

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulatory agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the Department semiannually to issue an inventory of rulemaking actions under development to provide the public a summary of forthcoming regulatory actions. This information will help the public more effectively participate in the Department's regulatory activity, and the Department welcomes comments on any aspect of this agenda.

FOR FURTHER INFORMATION CONTACT: Jennifer M. Cannistra, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal Government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. This agenda presents the rulemaking activities that the Department expects to undertake in the foreseeable future to advance this mission. The agenda furthers several Departmental goals, including strengthening health care; advancing scientific knowledge and innovation; advancing the health, safety, and well-being of the American people; increasing efficiency, transparency, and accountability of HHS programs; and strengthening the Nation's health and human services infrastructure and workforce.

HHS has an agency-wide effort to support the agenda's purpose of encouraging more effective public participation in the regulatory process. The Department's Public Participation Task Force, which was created as part of the HHS Retrospective Review plan in response to Executive Order 13563 (*Improving Regulation and Regulatory Review*), regularly meets to identify ways to make the rulemaking process more accessible to the general public. For example, to encourage public participation, HHS regularly updates its main regulatory webpage (<http://www.HHS.gov/regulations/>), which includes links to HHS rules currently open for public comment and provides a "regulations toolkit" with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, including through a comment form on the HHS retrospective review webpage (<http://www.HHS.gov/RetrospectiveReview>). In addition, a cross-agency team at HHS is currently considering how to increase efficiency in rulemaking by organizing public comment on proposed rules.

The rulemaking abstracts included in this paper issue of the **Federal Register** only cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant

economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at <http://www.RegInfo.gov>.

Dated: August 21, 2013.

NAME: Jennifer M. Cannistra,

Executive Secretary to the Department.