments. In 2012, we also conducted tribal consultations on the title IV-B plan requirements. In Spring 2014, we issued a Federal Register notice requesting public comment on a plan to replace the statewide data indicators and the methods for calculating associated national standards on those indicators. We consulted with experts (including a consultant that specializes in child welfare measurement and a panel of child welfare administrators and data measurement experts) and considered public comments in developing this plan. As discussed in the previous column, we are conducting a modified CFSR prior to finalizing the proposed rule and will use our experience with those reviews to inform our rulemaking. In addition, this will be a proposed rule with a public comment period, and we will consider those comments in drafting the final rule. | The proposed rule would streamline the child and family services reporting and monitoring for states and Indian tribes. It will also reduce the amount of duplicate effort and information created; align federal and state quality assurance activities; and provide flexibility for states to craft quality assurance procedures that line up with state child welfare practices. |

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| ACF | Family Violence Prevention and Services Program (FPVSA) -- 0970-AC62 | This proposed rule would rescind the requirement to publish quarterly funding opportunity announcements in the *Federal Register* and revise regulations to bring them into conformity with the reauthorized Family Violence Prevention and Services Act. | Ongoing | Proposed Rule target: July 2015 | 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 | This rule would clarify programmatic operating procedures. |
| ACF | Revision of Refugee Medical Assistance Regulations -- 0970-AC64 | Revise 45 CFR 400.90 - 400.107 regarding refugee medical assistance (RMA) to harmonize with the Affordable Care Act, specifically the eligibility determination methodology | Ongoing | Proposed Rule target: February 2016 | By updating the regulations to use the same income methodology specified in the Affordable Care Act, the process for determining eligibility of refugees for medical insurance is streamlined into one application and one system. The rule also will permit full-time college students to access health insurance and explicitly requiring states to get written approval to get Refugee Medical Assistance funding for medical screening without prior determination of eligibility. | Before drafting the proposed rules, ORR consulted with state agencies that implement ORR regulations, primarily State Refugee Coordinators and State Refugee Health Coordinators. This helped ORR identify regulations that were obsolete and outmoded and impose unnecessary burdens on states. | The update to the regulations will conform to changes to Medicaid resulting from the implementation of the Affordable Care Act. This update will harmonize RMA and Medicaid income methodologies and reduce the burden on States by eliminating the need for a separate income determination process for Medicaid and RMA. Aligning RMA with Medicaid will increase refugee access to healthcare and provide parity between RMA and Medicaid. |

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| ACF | Performance Standards for Runaway and Homeless Youth Grantees -- 0970-AC43 | This proposed rule would implement section VIII of the Reconnecting Youth Act of 2008, requiring HHS to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program. The proposed rule also would harmonize the regulations with existing statute and administrative and managerial provisions already in use and make changes to reduce burden associated with the grant application process. | Ongoing | Final Rule target: December 2015 | 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 extensive training, technical assistance, | The rule will increase transparency and streamline the grant application process using automation. |
| ASFR | Health and Human Services Acquisition Regulations (HHSAR) -- 0991- AB86 | HHS is amending its Federal Acquisition Regulation (FAR) supplement - the HHS Acquisition Regulation (HHSAR) - in its entirety to remove internal procedural matters which are non-regulatory and update to incorporate new policy and correct or clarify existing policy. This proposed rule will revise the HHSAR in its entirety to reflect statutory, FAR, and Government-wide and HHS policy changes since the last revision to the HHSAR in November 2010. | Completed | Final Rule target: December 2015 | This rule will increase efficiency through effective use of guidance, appropriate application of policy and remove unnecessary burden to the public. | Public comments and Analysis | Public comments and Analysis |
| ASFR | Revise, Update and Re-issue HHS Grants Administration Regulations | HHS is amending its Grant Administration Regulations at 45 CFR Part 75, and others to incorporate OMB changes to the new grants administration policy captured by the December 2014 OMB Grant Reform Guidance. OMB is working on finalizing their documents, and HHS will follow shortly thereafter. | Ongoing, but just beginning this phase. | 12/1/2015 | The government-wide changes streamline many of the grants requirements, and provide updated provisions to enhance stewardship of grants funds. | public comment | TBD |
| CDC | Medical Examination of Aliens -- 0920-AA28 | Proposes to update the definition of "communica | Ongoing; NRPM pul | Estimated publication of Final F | Streamlined requirements | Public comment | none |
| CDC | Administrative Functions, Practices, and Procedures -- 0920-AA55 | Proposes to rescind because work described in this regulation is no longer performed by NIOSH. | Ongoing | Proposed Rule target: July 2015 | N/A- This is a final rule to remove outdated regulations. | Public comment | N/A |

