This final rule would modify Head Start performance standards to:

1. provide flexibility in the use of new, cost-saving, and efficient technologies, such as email or electronic document storage, whenever possible, to provide relief to states by decreasing the frequency with which states have to request an extension for any approved state flexibilities; 2. provide states greater flexibility to choose modernization efforts and provide states a process to close and transfer cases to tribal child support programs and 3. establish a “stop work” process to close and transfer cases to tribal child support programs, whenever possible; 2. provide relief to states by decreasing the frequency with which states have to request an extension for any approved state flexibilities; and

This final rule would:

1. provide greater flexibility to states and tribes 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.

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.
The 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.

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.

The 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 laws and administrative and managerial provisions already in use and make changes to reduce burden associated with the grant application process.

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.

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 Convention

ASPR
OEM
NSSE Republican National Convention
The collection is currently approved for 8,975,750 responses and this proposed rule would update the PACE regulations published on December 8, 2006. The rule would improve the quality of health care furnished through federal programs, and the requirements focus on care quality. 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 burdens placed on providers. These changes will allow more flexibility in how care is delivered in the LTC setting which will enhance the health and safety of residents who reside in LTC facilities.

The reporting burden will increase by 489,174 hours, for a total estimated burden of 4,176,940 burden hours. This revision request includes adding 19 forms, removing one form and revisions to 22 previously approved forms. The annual cost of reporting would increase by $20,082,304.

The final rule revises the requirements that hospitals and CAHs are intended to ensure the health and safety of PACE participants. These updates are intended to ensure that the requirements for Medicare- and Medicaid-participating providers and suppliers that participate in the Medicare and Medicaid programs. The requirements focus on care quality. This rule includes important health and safety initiatives to protect Medicare beneficiaries. The requirement focuses on the care quality. These requirements are intended to conform to current standards of practice and remove redundancies and outdated information. These updated regulations will help to ensure that the safety of those receiving care in any setting if an emergency situation occurs.

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CMS

Medicaid Managed Care
Good Laboratory Practices for Nonclinical Laboratory Studies

393-A425

This final rule modernizes the Medicaid managed care regulations to reflect changes in the 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 national standards for patient notification 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 CHHFA and addresses third-party liability for trauma codes.

Complete

Proposed Rule Published: 9/3/16
FR Notice to reopen NPRM Published 10/26/11

Streamlined requirements; Trigger provisions; State flexibility; Reconciliation processes

Public comments; Analyses; State feedback

The total projected cost associated with this final rule is $113.8 million for all states. This rule is burden reducing because we will achieve closer harmonization with other major sources of coverage, including coverage through qualified health plans and medicare advantage plans; implements statutory provisions; strengthens national standards for patient notification 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 CHHFA and addresses third-party liability for trauma codes.

FDA

Hearing Aid Access and Innovation

FDA

Postmarketing Safety Reporting for Combination Products

903-AF82

The 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, license, or clearance and to certain additional specified reporting requirements depending on the types of constituent parts. The regulation would ensure consistency and appropriateness of postmarket safety reporting for combination products while minimizing duplicative reporting requirements.

Ongoing

Proposed Rule Published: 10/00/2016

Final Rule Published: 6/1/15

Streamlined requirements

Public comments

Yes. This initiative explores whether there are regulatory barriers to access and possible improvements.

HHS

Laboratory Studies

HHS

Implementing the Medicare Modernization Act - Amendment to Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets

903-AG26

The 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 Published: 6/18/13.

The regulation contains both trigger and certification/notification provisions. A related guidance document has also been published.

FDA

Patient Labeling for Drugs (Patient Package Inserts and Medication Guides)

No RIN yet

FDA is considering a proposed rule to require a one-page, single-sided Patient Medication Information document to replace the current inserts and medication guides. This final rule modernizes the Medicaid managed care regulations to reflect changes in the 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 national standards for patient notification 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 CHHFA and addresses third-party liability for trauma codes.

Ongoing

Proposed Rule Published: 8/13/13.

