HHS Retrospective Review Update

September 2012

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 17 proposed rules and 19 final rules related to retrospective review, in addition to completing substantive review of initiatives where agencies determined that no modifications were needed. This final update for 2012 highlights a few of our accomplishments since the Department's May 2012 update, including efforts to reduce paperwork and other regulatory burdens by approximately 2.5 million hours across a number of programs.

Improving Regulations through Retrospective Review

In the 2014 Edition Standards and Certification Final Rule, the Office of the National Coordinator for Health IT (ONC) updated the standards, implementation specifications, and certification criteria for certified EHR technology that providers can use to participate in the Medicare and Medicaid EHR Incentive Programs. In keeping with the principles expressed in E.O. 13563, and in consideration of comments received on the proposed rule, ONC adopted a revised Certified EHR Technology definition that gives providers participating in the Medicare and Medicaid EHR Incentive Programs more flexibility. This policy change reduced the regulatory burden related to the quantity of EHR technology an individual provider will likely need to adopt to achieve meaningful use. It also reduced the corresponding burden on EHR technology developers because they no longer need to invest development time to get capabilities certified that their customers may never need to demonstrate meaningful use. The final rule also reduces burden on EHR technology developers by eliminating requirements and processes under the ONC Health IT Certification Program that made the certification and upgrading of EHR technology inefficient and costly.

As a result of retrospective review, the Department is developing a final rule that would make significant modifications to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, Enforcement, and Breach Notification Rules.[1] The rule would streamline the process for scientists to obtain HIPAA authorizations for their research, which also harmonizes the privacy rule procedures with informed consent requirements in the Common Rule; changes requirements to facilitate the release of children's immunization records to schools, where required by state law; and change the requirements on health plans for distributing Notices of Privacy Practices. These reforms are aimed at increasing flexibility and reducing paperwork

[2] 0910-AF88

burden for researchers and health plans, reducing the burden on parents and health care providers, and helping avoid delays in children beginning school, resulting in a one-time reduction of 1,800,000 burden hours.

The Food and Drug Administration (FDA) issued a final rule requiring medical device manufacturers to list and register their products electronically, [2] while continuing to offer an avenue of registration and listing for those companies without web access. This reform will help FDA maintain updated, accurate listings of medical devices on the market, while also providing manufacturers with greater flexibility and encouraging the use of the latest technology for information collection. FDA anticipates this rule will save manufacturers time and money by allowing medical device makers to use the latest technology in submitting information.

Building on the reforms finalized in the May 2012 Hospital Conditions of Participation and Burden Reduction final rules, the Department is also planning to propose a second set of reforms to the Medicare health and safety regulations that govern hospitals and other providers participating in the Medicare program.[3] This second round of reforms would eliminate or streamline a dozen rules that are now unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers. For example, proposed revisions would grant hospitals more flexibility in organizing their governing bodies; provide more flexibility to critical access hospitals and rural health care facilities to structure their staffing and supervision plans according to the unique needs of rural communities; and expand hospital privileges for certain services to a wider range of qualified practitioners.

Reducing Reporting and Paperwork Burden

The Department is reducing reporting and paperwork burden in a variety of ways, ranging from simplifying or even eliminating current information collection requirements to automating information collection. HHS identified 12 paperwork burden reduction initiatives responsive to Executive Order 13610 *(Reducing Reporting and Paperwork Burdens)*, resulting in over 3 million hours of burden reduction. The ongoing impact of these initiatives will be over 1 million less hours of burden annually.

Information collections deemed no longer needed are being eliminated in two of the burden reduction initiatives. The Administration for Children and Families (ACF) is eliminating collection of information from states for verifying income and employment information, since the program providing the verification was found to not be cost effective. The Centers for Disease Control (CDC) will eliminate forms no longer needed from a larger set of forms

[2] 0910-AF88
[3] 0938-AR49.

collected electronically through the National Health Safety Network. The eliminated forms collected information on individual health care workers that is redundant with aggregate information also collected from the health care organizations that employ those workers.

Over half the initiatives the Department is pursuing to reduce reporting and paperwork burden simplify the forms used to collect information or reduce the amount of information that must be provided. The CDC initiative for the National Health Safety Network also changes some of the forms to make them easier to complete. Several initiatives at CMS simplify information collection by reducing the number of measures Medicare Advantage plans are required to report while maintaining core priorities, reducing the number of items that must be validated in Medicare Part C and Part D submissions, reducing the number of attestations required in Medicare Part D applications, eliminating questions in beneficiary perception surveys, and Medicare Part D formulary reductions.

Electronic communication is employed to reduce reporting and paperwork burden in several of the HHS initiatives, as well. ACF's National Directory of New Hires and Income Withholding for Support programs have both supported electronic communication for information collection in addition to paper-based information collection. Efforts to expand the use of electronic communication in those programs will result in reduced burden, making the time required to prepare and submit the information electronically significantly shorter than completing paper forms. For example, CMS will consolidate data entry to fewer screens in the online application that Part D plan sponsors use to submit formularies for approval; while revisions to the Part D application process are expected to reduce the time needed to complete the applications. An FDA initiative will require online submission of adverse event reports for medical devices, dramatically reducing the time required to report such events. The HIPAA Privacy Rule, discussed in the previous section, would also allow electronic distribution of a revised Notice of Privacy Practices for Protected Health Information, significantly reducing burden for third-party disclosures.

Encouraging Public Participation in the Regulatory Process

Finally, the HHS Public Participation Task Force continues its work identifying and implementing new approaches for involving the public in regulatory and retrospective review activities. As one of our recent accomplishments, this summer the Department launched www.HHS.gov/regulations, a one-stop shop for the public to find information about HHS regulations that are currently posted on www.Regulations.gov and other helpful information about rulemaking and retrospective review. Additionally, the Department seeks direct input from the public via email at RetrospectiveReview@hhs.gov. The Task Force members from across the Department are working together on Department-wide and agency-specific projects that will meet our collective goals of educating the public on the comment process; simplifying

the comment process; increasing access to individuals with disabilities or limited English proficiency; and increasing the public's role in the retrospective review process.