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| CMS | Medicare Shared Savings Program; Accountable Care Organizations (CMS-1461-F) -- 0938-AS06 | This rule addresses changes to the Medicare Shared Savings Program and contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program. These changes apply to existing ACOs and approved ACO applicants participating in the program beginning January 1, 2016. | Completed | Proposed Rule published: 12/8/14<br>79 FR 72759; Final Rule published: 6/9/15 80 FR 32691 | Trigger provisions; Streamlined requirements; Phase-ins; Exceptions processes | Public comment; Analyses | As participation in the Shared Savings Program continues to expand, we anticipate a broader focus on care coordination and quality improvement among providers and suppliers within the Medicare program that would lead to both increased efficiency in the provision of care and improved quality of care provided to beneficiaries. As a result of this final rule, the median estimate of the financial impact of the Shared Savings Program for calendar years (CYs) 2016 through 2018 is a net federal savings (after sharing savings) of $780 million, which is about $240 million higher than we estimate if none of the changes in this rule were made for this period. |
| 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 published: 12/27/13<br>78 FR 79082<br><br>Final Rule target: Before the MMA section 902 deadline - December 2016 | Pilot projects; Exceptions processes; Phase-ins | Public comment; Analyses; Industry Feedback | This rule includes important health and safety initiatives to protect Medicare beneficiaries. 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. |
| CMS | Fire Safety (Life Safety Code) Requirements for Certain Health Care Facilities<br>(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. | Ongoing | Proposed Rule published: 4/16/14<br>79 FR 21552<br><br>Final Rule target: Before the MMA section 902 deadline - April 2017 | State flexibilities; 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 $41,437,279 in the first year of implementation and $7,109,914 after the first year of implementation, and annually thereafter for an 11 year period. 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. |

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| 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 published: 10/9/14<br>79 FR 61163<br><br>Final Rule target: Before the MMA section 902 deadline - October 2017 | 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. |
| 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 published: 2/2/12<br>77 FR 5317<br><br>Final Rule target: October 2015 | 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. |
| CMS | Requirements for Long Term Care Facilities & Quality Assurance and Performance Improvement (QAPI) (CMS-3260-P) -- 0938-AR61 | This proposed rule would revise the requirements that Long-Term Care (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 published July 16, 2015 (citation not yet available); Final Rule target: September 2016 | Exceptions processes; Phase-ins | Public comment; Analyses; Industry Feedback | 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. |

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| 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 target: September 2015; Final Rule target date December 2016 | 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. |
| CMS | Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions related to Third Party Liability (CMS-2390-P) -- 0938-AS25 | This proposed rule would modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule would align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implement statutory provisions; strengthen actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; ensure appropriate beneficiary protections and enhance expectations for program integrity. This rule would also implement provisions of CHIPRA and addresses third party liability for trauma codes. | Ongoing | Proposed Rule Published: 6/1/15; 80 FR 31097; Final Rule Target: April 2016 | 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. |
| 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 79 FR 11879; 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% discount rate and $165 million per year at a 7% discount rate. We estimate benefits annualized over 20 years $2.0 billion per year assuming a 3% discount rate and $1.9 billion per year assuming a 7% discount rate. The benefits are based on consumers willingness to pay for the label information |

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| FDA | Post marketing Safety Reporting for Combination Products -- 0910-AF82 | This rule would describe the post market 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 post market safety reporting for combination products while minimizing duplicative reporting requirements. | Ongoing | Proposed Rule published: 10/1/09<br>74 FR 50744<br><br>Final Rule target: TBD | Streamlined requirements | Public comments | This regulation would ensure consistency and appropriateness of post market safety reporting for combination products while minimizing duplicative reporting requirements. |
| 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 decision making and dispensing. | Ongoing | NPRM published 12/18/14. Comment period ended 5/18/15 | 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. |
| 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 | Final Rule target: January 31, 2016 | The regulation contains both trigger and certification / verification provisions. A related guidance document has also been published. | Public comments | N/A |

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| 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. | Ongoing | Proposed Rule published: 1/13/12; Supplement published: 9/29/14<br>79 FR 58523 Court Ordered Final Rule: 8/30/15. | The proposed rule, if finalized, would allow 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. | TBD |
| FDA | Patient Labeling for Drugs (Patient Package Inserts and Medguides) | FDA is considering a proposed rule to require a one-page, single-sided Patient Medication Information document to replace the current forms of medication information distributed to consumers such as medication guides and patient package inserts. | Ongoing | Proposed Rule target: TBD | TBD | TBD | TBD |
| FDA | Revocation of the General Safety Test Requirements for Biological Products | This proposed rule would amend the biologics regulations by removing the general safety test (GST) requirements for biological products found in 21 CFR 610.11, 610.11a and 680.3(b). FDA is taking this action as part of its retrospective review of its regulations to promote improvement and innovation. | Ongoing | Proposed Rule published: 8/22/14<br>79 FR 49727<br><br>Final Rule target: TBD | No Regulatory Flexibility | Public Comment | Reduces certain regulatory burdens |
| 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] | The proposed rule would provide additional flexibility to manufacturers of licensed biological products by amending the general biological products standards relating to dating periods and removing certain regulations for standard preparations and limits of potency. FDA is taking this action to provide additional flexibility to manufacturers of licensed products and to update obsolete or outdated requirements. | Ongoing | Proposed Rule target: TBD | No Regulatory Flexibility | Public Comment | TBD |
| 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 | Proposed Rule published: 6/24/13<br>78 FR 37723<br><br>Final Rule target: TBD | Streamlined requirements | Public comments | We anticipate a burden reduction because we will achieve closer harmonization with international standards. |
| 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. | Ongoing | Proposed Rule published: 4/19/13<br>78 FR 23508<br><br>Final Rule target: TBD | Streamlined requirements | Public comments | Regulation would reduce burden of labeling requirements by harmonizing with international standards. |