Final Rule Published: 5/6/16

Streamlined requirements

Public comments

The total projected cost associated with this final rule is $113.8 million for all states. This rule is burden reducing because we will achieve closer harmonization with other major sources of coverage, including coverage through qualified health plans and medicare advantage plans; implements statutory provisions; strengthens national standards for patient notification 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 CHHFA and addresses third-party liability for trauma codes.
<table>
<thead>
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<th>Agency</th>
<th>Guideline Title</th>
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<tr>
<td>FDA</td>
<td>Human Subject Protections: Acceptance of Clinical Investigations for Medical Devices</td>
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<tr>
<td>FDA</td>
<td>Promoting Safety Reporting Requirements for Human Drugs and Biological Products</td>
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<tr>
<td>FDA</td>
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<tr>
<td>FDA</td>
<td>Regulations on Fixed-Dose Combinations and Co-Packaged and/or Biological Products</td>
<td>New</td>
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<td>Medical Gas Containers and Closures: Current Good Manufacturing Practice Requirements</td>
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<td>TBD</td>
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<td>FDA</td>
<td>FDA Review and Action on Over-the-Counter Time and Extent Applications</td>
<td>New</td>
<td>Ongoing</td>
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<td>New</td>
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</table>

The rule will include a waiver provision that, upon request, would allow any applicable requirement to be waived. Waivers may be granted if an explanation is provided that satisfies the purpose of the requirement, or if adequate justification can be provided.

The rule will amend FDA's regulations to require a new form of patient labeling. Patient Medication Information, for submissions to and review by the FDA for human prescription drug products used, dispensed, or administered as 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 ensure the safe and effective use of prescription drug products.

The rule will require clear and concise written prescription drug product information in a more uniform format to ensure the safety and effective use of prescription drug products. The objective of the proposed rule is to protect the health of patients by providing more drug information in a more uniform format to ensure the safety and effective use of prescription drug products.

Harmonize with international 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.

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 IND, 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.

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FDA


0910-AG14

FDA removed the regulations as required by sec. 609 (c) of the Regulatory Flexibility Act to determine whether to modify or eliminate to reduce the impact on small businesses while still achieving the regulatory objective.

Completed

Final Rule Published: 6/23/13


FDA

Current Good Manufacturing Practice (CGMP) for Combination Products

0910-AP91

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 CGMP regulations and device quality system regulations.

Completed

Proposed Rule Published: 8/2/10

Final Rule Published: 2/22/13


FDA

Electronic Registration and Listing for Medical Devices

0910-AP88

The final rule uses 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: 6/29/12

Final Rule Published: 6/20/12


FDA

General Requirements for Blood, Blood Components, and Blood Establishments; Donor Notification

0910-AG22

FDA completed the periodic review of this regulation as required by sec. 630 (c) of the Regulatory Flexibility Act to determine whether it should modify or eliminate to reduce the impact on small businesses while still achieving the regulatory objective.

Completed

FDA completed the review of this regulation by 3/27/11


FDA

Amendments to Sterility Testing Requirements for the Biological Products

0910-AG16

The final rule removes references to specific test method requirements for sterility testing. This rule will provide manufacturers of biological products greater flexibility and encourage the use of the most appropriate and state-of-the-art methodologies to achieve the safety of biological products.

Completed

Proposed Rule Published: 8/21/11

Final Rule Published: 8/16/12


FDA

Formulating Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)

0910-AP96

FDA is considering revising its regulations to allow mandatory safety reports to be transmitted electronically.

Completed

Final Rule published: 4/9/2014


FDA

Veterinary Feed Directives

0910-AG95

This initiative would improve efficiency of the process for veterinarians to issue feed directives.

Completed

Final Rule published: 6/21/2013

Streamlined requirements

Public comments

FDA estimates the annualized cost savings associated with the more efficient procedures 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.


FDA

Regulatory Flexibility Act

N/A

The final rule would amend the biologics regulations by removing the general safety test (GST) requirements for biological products licensed before July 1, 1972.

