

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 (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Karuna Seshasai, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690-5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services. 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 regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. The purpose of the Agenda is to encourage more effective public participation in the regulatory process. The regulatory actions forecasted in this Agenda reflect the priorities of the Biden-Harris Administration and HHS Secretary Xavier Becerra. Accordingly, this Agenda contains rulemakings aimed at advancing equity and ensuring nondiscrimination in health; ending the COVID-19 public health emergency; enhancing access to quality, affordable health care; addressing child welfare and maternal health; safeguarding the quality of medical products; protecting the public health by reducing tobacco use; revising prior actions that are inconsistent with the policy of this Administration; and supporting other priority areas.

Please note that because the Department's most recent Statement of Regulatory Priorities was published in Fall 2020 and under a previous Administration, it no longer reflects the views of the Department or this Administration. The Department will have the opportunity to issue a new Statement of Regulatory Priorities reflecting its policy direction alongside the Fall 2021 Agenda. At present, more information about the policy priorities of the Biden-Harris Administration is available through Executive Orders, Presidential Memoranda, other Presidential Actions, regulatory actions, and sub-regulatory guidance issued by the Biden-Harris Administration since January 20, 2021.

The rulemaking abstracts included in this paper issue of the **Federal Register** 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>.

NAME: Karuna Seshasai,

Executive Secretary to the Department.