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| FDA | Bar Code Rule for Drugs | FDA is conducting a retrospective economic review of this economically significant regulation, originally issued in 2004. The rule requires the inclusion of linear bar codes -- such as are used on millions of packages of consumer goods -- on the label of most prescription drugs and on certain over-the-counter drugs. Each bar code must contain, at a minimum, the drug's National Drug Code number and may include information about lot number and product expiration dates. | Ongoing | Proposed Rule published: 10/26/11<br>76 FR 66235<br><br>Final Rule target: TBD | TBD | TBD | TBD |
| FDA | Good Laboratory Practices for Nonclinical Laboratory Studies | FDA is reviewing regulations for nonclinical laboratory studies to determine how best to update them. | Ongoing | Target: TBD | Streamlined requirements | Public comments | TBD |
| FDA | New Animal Drugs--Records and Reports concerning experience with approved drugs and medicated feeds | FDA is reviewing regulations to determine how to clarify, streamline, and harmonize with international standards. | Ongoing | Target: TBD | Streamlined requirements | Public comments; Harmonization with Veterinary International Conference on Harmonization (VICH) | TBD |
| 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 | Proposed Rule published: 2/25/13<br>78 FR 12664<br><br>Final Rule target: 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. |
| FDA | Veterinary Feed Directives -- 0910-AG95 | This initiative would improve efficiency of the process for veterinarians to issue feed directives. | Completed | Proposed Rule published: 12/12/13<br>78 FR 75515; Final Rule published 6/2/2015 80 FR 31707 | 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. |
| FDA | Post marketing 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<br>Final Rule Published (pre-market safety reporting): 9/29/10 | Harmonize with international requirements | | |

# HHS July 2015 Retrospective Review

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| FDA | Mammography Quality Standards Act; Regulatory Amendments -- 0910-AH04 | FDA is proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes, such as breast density reporting, that have occurred since the regulations were published in 1997. | Ongoing | Target: TBD | Allow for technological advances. | Public comments | FDA anticipates burden reductions from this rule by updating the regulations to reflect current mammography technology. This NPRM could improve accuracy of mammography by decreases the number of false positives and false negative. |
| 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. | Proposed rule is still in development stage. | December-15 | 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 | Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators ("Common Rule") -- 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. It could eliminate unnecessary Institutional Review Board (IRB) reviews and enable IRBs to better focus their resources on review of research protocols that pose greater than minimal risks to subjects. | Ongoing | Proposed Rule target: July 2015 | Modernizes and streamlines requirements. | Public comments; Interagency partners; Analyses | Although the quantified costs of this rule outweigh the quantified benefits, the benefits of enhanced protections to research subjects and clear guidance to the research community further enhances the federal government and research partners' ability to conduct cutting-edge research to improve the health of all Americans. |
| 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<br>76 FR 31425<br><br>Final Rule: TBD (changes 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. |
| OS | Removal of Obsolete Provisions in the Code of Federal Regulations | This direct final rule would remove obsolete provisions from the code of federal regulations. | Ongoing | Direct Final Rule target: TBD | Allow for technological advances. | N/A | N/A |

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| SAMHSA | Oral Fluid Mandatory Guidelines for Federal Workplace Drug Testing Programs (OFMG) -- 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 | Comments close July 14, 2015 | SAMHSA proposes to issue the Federal Workplace Drug Testing Oral Fluid Mandatory Guidelines. The Guidelines will allow Executive Branch agencies and the regulated industry to implement an alternative testing process that is less intrusive and cost/time effective when compared to the current urine based testing program. The use of an electronic chain-of-custody form will also reduce the administrative burden of participating in this program. | SAMHSA's Drug Testing Advisory Board has been engaged in the comment and analyses of the revisions to the Oral Fluid Mandatory Guidelines. The FRN will allow for public comment and assessment. | The Oral Fluid Mandatory Guidelines 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. |