July 2015
HHS Retrospective Review Update

The Department of Health and Human Services (HHS) continues to make progress in its retrospective review work, as directed by the President’s Executive Orders (EOs) 13563 (Improving Regulation and Regulatory Review) and 13610 (Identifying and Reducing Regulatory Burdens). This July 2015 update highlights five published rules, two rules that we anticipate publishing later this year and five new rules. In sum, the update reflects HHS’ significant regulatory accomplishments over the past six months¹, but highlights its remaining work to improve quality of care for the American people while reducing costs.

Published: Medicare Shared Savings Program; Accountable Care Organizations

In July 2015, the Center for Medicare & Medicaid Services (CMS) issued a final rule that will increase efficiency and quality of services provided to Federal health care program beneficiaries. The rule advances the President’s efforts to transform our health care system by adding incentives for participation in care models that deliver enhanced quality to consumers and spend our health care dollars more wisely.

Transparent reimbursement to providers and suppliers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP) ensures ongoing participation in CMS’ efforts to coordinate care, improve quality and reduce costs. By soliciting public comment and undertaking economic analyses, CMS streamlined ACO participation requirements and enhanced program trigger, phase-in and exception processes, providing significant clarity to current participating providers and approved applicants beginning participation January 1, 2016.

The savings achieved through finalization of this rule are significant. With issuance of the final rule, the median estimate of the financial impact of MSSP for calendar years (CY) 2016-18 is a net federal savings of $780 million, which is about $240 million higher than MSSP savings accomplished without the changes in the final rule.

Published: Head Start Performance Standards

In June 2015, the Administration for Children and Families (ACF) in HHS issued a proposed rule updating Head Start performance standards, designed to streamline existing regulations to eliminate unnecessary or duplicative requirements. The Improving Head Start for School Readiness Act of 2007 required HHS to update the performance standards to reflect the latest research and program experience, and the standards have not been updated in over 15 years.

¹ We have removed from our chart submission items previously listed as “Completed” in our February 2015 submission. Items labeled “Completed” reflect items completed between February 2015 and this July 2015 submission.
These performance standards are the foundation upon which grantees strive to deliver comprehensive, high quality, individualized services to low income children.

The proposed rule builds upon extensive consultation with researchers, practitioners, recommendations from the Secretary’s Advisory Committee Final Report on Head Start Research and Evaluation and other experts, as well as internal analysis of program data and years of program input on the regulations. In addition, program monitoring has also provided invaluable experience regarding the strengths and weaknesses of the current regulations.

As part of the process of updating the standards, HHS sought to consolidate and simplify the standards to improve clarity and transparency. The proposed rule reduces the total number of requirements by 40 percent and organizes them into four logical sections to make it easier for grantees and other stakeholders to understand what is expected of Head Start programs. ACF and HHS plan to publish the final rule in March 2016.

**Published: Reform of Requirements for Long-Term Care Facilities**

In July 2015, CMS published a proposed rule revising 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. CMS solicited public comment and feedback from industry in connection with this initiative. CMS expects to publish the final rule in September 2016.

**Published: Veterinary Feed Directives**

In June 2015, the U.S. Food and Drug Administration (FDA) in HHS finalized a rule to improve the process for veterinarians to issue feed directives to align with other initiatives related to FDA’s antimicrobial resistance strategy. In particular, the final rule streamlines the veterinary feed directive process for regulated parties, including veterinarians.

The final rule develops a smarter, more cost-effective regulatory program in the context of agency-wide antimicrobial resistance strategy. In particular, FDA estimates reduction in veterinarian labor costs due to this rule to result in a cost savings of about $7.87 million annually; other, additional annualized cost savings associated with the final rule amount to about $13,000 over 10 years.
Published: Medicaid Managed Care

In June 2015, CMS published a proposed rule that 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. The proposed rule strengthens the actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates, ensures appropriate beneficiary protections and enhances CMS expectations for program integrity.

Through public comment, program analyses and feedback from Medicaid state partners, the proposed rule streamlines requirements and enhances state flexibilities within the Medicaid managed care framework.

In the first year alone, the overall economic impact of the proposed rule is estimated to be $112 million. Aside from the economic benefits of implementation, the proposed rule would improve health outcomes, reduce unnecessary services, improve beneficiary experience and improve program access and transparency. CMS plans to issue the final rule in April 2016.

