

Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

2 CFR Chapters III and XXX

5 CFR Chapter XLV

21 CFR Chapter I

25 CFR Chapter V

42 CFR Chapters I, IV and V

45 CFR Subtitle A and Chapters II, III, IV, X, XIII

48 CFR Chapter 3

HHS Plan for Retrospective Review Under Executive Order 13563

AGENCY: Department of Health and Human Services.

ACTION: Notice; request for information.

SUMMARY: In accordance with Executive Order 13563, “Improving Regulation and Regulatory Review,” the Department of Health and Human Services (HHS) seeks comment from interested parties to assist in the development of its preliminary plan to review existing regulations. The purpose of the plan is to establish a process by which HHS can determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make HHS’s regulatory program more effective or less burdensome in achieving its regulatory objectives.

DATES: Submit electronic or written comments on this notice by May 12, 2011.

Instructions: All submissions received must include the Agency name HHS—ES–2011–001 for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

ADDRESSES: You may submit comments, identified by HHS—ES–2011–001 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. HHS will post all comments received before the close of the comment period as soon as possible after they have been received:

Written Submissions

Submit written submissions in the following ways:

FAX: (202) 690–7203.

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): 200 Independence Avenue, SW., Room 639G, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Oliver Potts at (202) 690–6392.

SUPPLEMENTARY INFORMATION:

On January 18, 2011, President Obama issued Executive Order 13563 to improve regulation and regulatory review by requiring Federal agencies to design cost effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness, and which rely on the best, most innovative, and least burdensome tools to achieve regulatory ends. To meet that objective, the President directs each Executive Branch agency to consider how best to promote periodic retrospective review of existing significant rules to determine if they are outmoded, ineffective, insufficient, or excessively burdensome. Each agency is to develop and submit to the Office of Management and Budget’s Office of Information and Regulatory Affairs a preliminary plan under which the agency will periodically review existing rules to determine whether any such regulations should be modified, streamlined, expanded, or repealed.

Background

HHS is the Federal Government’s principal agency charged with protecting the health of all Americans and providing essential human services. HHS’ responsibilities include: Medicare, Medicaid, increasing access to care and insurance coverage, support for public health preparedness and emergency response, biomedical research, substance abuse and mental health treatment and prevention, assurance of safe and effective drugs and other medical products, protection of our

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Nation’s food supply, assistance to low income families, the Head Start program, services to older Americans, and direct health services delivery. HHS is comprised of 18 staff divisions and 12 operating divisions, many of which have responsibility for promulgating regulations pursuant to HHS’s statutory authority. Although many components of HHS, currently conduct periodic retrospective reviews, until now there has been no single HHS-wide plan for ongoing review of HHS regulations.

HHS’s goal is to establish a robust and resilient framework for each HHS agency to undertake a periodic thoughtful analysis of its significant existing regulations, resulting in a more streamlined, flexible, less burdensome regulatory structure. HHS seeks comments from the public on various aspects of the framework that might be considered as HHS develops its plan.

Request for Information

HHS has determined that the plan called for by the President should reflect HHS’s overall approach to regulatory review, leaving implementation of that plan to each individual regulatory agency. Accordingly, HHS solicits comments on the following elements to be included in its preliminary plan:

- **Schedule for Ongoing Review**—The public is first asked to comment on how HHS should determine a schedule for review. Understanding that an effective review process can be time consuming, comments might address how best to schedule periodic reviews that will be meaningful, yet not unduly burden individual agencies within HHS, or how best to integrate mandatory reviews of HHS regulations—for example, reviews of regulations at least every ten years that have a significant economic impact on a substantial number of small businesses as required by the Regulatory Flexibility Act; annual reviews of hospital, physician, nursing facility, dialysis facility, and other provider payment rules setting reimbursement rates under Medicare for each fiscal year; or reviews every five years of regulations establishing relative value units for health care provider activities for Medicare reimbursement purposes—with the retrospective reviews called for under the new Executive Order.

