



Testimony of

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Chairman Stearns, Ranking Member DeGette, and Members of the Subcommittee:

My name is Sherry Glied, and I am the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services (HHS). I am the principal advisor to the Secretary of HHS on policy development, and I am responsible for major activities in policy coordination, strategic planning, policy research, evaluation, and economic analysis.

I am grateful to have the opportunity to appear before you today to discuss issues relating to regulation and to Executive Order 13563, "Improving Regulation and Regulatory Review." I will focus in particular on retrospective review of existing rules.

With Executive Order 13563, issued on January 18, 2011, the President laid the foundation for a regulatory system that is designed to protect public health and welfare while also promoting economic growth, innovation, competitiveness, and job creation. Executive Order 13563 provides a series of directives and requirements. Among other things, and to the extent permitted by law, the Executive Order:

- Requires agencies to consider costs and benefits, to ensure that the benefits justify the costs, and to select the least burdensome alternatives.
- Requires increased public participation and an open exchange.
- Directs agencies to take steps to harmonize, simplify, and coordinate rules.
- Directs agencies to consider flexible approaches that reduce burdens and maintain freedom of choice for the public.

As you are aware, the Executive Order also requires a government-wide "look back" at existing Federal regulations. The requirement of retrospective analysis directs agencies to review their significant rules and to decide, on the basis of that review, which of such rules should be streamlined, reduced, improved, or eliminated. One of the goals of this approach is to eliminate unnecessary regulatory burdens and costs on individuals, businesses—both large and small—and state, local, and tribal governments.

On May 18, and in compliance with the Executive Order, HHS released our preliminary plan. While HHS's systematic review of regulations will focus on the elimination of rules that are no longer justified or necessary, the effort will also consider strengthening, complementing, or modernizing rules where necessary or appropriate – including, if relevant, undertaking new rulemaking. The plan highlights regulations already being modified or streamlined and identifies additional candidates for further review.

For example:

- The Centers for Medicare & Medicaid Services (CMS) is working to address conflicting requirements between Medicaid and Medicare that potentially create barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries. By improving coordination and partnering with states, we can improve access, quality, and cost of care for people who depend on both programs.

- The Secretary is reviewing and updating the methods and criteria used to identify Health Professional Shortages and Medically Underserved Areas. The previous criteria were last established in 1978. Establishing more consistent and comprehensive criteria will allow the Department to more effectively serve some of our most vulnerable populations.
- We are looking for opportunities to incorporate modern technology into our regulations in a way that increases flexibility for states and businesses while improving people's lives. For example, the Administration for Children and Families (ACF) is encouraging states' child support programs to use cost-effective technologies like electronic signature and document storage; the Food and Drug Administration (FDA) is also going paperless with its adverse events reporting requirements for medical devices; and CMS is working to reduce the barriers to telemedicine to provide better access to care.

In order to increase public participation in this retrospective review, we are now soliciting public comment on the HHS Preliminary Plan on the [www.hhs.gov/open](http://www.hhs.gov/open) website through June 30. Suggestions are welcome, and HHS will carefully review all comments before finalizing our plans.

### **Statement of Commitment to a Culture of Ongoing Retrospective Review**

The Department of Health and Human Services is the principal federal agency charged with providing health and other essential human services so Americans can live healthier, more prosperous, and more productive lives. Many of its activities are regulatory in nature. Through the FDA, HHS regulates the safety of the food we eat, and the safety and effectiveness of the drugs we take to improve our health and the medical devices we rely on for diagnosis and treatment of disease. Congress also recently gave FDA regulatory oversight of cigarettes and other tobacco products to reduce youth tobacco use and the illnesses and death caused by tobacco. Medicare, Medicaid, and the Children's Health Insurance Program, run by CMS, insure roughly one in three Americans. ACF provides guidance and funds to states and territories, as well as local and tribal organizations, so they can provide family assistance, child support, child care, child welfare, Head Start, and other programs serving the needs of children and families. Offices within HHS have responsibility for oversight of health information privacy and electronic health and medical records, protection of human subjects for research, and oversight of health insurance rate review and Exchange requirements.

While regulations can establish clear and transparent frameworks for competition and economic activity, unnecessary and duplicative regulations can also damage the economy by imposing unnecessary costs on the private sector and citizens.

