



# Institute for Policy Integrity

*new york university school of law*

June 30, 2011

VIA ELECTRONIC SUBMISSION

Dawn Smalls, Executive Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201  
[www.hhs.gov/open](http://www.hhs.gov/open)

Attention: Docket No. HHS-ES-2011-002

Subject: Reducing Regulatory Burden; Retrospective Review under Executive Order 13,563; Request for Information, Preliminary Plan for Retrospective Review of Existing Rules, dated May 18, 2011, 76 Fed. Reg. 108, 32,330 (June 6, 2011)

Dear Ms. Smalls,

The Institute for Policy Integrity at New York University School of Law submits the following comments to the Department of Health and Human Services in response to its request for comments on improving regulations through periodic retrospective review as required by Executive Order 13,563.<sup>1</sup> Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

This comment assesses HHS's "Preliminary Plan for Retrospective Review of Existing Rules"<sup>2</sup> and offers recommendations for how the Plan can be improved to be more in line with the regulatory priorities outlined by the President, as well as administrative law principles and best practices.

- The Plan currently fails to articulate a clear list of criteria for selecting and prioritizing rules for retrospective review. Specific criteria should be established and applicable Department-wide. The two most important criteria should be whether enough time has passed to allow for meaningful evaluation of how well a rule is performing, and whether changed circumstances warrant the reexamination of a rule.
- The Plan's language and content suggest a deregulatory focus, targeting areas where regulatory burdens and redundancies can be eliminated. A more balanced framework

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<sup>1</sup> Policy Integrity would also like to direct HHS's attention to our comments submitted during the agency's initial call for public input.

<sup>2</sup> U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PRELIMINARY PLAN FOR RETROSPECTIVE REVIEW OF EXISTING RULES (May 18, 2011) [hereinafter HHS Plan].

would focus on maximizing net benefits, not merely reducing administrative costs. In addition to streamlining paperwork requirements, retrospective review may, for instance, call for new areas to be regulated or for the expansion of existing services.

- The Plan should include a discussion of how HHS will use retrospective reviews to improve the quality of future prospective impact analyses. Properly conceived, retrospective reviews will be used to verify the accuracy of initial impact analyses and reveal any tendencies toward the overestimation or underestimation of costs and benefits.
- Where the Plan establishes a new HHS Analytics Team that will be responsible for designing protocols, the Plan should also set forth guidelines to ensure the Team's work is, from the outset, independent, unbiased, and methodologically rigorous.

### **HHS's Factors for Rule Selection, Prioritization, and Evaluation Should Focus on Net Benefits**

Throughout the Plan, HHS names various factors that sub-agencies currently consider, or will probably consider, in conducting retrospective reviews. For instance, page 3 disclaims that “[b]ecause resources will not allow the Department to undertake a detailed analysis on each candidate regulation, the priority will be to identify regulations that agencies can *easily* modify, streamline, or rescind to address regulatory burdens or inefficiencies.”<sup>3</sup> Shortly thereafter, under the heading “Existing Retrospective Review Requirements,” the Plan notes that “HHS agencies currently conduct routine reviews of existing regulations pursuant to a variety of authorities or circumstances,” such as changes in Congressional appropriations or advancements in technology.<sup>4</sup>

While all of the factors mentioned in the Plan are legitimate and relevant, none are set out as required criteria in selecting rules for retrospective review. Nor are the factors organized in a manner that would suggest a hierarchy or blueprint for invoking them during the review process. Moreover, although all of the criteria share the overarching goal of enhancing net regulatory benefits, articulating more targeted criteria that apply across sub-agencies might better direct analysts' attention, conserve agency resources, ensure consistency and quality of reviews, and clarify for the public the agency's basis for various decisions.

Going forward, a revised Plan should articulate a clear list of criteria for prioritizing and systematizing retrospective reviews. Specific criteria should be established and applicable Department-wide.

