HHS Retrospective Regulatory Review Update

May 2012

The Department of Health and Human Services (HHS) has made significant progress in its retrospective review activities since the President's January 2011 Executive Order on Improving Regulation and Regulatory Review. To date, HHS has published 15 proposed rules and 13 final rules related to retrospective review, and the Department has also completed a number of other actions including the Food and Drug Administration's (FDA) regulatory review analysis on blood donor notification (0910-AG62), a Center for Medicare and Medicaid Services (CMS) report to Congress identifying alignment opportunities for beneficiaries eligible for both Medicare and Medicaid, and an FDA draft notice to improve the efficiency of veterinarians issuing veterinary feed directives.

These rules and initiatives will save billions of dollars while reducing unnecessary, obsolete, and/or burdensome regulations. The Department expects that two of the final rules published in May 2012 – addressing the Medicare conditions of participation for hospitals and critical access hospitals (CAH) (0938-AQ89) and regulatory requirements for a broader range of health care providers and suppliers regulated under Medicare and Medicaid (0938-AQ96) – will alone save approximately $1.1 billion across the health care system in just the first year while reducing unnecessary burdens on hospitals and other health care providers.

The first final rule, a major revision to the Medicare conditions of participation (0938-AQ89*)*, is likely to result in an estimated savings of approximately $940 million each year – nearly $5 billion over the first five years – and its savings will likely grow over time as hospitals and CAHs increasingly use their new flexibility. The Medicare hospital and CAH conditions of participation are federal health and safety requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs in order to ensure high quality care for all patients. The rule encourages hospitals and CAHs to seek out, implement, and develop their own innovative practices to improve the standard of care. This final rule thus lowers the overall cost of hospital compliance efforts, giving hospitals and CAHs the ability to focus on aspects of care that have the greatest impact on patients and their caregivers.

In addition to tremendous savings for the health care industry, this rule exemplifies the Department's commitment to engage with stakeholders and be responsive to their concerns and suggestions. CMS carefully considered the over 1,700 public comments on the October 24, 2011 proposed rule during the 60-day public comment period. The final rule takes the best ideas from providers, patients, accreditation organizations, and other experts in the field to eliminate obsolete and burdensome regulations and encourage patient-centered care.

The second final rule, which reduces regulatory requirements for a broader range of health care providers and suppliers regulated under Medicare and Medicaid (0938-AQ96), will produce savings of $200 million in the first year and will save approximately $100 million per year in the following years. This rule eliminates duplicative, overlapping, outdated, and conflicting regulatory requirements for a host of health care providers and suppliers, including ambulatory surgical centers, end-stage renal disease facilities, durable medical equipment suppliers, and others regulated under Medicare and Medicaid. This rule, which includes more than two dozen regulatory changes, will help reduce unnecessary burdens on health care providers, allowing them to dedicate more resources to improving patient care.

Some of the key reforms of these final rules include:

- Allow hospitals to determine the total number of directors needed for the various outpatient services that a hospital offers, *saving $300 million per year*.
- Allow hospitals to structure their medical staff and privileging process regarding the duties and privileges of Advanced Practice Registered Nurses, Physician Assistants, and other licensed non-physician practitioners in accordance with their state laws and scope-of-practice acts, *saving hospitals roughly $330 million per year*.
- Permit the integration of hospital nursing service care plans into the hospital's overall interdisciplinary care plan, thereby eliminating the requirement that nursing staff develop a specific nursing care plan and encouraging patient-centered, coordinated care, *saving roughly $110 million per year.*
- Remove burdensome and outdated rules regarding prescribing and authenticating medical orders, and encourage the use of evidence-based pre-printed and electronic standing orders and protocols that ensure the consistency and quality of care provided to all patients by allowing nurses the ability to implement orders that are timely and clear, *saving hospitals an estimated $170 million per year*.
- Remove certain Medicare reenrollment bars and revocations for incidental failures to comply with Medicare requirements, such as failure of a provider or supplier to respond timely to a re-validation request or failure to submit a Medicare claim for a consecutive 12-month period, *saving an estimated $100 million per year.*
- After assessing that the Life Safety Code requirements are more appropriate for inpatient settings like hospitals or nursing homes, require only higher risk end-stage renal disease (ESRD) facilities to comply with the full National Fire Protection Agency Life Safety Code requirements, *saving ESRD providers an estimated $110 million over the next five years.*

In another major undertaking, retrospective review will result in significant modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (0945-AA03). The

reforms in this final rule under development include changes to the requirements for distribution of Notices of Privacy Practices by health plans. The reforms also include changes that are expected to reduce burdens and delays in obtaining immunization records for children beginning school and streamline the process of obtaining HIPAA authorizations for research.

In addition to these regulatory updates, the Department continues to advance its efforts to improve its regulatory analysis. Established in HHS's August 2011 Final Retrospective Review Plan, the Department's Analytics Team is working to improve regulatory analysis across agencies by making the quality of analysis more consistent and by better integrating this analysis into regulatory decision-making. This team plays an integral role in assisting agencies with developing sophisticated regulatory analyses.

Finally, the Department's Public Participation Task Force, which was established in the Department's August 2011 Final Retrospective Review Plan, continues to explore innovative strategies to encourage the public to actively participate in the regulatory process. The Task Force, which includes representatives from across the Department, is developing and implementing recommendations to expand and improve public participation in regulatory rulemaking and review, including participation by individuals with disabilities and individuals with Limited English Proficiency.

This year, the Task Force surveyed all HHS agencies to compile an inventory of current practices. For example, several HHS agencies provide information online about regulatory activities. The Office of the National Coordinator for Health IT (ONC) has a comprehensive website with links to press materials, frequently asked questions, rule summaries, and in some instances, direct links to questions posed to the public.[1] FDA also offers a one-stop-shop for regulations and guidance on the Web[2] and has a Transparency Initiative that includes some references to regulations.[3] In addition, agencies have used public meetings and webinars to announce, explain, and encourage written comment on new proposed rules or changes in agency policy. Many agencies work cooperatively with the HHS Office of Intergovernmental and External Affairs (IEA) to amplify their outreach, particularly for subjects that have significant stakeholder interest.

In the coming months, the Task Force will implement new strategies to solicit feedback from the public for retrospective review. In addition to traditional strategies such as posting public notices in the *Federal Register*, the Department is revamping its website (HHS.gov) to include a user-friendly regulations page. This webpage will provide a central location for the public to learn more about HHS regulations and retrospective review and will provide resources to help

[1] *See* http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__regulations_and_guidance/1496.
[2] *See* http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm.
[3] *See* http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__regulations_and_guidance/1496.

the public engage in the regulatory process. In the coming months, the Department plans to post educational materials on this webpage about the rulemaking and retrospective review processes and is exploring ways to use social media and other technological advances to facilitate public participation.

Using public feedback, HHS will continue to take inventory of its existing regulations to identify potentially outdated regulations, which can be integrated into the Department's retrospective review plan on an ongoing basis. HHS remains committed to the President's vision of incorporating and integrating the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework.