January 2014
HHS Retrospective Review Update

The Department of Health and Human Services (HHS) continues making progress on its retrospective review activities, as directed by the President in Executive Order 13563 *(Improving Regulation and Regulatory Review)* and Executive Order 13610 *(Identifying and Reducing Regulatory Burdens).* To date, HHS has published 32 proposed rules and 32 final rules related to retrospective review, in addition to completing substantive review of initiatives where agencies ultimately decided not to make regulatory changes. This January 2014 update highlights a few of our accomplishments since the Department's last update in July.

Modernizing Health and Safety Standards for the 21st Century

A number of recently published rules share the dual goals of enhancing safety for the public while modernizing standards for providers and suppliers. This fall, the Centers for Medicare and Medicaid Services (CMS) finalized a rule that establishes patient care and operational standards for community mental health centers (CMHCs).[1] These new Conditions of Participation will help raise standards for the 100 CMHCs that participate in Medicare, ensure high quality and safe care for the more than 13,000 Medicare beneficiaries they serve, and strengthen the Medicare program's ability to oversee the quality, effectiveness, and safety of care provided in these settings. Another CMS rule proposes to establish national emergency preparedness requirements for Medicare and Medicaid providers and suppliers, building on lessons learned by natural and man-made disasters in recent years.[2] If finalized, this rule would require Medicare and Medicaid providers to meet four standards to demonstrate preparedness for imminent emergencies, including completing a risk assessment; developing an emergency plan based on the specific capacities and capabilities of the provider setting; establishing a communications plan for coordinating patient care; and establishing training and testing programs for each participating health system.

Finally, the Food and Drug Administration has issued a proposed rule to update veterinary feed directive (VFD) that published on December 12, 2013 (78 FR 75515).[3] The provisions included in this proposed rule are based on stakeholder input received in response to multiple opportunities for public comment, including publication of the draft text of the proposed amendments (77 FR 22247, April 13, 2012). This rule would, among other things, update the VFD program to increase flexibility for licensed veterinarians, reorganize the structure of the VFD program to make it more user-friendly, and lower record-keeping burden for the industry.

[1] 0938-AP51.
[2] 0938-AO91.
[3] 0910-AG95.

Integrating Public Feedback into the Regulatory Process

In the fall of 2013, HHS published its second request for public comment in the *Federal Register* to solicit potential ideas for retrospective review.[4] This request garnered comments from a variety of stakeholder groups, including health care providers, insurance issuers, and trade associations. Most commenters offered suggestions on multiple topics, including requesting clarification on Affordable Care Act private market rules, Medicare payment policies, HIPAA enforcement, and the drug approval process for combination products. Relevant HHS agencies received feedback for issues and programs they administer, and those agencies are currently reviewing the public comments for consideration in ongoing regulatory activities.

The Department is using our integration of public comments from HHS's 2011 Request for Information on our 2011 Retrospective Review Plan to help guide our review of the most recent request for comment because we successfully incorporated the 2011 feedback into our ongoing regulatory review activities. For example, in 2012 CMS finalized the Hospital Conditions of Participation Reform rule,[5] which updated a number of policies regarding how hospitals treat Medicare and Medicaid patients. This rule, along with a final rule modernizing policies for health care provider settings other than hospitals,[6] responds to a number of comments that suggested that CMS should update or rescind outdated paperwork and procedural requirements that are no longer needed due to technological advances or changing best practices. These two rules incorporate feedback from hospitals, other health care providers, accreditation organizations, patient advocates, professional organizations, members of Congress, and a host of others who are working to improve patient care, and the rules are expected to save more than $5 billion dollars over five years.

Feedback received during the 2011 Request for Information as well as ongoing public participation efforts also informed regulations on a variety of other topics, including administrative simplification[7], HIPAA[8], Medicare payment policies[9], electronic health record technology[10], and FDA reporting requirements.[11] In the coming year, HHS agencies anticipate publishing other key rules that would respond to additional feedback, including a proposal for

[4] http://www.gpo.gov/fdsys/pkg/FR-2013-09-13/pdf/2013-22376.pdf
[5] 0938-AQ89.
[6] 0938-AQ96.
[7] Administrative Simplification: Standard Unique Identifier for Health Plans & ICD-10 Delay (0938-AQ13); Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfers (EFT) and Remittance Advice (RA) Transactions (0938-AR01).
[8] Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules (0945-AA03).
[9] *See, e.g.,* CY 2013 OPPS Proposed & Final Rules (0938-AR10).
[10] Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (EHR Stage 2) (0938-AQ84); Health Information Technology: New and Revised Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology ("2014 Edition") (0991-AB82).
[11] *See, e.g.,* Electronic Registration and Listing for Medical Devices (0910-AF88).

updating standards and protections for human subjects research[12] and a final rule that would facilitate patients' access to clinical laboratory reports.[13]

Finally, our Requests for Information yielded suggestions about how the Department can think strategically about our resources for developing regulations, more proactively seek public participation, and bolster our regulatory analysis. In response, two HHS working groups – the Public Participation Task Force and the HHS Analytics Workgroup – have worked diligently to address this feedback. These groups include agencies across the Department and both continue to identify and implement new, innovative regulatory approaches. For example, the Public Participation Task Force has developed new ways to involve the public in regulatory and retrospective review activities by developing new tools for educating the public about their role in regulatory review and making information about rules open for comment more easily accessible, including refreshing HHS's regulations page. The HHS Analytics Workgroup works with HHS components to develop resources for bolstering economic analyses for HHS regulations, as well as providing trainings across the Department on the role of regulatory analysis in the rulemaking process.

[12] 0937-AA02.
[13] 0937-AA02.