#### *Factors for Rule Selection Should Concentrate on Changed Circumstances and Updated Data*

In the area of rule selection, the goal of enhancing net benefits suggests two appropriate contexts for conducting retrospective review. First, rules should be selected for review if changed circumstances indicate a rule no longer functions efficiently or effectively. New technology may drastically reduce compliance costs, indicating a stronger rule might better deliver net social benefits; new economic circumstances may have raised compliance costs, perhaps pointing to the need for more flexibility to restore efficiency; or new legislation may make a rule obsolete. Second, new data on the costs and benefits of rules may raise the opportunity for retrospective review. If the original analysis underestimated the costs, the rule may need to be restructured to ensure that benefits once again justify costs; if the original analysis underestimated the benefits, the rule may not be fully capturing the potential for effective performance, and a stronger rule could be justified. When enough time has passed, this type of reevaluation based on new data is possible.

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<sup>3</sup> *Id.* at 3 (emphasis added).

<sup>4</sup> *Id.* at 4-5.

In general, the Plan should prioritize those rules that pose the greatest opportunity to increase net benefits, rather than those that appear to be “easiest” to review or amenable to paperless recordkeeping. More specifically, HHS should clearly list two primary factors for rule selection: whether circumstances have changed, and whether there is updated data on costs and benefits. Articulating specific selection criteria will also help interested parties anticipate those regulations EPA is likely to review, which will improve the quality of public comments submitted.

The Plan’s initial list of candidates for retrospective analysis does not specify the basis for the selection of each rule. Some selections seem motivated by factors aligned with the main goal of retrospective review. For instance, the CMS rule relating to telemedicine and the FDA’s rules on bar codes and electronic reporting appear well justified in light of technological advancements.<sup>5</sup> It is worth noting, however, that nearly all of the candidates listed in the Plan appear to have been selected with this sole criterion in mind. In revising the Plan, HHS should indicate the scope of its initial inquiry into existing rules and specify what criteria were used in selecting these particular rules.

#### *Factors Should Promote and Systematize Review of Agency Inaction*

The retrospective review process offers agencies a valuable chance to assess areas of agency inaction. Inaction has been historically overlooked by the existing system of regulatory impact analysis,<sup>6</sup> which suggests that there may be significant missed opportunities for cost-effective regulation that maximizes social benefits. HHS’s Plan notably does address regulatory inaction with respect to aligning Medicare and Medicaid rules.<sup>7</sup> To promote this goal in future retrospective reviews as well, review of inaction could be systematized by including a specific step or criterion for the review of pending and recently denied public petitions and other areas of regulatory gaps, to see whether changed circumstances or updated data now warrant new regulations.

#### *Factors for Rule Prioritization Can Conserve Agency Resources and Should Move Beyond Paperwork*

Based on which rules have been selected during this initial round, it seems HHS is prioritizing reviews of inefficient paperwork or other reporting burdens. Streamlining bureaucratic requirements and harnessing the latest digital technologies to reduce compliance costs are worthwhile goals, and HHS should pursue such changes. However, the appeal of these low-hanging fruit should not monopolize the agency’s attention or distract it from other opportunities to use retrospective review to enhance net benefits. Paperwork reduction and technological upgrade opportunities should definitely be included in the rule selection process, but such regulations should only be prioritized for review when the agency believes these rules represent the best opportunity to enhance net benefits. Other rule changes, including rule expansions justified by new data or changed circumstances, should not be ignored simply because analyzing their effects may be more difficult.

#### *Factors for Rule Reassessment Should Utilize Balanced Cost-Benefit and Distributional Analyses*

The Plan’s language and criteria for rule evaluation reflect a slight deregulatory bias. As noted above, the Plan repeatedly steers the objectives of retrospective analysis toward utilizing electronic platforms to revise or eliminate “obsolete, unnecessary, or burdensome provisions.”<sup>8</sup> In some cases, HHS goes so far as to predict that the outcome of its analysis will indeed be the removal or

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<sup>5</sup> *Id.* at 6-8.

<sup>6</sup> See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1271-80 (2006).

<sup>7</sup> HHS Plan, *supra* note 2, at 11.