HHS is committed to the President's vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objective is to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

HHS has four goals in mind as we develop our retrospective review plan:

- To increase transparency in the retrospective review process;
- To increase opportunities for public participation;
- To set retrospective review priorities; and
- To strengthen analysis of regulatory options.

All HHS Operating and Staff Divisions (Agencies) that establish, administer, or enforce regulations are included in our plan. The types of documents covered under this plan include final, significant regulations, as defined by Executive Order 12866; significant pending proposed regulations; and significant interim final regulations for which no final rule has yet been issued.

### **Undertaking the Initial Retrospective Review**

As the first task in the regulatory review, HHS asked each agency to inventory its existing, significant regulations to provide information that will assist the Department in structuring an ongoing retrospective review process. Specifically, each agency identified when its significant regulations were originally promulgated and when they were last modified in any substantive way and pursuant to what authority (e.g., required by statute, response to citizen petition, pursuant to regulatory review requirements of prior administrations, etc.).

Prior to undertaking review of its regulations, each agency determined what priorities it would use to determine candidate regulations for retrospective review. The priority is to identify regulations that agencies can easily modify, streamline, or rescind to address regulatory burdens or inefficiencies. Agencies will thoroughly review other regulations to determine their regulatory impact in accordance with the President's objective to develop a streamlined, robust, and balanced regulatory framework.

For many regulations undergoing an extensive and thorough review, the agency will need to conduct a sound regulatory analysis to determine whether the regulatory activity is meeting the original objectives or whether an alternative, less prescriptive, activity would achieve the same result.

### **Existing Retrospective Review Requirements**

HHS agencies currently conduct routine reviews of existing regulations pursuant to a variety of authorities, changes in law, or other circumstances. For example:

- The Regulatory Flexibility Act requires agencies to conduct reviews within ten years of regulations that have a significant economic impact on a substantial number of small businesses.
- Congressional appropriations as well as frequent amendments to authorization statutes require review and publication of Medicare provider payment rules every year.

- Retrospective review often occurs when there is a significant change in circumstances, such as advances in technology, new data or other information, or legislative changes.
- Under 21 CFR 10.25(a) and 10.30, the FDA may review a regulation if a person submits a petition asking the Commissioner of Food and Drugs to issue, amend, or revoke a regulation.

### **Initial List of Significant Rules that are Candidates for Retrospective Review Pursuant to Executive Order 13563 over the Next Two Years**

Along with our plan for retrospective review, HHS put out for comment a list of regulations the agencies within the Department have identified as candidates for review over the next two years. These include the following categories of regulations:

- Revisions intended to increase flexibility for the regulated community
- Revisions intended to reduce burdens
- Rescissions or revisions to streamline the regulatory process
- Revisions that may increase benefits or reduce costs
- Notices of Proposed Rulemaking (NPRMs) that may not proceed to final rules
- Interim Final Rules that may be rescinded

### **HHS Goals for Ongoing Retrospective Review**

#### **Increasing Transparency**

Ongoing retrospective regulatory review efforts will be more effective if they are accompanied by efforts to make more information available to all interested parties, introduce clarity into the regulatory system, and provide the foundation for regulatory decisions. Executive Order 13563 places a strong emphasis on an open exchange of information among government officials, experts, stakeholders, and the public. In particular, the President refers to a process in which the exchange of information and perspectives among state, local, and tribal officials; experts in relevant disciplines; affected stakeholders in the private sector; and the public will inform an agency's proposed regulatory scheme in advance of rulemaking activity. The President also directs agencies to give the public timely online access to the rulemaking docket on [www.regulations.gov](http://www.regulations.gov), including access to the relevant scientific and technical findings on which a proposed regulatory scheme rests.

HHS will increase transparency in its regulatory process by making available, to the extent feasible and permitted by law, information that is useful for businesses, state, local and tribal governments, and the public to understand the basis of a proposed regulatory activity, especially information on the scientific or evidence-based data underpinning the regulation.

#### **Increasing Public Participation in the Ongoing Review of Regulations**

HHS intends to increase the breadth and quality of public participation in its rulemaking and retrospective review activities. Consistent with this goal, HHS published a notice soliciting

preliminary comment on certain elements HHS should consider in drafting this plan. We are now soliciting public comment on the HHS Preliminary Plan on the [www.hhs.gov/open](http://www.hhs.gov/open) website through June 30.