Anticipated: Hazard Analysis and Risk-Based Preventative Controls for Human Food

By Fall 2015, FDA plans to publish a final rule requiring food facilities 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. The final rule is a significant milestone in FDA’s ongoing, public health protection efforts.

The rule would modernize current good manufacturing practices for food; it is intended to prevent – or at a minimum, quickly identify – food-borne pathogens before entrance into the food supply. Very small businesses would be permitted to comply with modified requirements that 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.

Anticipated: Flexibility, Efficiency and Modernization of Child Support Enforcement Programs

By the end of 2015, ACF, through HHS, plans to finalize a rule that would make child support program operations and enforcement procedures more flexible and more efficient by recognizing advancements in technology and the move toward electronic communications and document management. The rule advances HHS’ department-wide regulatory goal of assisting working families secure the building blocks for success at every stage of life.

The rule would improve document management by allowing states to submit and accept information electronically; increase statutory state law exemption approval periods from three to five years; update case closure criteria to increase state flexibility and facilitate effective transfer
between states and tribes; and, discontinue the mandate for states to notify other states involved in enforcing a support order when they submit an interstate case for offset.

**New: Medical Examination of Aliens**

The Centers for Disease Control (CDC), through HHS, issued a proposed rule in June 2015 to update the definition of “communicable disease of public health significance” by removing three minor and uncommon bacterial sexually transmitted infections (*chancroid*, *granuloma inguinale*, and *lymphogranuloma venereum*). Other proposed changes are technical and administrative in nature and include: updating the notification of the health-related grounds of inadmissibility to include proof of vaccinations to align with existing requirements established by the Immigration and Nationality Act; and clarifying and revising the evaluation requirements for tuberculosis to reflect current terminology and practice. CDC plans to issue a final rule in December 2015.

**New: Post-market Safety Reporting Requirements for Human Drugs and Biological Products**

FDA is considering whether to revise certain definitions and reporting requirements based on recommendations of the International Conference on Harmonization of Technical Requirements in order to enhance the quality of post-market safety reports.

**New: NIH Construction Grants**

The National Institutes of Health (NIH), through HHS, is developing a proposed rule that would revise the current NIH construction grants regulations (last updated in November 1999) to reflect updated standards and practices. Updating the regulations to reflect these changes will increase transparency of current procedures and practices and ensure that the most current information is readily available to potential grantees.

**New: Mandatory Guidelines for Federal Workplace Drug Testing Programs; Request for Information Regarding Specific Issues Related to the Use of the Hair Specimen for Drug Testing**

The Substance Abuse and Mental Health Services Administration (SAMHSA) through HHS, is requesting public comment on hair testing to establish scientific and technical guidelines for the inclusion of hair testing in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines). The inclusion of hair within the Guidelines would allow Executive Branch agencies and regulated industry to implement an alternative testing process to the current, urine-based testing program (and proposed addition of oral fluid specimens). The use of an electronic chain-of-custody form will also reduce the administrative burden of program participation. Public comment on the proposal closes July 29, 2015.
New: Revise, Update And Re-issue HHS Grants Administration Regulations

HHS’ Office of the Assistant Secretary for Financial Resources (ASFR) is amending its Grant Administration Regulations at 45 CFR Part 75, and others, to incorporate the new grants administration policy captured by the December 2014 OMB Grant Reform Guidance. These updates will streamline many of the grants requirements, and enhance stewardship of grants funds.
The proposed rule would rescind the requirement to publish quarterly funding IV-B plans for Indian tribes (revise 45 CFR 1357).

We are proposing a 24 month transition period of uninterrupted resources. We also identified obsolete and outmoded requirements and technical fixes that are needed. This NPRM builds upon extensive consultation with researchers, practitioners, recommendations from the Secretary's Advisory

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This proposed rule would implement section 902 of the Affordable Care Act, specifically the eligibility determination methodology for both public and nonprofit programs, and revise 45 CFR 400.90 - 400.107 regarding refugee medical assistance (RMA) to harmonize assistance funding for medical screening without prior written approval. The proposed rule also would harmonize the regulations with existing statute and require states to get written approval to get Refugee Medical Assistance funding for medical screening without prior written approval. This will increase transparency and ensure the grant application process proceeds, if applicable.