<sup>8</sup> *Id.* at 10.

reduction of regulatory requirements. The Plan asks whether increases in regulatory flexibility or administrative efficiency are possible, but does not inquire into whether net benefits have grown. Likewise, the Plan looks for ways to alter regulations to achieve greater cost effectiveness while maintaining or improving patient outcomes, but does not seek to identify opportunities to modify rules that might enhance patient care without significantly increasing costs. Once HHS has selected a rule for review, the evaluation should consist of simply comparing the full quantitative and qualitative costs and benefits of the feasible policy alternatives, and selecting the option that maximizes net benefits. HHS should follow the same best practices in its retrospective analyses as it does when conducting a regulatory impact analysis during the notice-and-comment process.<sup>9</sup> This includes identifying an appropriate baseline and identifying the proper scope of analysis.<sup>10</sup> The Plan should direct HHS to pay special attention to any unquantified benefits and costs that might be easier to identify and measure after implementation of a regulation.

To evaluate rules, a balanced cost-benefit analysis should also be accompanied by a balanced distributional analysis. Currently, the Plan does look at the cumulative burdens on regulated parties, with special attention to hospitals and state governments. Though review of small business and local government impacts may be statutorily required, a broader distributional analysis may better comport with the goals of Executive Order 13,563.<sup>11</sup> Retrospective review is an opportunity for agencies to assess how benefits and burdens fall across all affected subpopulations, not just costs and not just small businesses.

Finally, throughout HHS should be careful with its word choice, remembering that the Executive Order looks for opportunities to expand as well as eliminate or modify rules. At times the Plan seems to focus more on the reduction of burdens than on the potential to enhance benefits by expanding rules. There are notable exceptions, such as the call to establish a new methodology for designating Medically Underserved and Health Professional Shortage Areas under the Affordable Care Act.<sup>12</sup> But more generally, the Plan should not contain language that might bias analysts against opportunities to increase efficiency by expanding rules, or discourage the public from submitting useful data on why rule expansions might be warranted.

### **HHS Should Design Rules that Monitor and Collect Data Necessary for Retrospective Review**

HHS can facilitate retrospective review and help ensure the longevity of a successful retrospective review plan if the agency anticipates the future need for data on a rule's efficiency and effectiveness. Though the Analytics Team is intended to "strengthen [the agency's] analytic capacity,"<sup>13</sup> the Plan does not clearly specify how the Team, or other departments within HHS, will use the entire rulemaking process to support the goals of retrospective review.

The Plan notes the Department's ongoing effort to "harmonize regulations that apply in the research context,"<sup>14</sup> however HHS should also consider integrating data collection platforms into its retrospective review processes. Research should be coordinated and shared in order to facilitate periodic comparisons between actual and estimated values, and procedures should be put into place to alert retrospective review analysts to possible or emerging discordance between projected

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<sup>9</sup> See OFFICE OF MGMT. & BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT, CIRCULAR NO. A-4, 14-42 (Sept. 17, 2003).

<sup>10</sup> *Id.* at 15.

<sup>11</sup> Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 18, 2011) (noting the need for agencies to consider "fairness" and "human dignity").

<sup>12</sup> HHS Plan, *supra* note 2, at 10.

<sup>13</sup> *Id.* at 17.

<sup>14</sup> The Plan at 9.

and actual impacts, thus triggering an inquiry into whether a full retrospective analysis would be timely.

Careful planning during a rule's formation is integral to determining what reporting requirements and data collection systems will reduce the costs and improve the quality of subsequent retrospective reviews. When drafting new rules, HHS should consider how it "will measure the performance of the regulation, including how and when [it] will collect, analyze, and report the data needed to conduct a retrospective review."<sup>15</sup>

### **HHS Should Study Ex Ante Versus Ex Post Benefits as well as Costs**

Retrospective review provides a valuable opportunity for HHS to systematically compare the actual consequences of regulations with original impact projections. Currently, the Plan is silent on this point. The revised Plan should recognize and set forth how HHS will capitalize on this opportunity, on an ongoing basis.

