

HHS Retrospective Review Update

July 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 27 proposed rules and 28 final rules related to retrospective review, in addition to completing substantive review of initiatives where agencies ultimately decided not to make regulatory changes. This July 2013 update highlights a few of our accomplishments since the Department's last update in January, as well as some new initiatives under consideration.

Improving Regulations through Retrospective Review

In the past six months, HHS agencies have published several rules that serve to bolster public health. For example, the Centers for Disease Control's Requirements for Foreign Importation of Nonhuman Primates final rule¹ extends importation requirements that previously applied to three species of monkeys to all nonhuman primates, while simultaneously simplifying other requirements for importers to register these animals. These updated requirements, developed based on public health surveillance efforts, will provide enhanced safety measures to protect nonhuman primates as well as the people who work with these animals from communicable diseases.

The Health Resources and Services Administration finalized a rule that would merge two health care practitioner databases – the Healthcare Integrity and Protection Data Bank (HIPDB) and the National Practitioner Data Bank (NPDB), which serves as a clearinghouse to facilitate comprehensive review of the professional credentials of health care practitioners, providers, suppliers, and facilities.² The updated NPDB reduces costs and administrative burden by eliminating the need for hospitals and other health care institutions from reporting similar information in two separate databases, and likewise it eases the administrative burden for interested entities that would have previously queried both databases.

As well, the Food and Drug Administration published a number of proposed rules that aim to modernize certain reporting and labeling standards for drugs and biologics,³ laser products,⁴ and devices.⁵ These proposed rules would harmonize U.S. regulations with international

¹ 0920-AA23

² 0906-AA87

³ 0910-AA97

⁴ 0910-AF87

⁵ 0910-AG74

standards for these products as well as take advantage of advances in technology, and they are expected to reduce administrative burden for manufacturers or suppliers with international components.

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. The Department recently posted a toolkit explaining how to participate in the regulatory process on our regulations webpage, <http://www.HHS.gov/regulations>. Individual agencies are also implementing a variety of strategies to 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.

In addition, we updated the Department's Retrospective Review webpage – <http://www.HHS.gov/RetrospectiveReview> – to include a webform that solicits suggestions of regulations or policies to review. This asks the public to provide the:

- Relevant Statute and/or *Federal Register* citation;
- Description of Problem (“For example, why do you think the regulation is outmoded, ineffective, insufficient, and/or excessively burdensome?”);
- Available data on cost or economic impact (“Please provide quantified benefits and costs of the regulation if possible. Otherwise, provide a qualitative description of the cost or economic impact of the regulation.”); and
- Proposed Solution (“Please include your suggestion to address the problem. For example, what would be the best way to modify, streamline, expand, or repeal the regulation? Who would the proposed solution benefit?”)

As we begin the next phase of the retrospective review initiative, we have asked HHS agencies to think creatively about additional regulations that might be ripe for retrospective review; the July update reflects a few of these new ideas. The Department is also planning to publish a Request for Information in the *Federal Register* to solicit new ideas for retrospective review.