All HHS agencies already reach out in various ways to obtain public input and advice on regulations subject to review and modification. For example, as one of the major HHS regulatory agencies, FDA sends bi-annual letters to state and local elected government officials asking for suggestions on its regulatory activities. These letters are also posted on FDA's website. FDA also issues a bi-annual letter for small business entities, by posting it on the FDA website and sending it to the Small Business Administration for distribution to the small business community. These two letters highlight upcoming regulations that FDA believes may have an impact on these two groups. Additionally, as part of its Transparency Initiative, FDA recently established a new webpage specifically devoted to its regulatory review activities.

As another agency with substantial routine regulatory activity, CMS also seeks input from states, providers, stakeholders, and members of the public. CMS conducts monthly Open Door Forums and provider outreach activities, and is incorporating feedback from these activities into routine rulemaking efforts for 2011. This feedback allows CMS to identify and change obsolete regulatory requirements, reduce regulatory burden, and identify information that CMS can post online concerning the performance of CMS-regulated providers and suppliers. Further, CMS posts Quarterly Provider Updates on its website so the public, healthcare providers, and our partners in the states are aware of:

- Regulations and major policies currently under development during the quarter;
- Regulations and major policies completed or cancelled; and
- New or revised manual instructions.

HHS intends to increase its efforts to promote and develop meaningful public participation. As an initial matter, HHS is establishing a Public Participation Task Force within the Department to explore ways to increase interactivity in the public comment process with respect to regulatory review and ongoing regulatory activity, including the use of podcasts, webinars, video teleconference sessions, Wikis, YouTube and other social media. Some HHS agencies already use some of these technologies to great advantage. Other agencies can usefully enhance the regulatory review and development process with increased use of these technologies. With the advice and assistance of the HHS Chief Information Office (CIO) and Chief Technology Officer (CTO), the Department will identify and develop these and other online capabilities for the public to be involved in evaluating regulations over time. The Public Participation Task Force will pay particular attention to increasing the diversity of participation and improving the ability of persons with limited English proficiency or disabilities through podcasts and other vehicles to participate in the regulations review and development process.

Additionally, HHS will ask the Public Participation Task Force to work with agencies to develop a set of principles toward increased public participation and transparency in the ongoing review of regulations throughout the Department. These principles will help agencies think about innovative ways to involve interested parties in the retrospective review process so they

can more easily react to and benefit from the comments, arguments, and information of others as they refine their own comments. Among the principles to be considered are:

- Active engagement with thought-leaders through meetings and sponsored listening sessions on specific regulatory reform proposals. Thought-leaders might include the regulated community, affected groups, academics, public interest groups, and state, local, and tribal government leaders.
- Real-time access to information for the public and business community so they can provide more immediate, real-time, feedback to the agency on specific regulatory actions.
- Involvement of outside groups who may have not been included in past regulatory review activities through the Office of Intergovernmental Affairs and the Office of External Affairs as, well as other HHS offices to increase the level and diversity of public participation.

HHS will continue to seek, consider, and accommodate public input and comment while managing different statutory implementation schedules as we move forward in implementing the Affordable Care Act. For example, CMS received and considered input from consumers, industry, states, and other stakeholders through formal requests for comment as they developed regulations on rate review and medical loss ratio. In addition, CMS, with the Departments of Labor and the Treasury, considered input from comments received in the development of regulations regarding grandfathered health plans. CMS also held a public forum on Exchanges, and jointly hosted a forum on wellness with the Departments of Labor and the Treasury to provide additional opportunities for public input by affected stakeholders. As a result of these processes and the feedback received by CMS, the regulations that have been issued to implement the Affordable Care Act have been strengthened by the views and opinions expressed by affected stakeholders. As we transition to 2014, when many provisions of the Affordable Care Act will be fully in effect, HHS will continue to work closely with all interested stakeholders and to use the transparency of the regulatory process to ensure the new law best serves the American people.