- **Process for Setting Priorities**—HHS solicits comments about factors it should consider and the process it should use in setting priorities and

selecting rules for review. For example, should the amount of time a regulation is in effect be criteria for review? If so, how much time should that be? Should HHS involve outside experts in setting its review priorities? What metrics should HHS use to evaluate regulations after they have been implemented? For example, should review be limited to rules based on their projected or actual impact?

- Public Participation—HHS solicits comments on ways to further engage and increase public comment in its rulemaking. Comments might suggest ways to improve HHS' continuing efforts to use online technologies to facilitate greater participation in the rulemaking process, particularly social media and regulations.gov. Comments might also suggest ways to increase open exchanges of information by interested parties, or ways to allow interested parties the opportunity to react to (and benefit from) the comments, arguments, and information of others during the rulemaking process. HHS also welcomes comments on how it can remain informed on new technologies, events or processes that may render significant rules potentially obsolete, outdated, or require modification.

- Analysis of Costs and Benefits—HHS invites public comment on how it ought to develop its analysis of costs and benefits of those rules under consideration for retrospective review. The metrics used to assess costs and benefits at the time a rule is promulgated are likely to be different from those available or necessary to assess costs and benefits of a rule in its present form. Comments might usefully address data sources that will help assess the cost benefit analysis of a regulation after the initial projection has been made or whether there are existing sources of data that HHS should use to evaluate the post-promulgation effects of regulations over time. Additionally, HHS is interested in comments on ways to quantify values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

- Coordination with Other Departments—HHS is interested in public comment on ways that HHS can consider the combined effects of regulations (together with those of other agencies) on particular sectors and industries, particularly small businesses, and State, local and tribal governments; and ways to promote greater coordination across agencies, harmonization of regulatory requirements, and the identification of

regulations that are redundant, inconsistent or overlapping.

- General Comments on What HHS Should Include in Its Plan—HHS seeks comment on how best to structure its framework for conducting ongoing retrospective reviews, and other criteria that should be considered in preparation of its preliminary plan.

HHS notes that this RFI is issued solely for information and program-planning purposes. HHS will not respond to individual comments, but will consider them as it formulates its preliminary plan. While responses to this RFI do not bind HHS to any further actions related to the response, all submissions will be made publicly available on <http://www.regulations.gov>.

Dated: April 7, 2011.

Dawn L. Smalls,

Executive Secretary to the Department.

[FR Doc. 2011-8780 Filed 4-12-11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 11

[Docket No. APHIS-2011-0006]

Horse Protection Act; Petition for Amendments to Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service has received a petition requesting changes to our horse protection regulations and our current enforcement practices and related policies regarding those regulations. We are making this petition available to the public for review and comment. We are noting, however, that certain requests in the petition lack authority in the Horse Protection Act to implement.

DATES: We will consider all comments that we receive on or before June 13, 2011.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2011-0006> to submit or view comments and to view supporting and related materials available electronically.

- *Postal Mail/Commercial Delivery:* Please send one copy of your comment

to Docket No. APHIS-2011-0006, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2011-0006.

Reading Room: You may read any comments that we receive on the petition in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Dr. Rachel Cezar, Horse Protection Program National Coordinator, Animal Care, APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1238; (301) 734-5784.

SUPPLEMENTARY INFORMATION:

Background

The Horse Protection Act (HPA, 15 U.S.C. 1821–1831) authorizes the Secretary of Agriculture to promulgate regulations prohibiting the showing, exhibition, transport, or sale of horses subjected to soring, a practice of accentuating a horses' gait through the infliction of pain. The Secretary of Agriculture has delegated the responsibility for enforcing the HPA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Exercising its rulemaking authority under the Act, APHIS enforces regulations that are contained in 9 CFR part 11, referred to below as the regulations, that prohibit, among other things, devices and methods that might sore horses.

In a petition sent on August 4, 2010, The Humane Society of the United States, the American Society for the Prevention of Cruelty to Animals, the American Horse Protection Association, Inc., Friends of Sound Horses, Inc., and former Senator Joseph D. Tydings (referred to below as the petitioners) requested that APHIS change its regulations and policies regarding the protection of horses from the practice of soring. The petitioners' requests included permanently disqualifying horses that have been scarred from soring from competitions, permanently disqualifying repeat violators of the HPA, requiring horse industry