This rule includes important health and safety initiatives to protect Medicare beneficiaries. It also includes a number of exceptions from regulations, specifically in the context of the Affordable Care Act. The proposed rule provides that CMS-established emergency preparedness requirements are applicable to all participating providers and suppliers, including Medicare and Medicaid-participating providers and suppliers. The proposed rule also includes a number of exceptions from regulations, specifically in the context of the Affordable Care Act.
This proposed rule aims to address the safety and quality of drug products for home healthcare, specifically focusing on home health agencies (HHAs) and home health care providers (HHCPs).

The proposed rule would require HHAs to establish and maintain comprehensive quality assurance programs that ensure the proper administration of drug products to patients. This includes ensuring that all home health care providers use drug products in accordance with the drug's labeling instructions. The rule would also require HHAs to have in place procedures to prevent the administration of drug products to patients in a manner that may cause harm or injury.

In addition, the proposed rule would mandate that HHAs maintain accurate and complete records related to the administration of drug products, including documentation of the drug product administered, the dose administered, and any adverse reactions reported by patients.

Overall, this proposed rule is intended to improve the quality and safety of drug products administered to patients in the home health setting, thereby reducing the risk of adverse events and improving patient outcomes.
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<tr>
<th>Initiative</th>
<th>Status of Initiative</th>
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<th>n/a</th>
<th>Target Completion Date (if known)</th>
<th>From the initiative include regulatory flexibility such as pilot projects, safe harbor exemptions, center procedures, trigger provisions, streamlined requirements, state flexibilities, or other similar strategies?</th>
<th>What methods will you engage to identity improvements? (public comment, events, third party assessments, etc.)</th>
<th>Phase</th>
<th>Potential cost savings in costs/fee burden and anticipated in dollar amounts (if known)</th>
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<td>Bar Code Rule for Drugs</td>
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<td>Ongoing</td>
<td>n/a</td>
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<td>Public Comment</td>
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<td>Federal Workplace Drug Testing</td>
<td>HHS</td>
<td>Proposed</td>
<td>Yes</td>
<td>Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines)</td>
<td>SAMHSA is proposing to expand its regulations governing workplace drug testing. These amendments are necessary to ensure that the regulations remain effective in the face of new scientific and technological advances.</td>
<td>Federal Workplace Drug Testing</td>
<td>May 2015</td>
<td>The final rule would update the current provisions of the Federal Workplace Drug Testing Rules to improve availability and to better balance the burden with the benefits to stakeholders.</td>
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<td>Oral Fluid Mandatory Guidelines</td>
<td>HHS</td>
<td>Proposed</td>
<td>Yes</td>
<td>Oral Fluid Mandatory Guidelines for Federal Workplace Drug Testing Programs</td>
<td>SAMHSA proposes to issue the Federal Workplace Drug Testing Oral Fluid Mandatory Guidelines. The final rule would update the current provisions of the Federal Workplace Drug Testing Rules to improve availability and to better balance the burden with the benefits to stakeholders.</td>
<td>Federal Workplace Drug Testing</td>
<td>May 2015</td>
<td>The final rule would update the current provisions of the Federal Workplace Drug Testing Rules to improve availability and to better balance the burden with the benefits to stakeholders.</td>
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<td>HIPAA Privacy Rule Accounting</td>
<td>HHS</td>
<td>Proposed</td>
<td>Yes</td>
<td>HIPAA Privacy Rule Accounting of Disclosures Required under the HIPAA Privacy Rule</td>
<td>NIH is revising the current HIPAA Privacy Rule Accounting of Disclosures Required under the HIPAA Privacy Rule.</td>
<td>HIPAA Privacy Rule Accounting</td>
<td>May 2015</td>
<td>The proposed rule would revise the current HIPAA Privacy Rule Accounting of Disclosures Required under the HIPAA Privacy Rule.</td>
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<td>Mammography Quality Standards Act Allow for technological advances.</td>
<td>HHS</td>
<td>Proposed</td>
<td>Yes</td>
<td>Allow for technological advances.</td>
<td>FDA is proposing to amend its regulations governing mammography. The amendments are necessary to ensure that the regulations remain effective in the face of new scientific and technological advances.</td>
<td>Mammography Quality Standards Act Allow for technological advances.</td>
<td>May 2015</td>
<td>The proposed rule would revise the current mammography technology regulations.</td>
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For the Initiative/Rule or ICR, identify all that apply: \[\text{proposed rule, final rule, OMB number, RIN, Federal Register number, Federal Register page number}\]