As a preliminary measure, the Plan should call for an initial agency-wide study of ex ante versus ex post cost and benefit estimates. Both benefits and costs must be included, as both can be easily over- or under-estimated during initial analyses. In designing such a study, the Department should carefully consider its chosen methodology. The number of rules evaluated and their representativeness of the range of HHS rulemakings, will determine how useful the findings will ultimately prove to be in revealing any patterns of bias or analytical errors in initial impact assessments. In order to ensure impartial and useful results, the Plan should require a sufficiently large sample size, chosen randomly and reflecting the full range of regulations promulgated by HHS's sub-agencies. Naturally, a threshold issue may be whether enough data exists on a regulation's ex ante and ex post estimates.

### **HHS Should Set Forth Procedural Rules and Guidelines for the New Analytics Team**

Recognizing that many sub-agencies already utilize cost-benefit analysis and other tools in their policymaking, the Plan calls for the creation of a new Analytics Team that will "buttress those efforts" throughout HHS.<sup>16</sup> Staffed by economists and other analysts from various sub-agencies, the Analytics Team will be responsible for facilitating intra-Department information-sharing, ensuring the integration of analytic tools in decision-making, and improving the quality and consistency of analyses throughout HHS. The Analytics Team will also lead the agency's retrospective review initiative going forward. After reviewing existing practices, it will "establish the protocols for review of regulations on an ongoing basis, establish best practices, and promote consistent approaches to analysis."<sup>17</sup> The Plan calls for the Analytics Team to provide the Deputy Secretary with a set of written recommendations by December 31, 2011.

The Analytics Team is an innovative and promising approach to fulfilling the aims Executive Order 13,563 and improving the quality of agency-wide prospective and retrospective impact analyses. However, given the broad scope of its responsibilities and the fact that it is a new institution HHS should articulate guiding principles for the organization of the Team and the execution of its duties. These principles should strive to ensure the team has as much independence as possible from those who were responsible for the rule during the proposal stage. They should also advance public participation and transparency. While public participation can take many shapes, it may be appropriate for the Analytics Team to accept public input at certain points, or to periodically

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<sup>15</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-791, REEXAMINING REGULATIONS: OPPORTUNITIES EXIST TO IMPROVE EFFECTIVENESS AND TRANSPARENCY OF RETROSPECTIVE REVIEWS 53 (2007).

<sup>16</sup> The Plan at 17.

<sup>17</sup> *Id.*

release a report documenting trends that have come to light through the retrospective review process, such as problems with particular data or cost-benefit estimates.

### **HHS Should Actively Seek Public Participation During All Steps in Retrospective Review**

HHS's guidelines for retrospective review should strive for both public participation and transparency in accordance with Executive Order 13,563. The current Plan makes many nods toward that goal: for example, the Plan discusses the amount of public feedback it has already received concerning which rules should be prioritized for retrospective review,<sup>18</sup> explores potential changes to the agency's website aimed at increasing transparency, and proposes the establishment of a Public Participation Task Force that will further assess "ways to increase interactivity in the public comment process with respect to regulatory review."<sup>19</sup> The creation of a Task Force would indeed be an innovative approach to enhancing public participation, although the description currently offers little in the way of specific goals. HHS needs to ensure that the Task Force, if created, has a mandate that deals concretely and lays out clear objectives for facilitating public participation in the retrospective review process. HHS needs to ensure that stakeholders have a reasonable opportunity to comment on various phases of retrospective review, from the selection of rules for review to assessments of the rules' ex post impacts. Additionally, the Plan needs to clarify if and when the actual rule reevaluations will be presented for public inspection and comment. During the initial rule selection phase, stakeholders may be overwhelmed by efforts to comment on the vast number of regulations that HHS may possibly select for review; it is important that public has had sufficient time to weigh in on those regulations actually chosen for review.

Sincerely,

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<sup>18</sup> *Id.* at 3.

<sup>19</sup> *Id.* at 15.