

HHS Retrospective Review Update

January 2013

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 19 proposed rules and 22 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 2013 update highlights a few of our accomplishments since the Department's September 2012 update.

Improving Regulations through Retrospective Review

As a result of retrospective review, the Department has issued a final rule that significantly modifies the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, Enforcement, and Breach Notification Rules.¹ The rule streamlines 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 changes the requirements on health plans for distributing Notices of Privacy Practices. These reforms are aimed at increasing flexibility and reducing paperwork 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.

Building on the reforms finalized in the May 2012 Hospital Conditions of Participation and Burden Reduction final rules, the Department issued a proposed rule that outlines a second set of reforms to the Medicare health and safety regulations that govern hospitals and other providers participating in the Medicare program.² 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.

¹ 0945-AA00.

² 0938-AR49.

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. In the fall 2012 update, HHS identified a number of 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.

In several burden reduction initiatives, agencies opted to eliminate outdated or unnecessary information collection requirements. 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 not cost effective. The Centers for Disease Control (CDC) will eliminate forms no longer needed from a larger set of forms collected electronically through the National Health Safety Network. The eliminated forms collected information on individual health care workers that was redundant with aggregate information also collected from the health care organizations that employ those workers.

Over half of 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 has also helped to reduce reporting and paperwork burden in several of the HHS initiatives. 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, allows plans to post the revised NPP on their web sites and

then send it in the next annual mailing to enrollees, rather than within 60 days of the material change, 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.