The process for seeking public input continues after the issuance of regulations, including regulations under the Affordable Care Act. Based on comments and questions received by HHS, the Department of Labor, and the Department of the Treasury on regulations issued to date, we have provided additional interpretive guidance to affected parties on regulations relating to grandfathering, Medical Loss Ratio (MLR), the Pre-Existing Condition Insurance Plan (PCIP), the Early Retiree Reinsurance Program (ERRP), internal and external appeals, and provisions relating to annual limits on health plan coverage.

### **Setting Priorities**

The President has repeatedly stated his goal of achieving a regulatory system that is balanced, flexible, and maintains freedom of choice. Thus, it is essential that agencies reduce burdens, redundancy, and conflict, and at the same time promote predictability, certainty, and innovation in their rulemaking activities. Two things are important to achieve this goal: establishing clear guidelines for the selection of candidate regulations subject to review and reform; and the sound, robust analysis of candidate regulations to determine whether and how

the regulation might be improved or whether viable alternatives exist. Retrospective review priorities must be ultimately guided by the goals of protecting the public health, welfare, safety, and environment based on the best available science, while using best efforts to promote economic growth, innovation, competitiveness, and job creation, to the extent permitted by law. The analysis applied to the retrospective review of regulations should inform decision-makers of the consequences of any proposed action and its alternatives in order to help those decision-makers determine the least burdensome and most effective approach (e.g., maximizing net benefits) to achieving the desired result.

HHS agencies already understand the importance of setting priorities in the retrospective review process. Agencies routinely take into account the following factors when reviewing regulations under existing retrospective review frameworks:

- Whether an action will have a positive impact on innovation in an area of public health, safety, or delivery of or access to care;
- Whether the public health benefits of an action have been realized;
- Whether the public or regulated community view modification or revocation of the regulations as important and have offered useful comments and suggestions for change;
- Whether the impact and effectiveness of a regulation has changed or been superseded by changes in conditions or advances in scientific or technological information;
- Whether there are or continue to be significant, unresolved issues with implementation or enforcement; and
- How long the regulation has been in effect and whether it has been subject to prior reviews.

Agencies will continue to use and refine these factors as they implement the retrospective review called for in Executive Order 13563 and the requirements of Section 610 of the Regulatory Flexibility Act. In particular, agencies will pay careful attention to the costs and benefits of rules; to choosing the least burdensome approaches and reducing administrative burdens on the private sector as well as state, local, and tribal governments; to the need to simplify rules and harmonize overlapping rules, both within HHS or between HHS and other federal departments; to the importance of promoting flexibility for the private sector; and to scientific integrity and the development of rules based on the best available science.

### **Strengthening Regulatory Analysis**

Agencies already use analytic tools such as cost-benefit analysis, as appropriate, in setting priorities. To buttress those efforts, the Secretary has asked me to establish an agency-wide Analytics Team to share information, make the quality of analysis more consistent across the Department, and ensure the integration of such analysis into regulatory decision-making to improve the quality of regulation. Because many resources already exist within the Department to strengthen this analytic capacity, the Analytics Team will be composed of economists and other analysts from the various HHS agencies. For example, while FDA and CMS have very different regulatory missions, it may be that one agency's approach to regulation can inform how

the other agency approaches its regulatory activity. Interagency cross pollination may offer opportunities to take advantage of existing expertise.

The Analytics Team will review existing practices, establish the protocols for review of regulations on an ongoing basis, establish best practices, and promote consistent approaches to analysis. My office will provide guidance and expertise to help the Department ensure that its regulatory impact analyses are as comprehensive as possible. ASPE is a staff office to the HHS Secretary and independent of operating divisions that draft regulations.

It is important to emphasize that while a great deal has been accomplished in a short time, our plan is preliminary. As such, it is being offered to the public for their views and perspectives. Suggestions are eagerly welcome. HHS will be carefully reviewing all comments and suggestions before finalizing our plans.

While the current retrospective review is important, Executive Order 13563 reflects a broader ambition. To protect public and private dollars, and our future safety and prosperity, we are seeking to change the regulatory culture by eliminating unjustified burdens and constantly exploring what is working and what is not, using evidence and data. Our plan emphasizes the careful empirical investigation of rules, to be undertaken in advance if possible, and retrospectively as well.

I greatly look forward to working with you in this endeavor. I would be happy to answer your questions.