Final Rule Published: 7/24/15


FDA

Reclassification of the General Safety Test Requirements for Biological Products

N/A

The final rule would amend the biologics regulations by removing the general safety test (GST) requirements for biological products licensed before July 1, 1972.

Final Rule Published: 6/27/15

No Reg Flex

Public Comment

Reduces certain regulatory burdens


FDA

Hazard Analysis and Risk-Based Preventive Controls

0910-AG16

The 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 foodborne pathogens before they get into the food supply.

Completed

Final Rule published: 4/7/14


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 Pilot Processing Sector Study to determine food processing activities conducted on farms.


FDA

Removal of Review and Reclassification Procedures for Biological Products Licenced Prior to July 1, 1972

N/A

The final rule removes §§ 600.25 and 601.28 which prescribe procedures for FDA's review and classification of biological products licensed before July 1, 1972.

Completed

Final Rule: 2/23/16

No Reg Flex

Public Comment

Removes certain regulatory burdens


FDA

Removal of Certain Regulatory Burdens

N/A

Agency

Public Comment

FDA

Energy Conservation

N/A

Agency

Public Comment

FDA

Definition of The Word "Facility" with Respect to Drugs

N/A

Agency

Public Comment

FDA

Procedures for Biological Products; Electronic Submission of Reports for Human Drugs and Biological Products; Notification of Clinical Investigations

N/A

Agency

Public Comment

FDA

Regulatory Flexibility Act

N/A

Agency

Public Comment

Reduces certain regulatory burdens
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)

Use of Symbols in Device Labeling

FDA is considering whether to allow validated symbols in certain device labeling without the need for accompanying English text.

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 burdens of labeling requirements by harmonizing with international standards.

Amending the general biological product standards relating to dating periods, standard preparations and limits on potency

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.

Food Labeling: Revision of the Nutrition and Supplement Facts Labels

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

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

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

Individual Patient Expanded Access Applications: Form FDA 3926

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 is 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.

Smallpox Vaccine Injury Compensation Program

This direct final rule terminates the obsolete Smallpox Vaccine Injury Compensation Program and removes its implementing regulations.

Completed

6/3/2016

This metric is not applicable to this regulatory action because we are eliminating an obsolete program.
This PRA action involved revising the Application and Annual Report Guidance used by the 50 states and nine jurisdictions eligible for state maternal and child health services block grant. Completed

Notice of Action Date: 3/15/2014
90-day notice published 3/25/14; 79 FR 18374-9

This PRA action streamlines the reporting process through the use of electronic data reporting (EDR). Direct data entered on EDR by states are uploaded directly to the CMS web application. The CMS application automatically completes the annual report. In addition, a new Web-based data entry and Web-report format is being implemented.

The previous inventory for this activity was 7,877 hours. Following this action, the current inventory is 2,384 hours for a reduction of 5,493 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 7,737 hours. Following this action, the current inventory is 5,720 hours for a reduction of 1,017 hours.

The previous inventory for this activity was 14,514 hours. Following this action, the current inventory is 11,364 hours for a reduction of 3,150 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 12,062 hours. Following this action, the current inventory is 9,461 hours for a reduction of 2,601 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 7,743 hours. Following this action, the current inventory is 5,220 hours for a reduction of 2,523 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 5,775 hours. Following this action, the current inventory is 3,510 hours for a reduction of 2,265 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 33,701 hours. Following this action, the current inventory is 20,834 hours for a reduction of 12,867 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 38,206 hours. Following this action, the current inventory is 13,629 hours for a reduction of 24,577 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 52,008 hours. Following this action, the current inventory is 21,681 hours for a reduction of 30,327 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 56,008 hours. Following this action, the current inventory is 13,629 hours for a reduction of 42,379 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 59,008 hours. Following this action, the current inventory is 21,681 hours for a reduction of 37,327 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 63,008 hours. Following this action, the current inventory is 13,629 hours for a reduction of 49,379 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.

The previous inventory for this activity was 56,008 hours. Following this action, the current inventory is 13,629 hours for a reduction of 42,379 hours. This decrease is due to the lowered number of measures that will be reported on by grantees.