

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
*Preliminary Plan for Retrospective Review of Existing Rules*  
May 18, 2011

**I. Statement of Commitment to a Culture of Ongoing Retrospective Review**

The Department of Health and Human Services (HHS) 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 Food and Drug Administration, HHS regulates the safety of the food we eat, the drugs we take to improve our health, and the medical devices we rely on for diagnosis and treatment of disease. HHS's Medicare and Medicaid programs insure one in four Americans and issue guidance on who can receive health services and the conditions health care providers must meet to participate and receive reimbursement. HHS's Agency for Children and Families provides guidance and funds to state, territory, local, and tribal organizations so they can provide family assistance, child support, child care, Head Start, child welfare, and other programs relating to children and families. Other regulatory offices within HHS have responsibility for oversight of health information privacy and meaningful use of electronic health and medical records, protection of human subjects for research, and oversight of health insurance rate review and exchange requirements.

In Executive Order 13563, the President recognized the importance of a streamlined, effective, efficient regulatory framework to achieve economic growth, investment flows, job-creation, and competition. The very first paragraph of that Order sets out the President's regulatory priorities:

- To protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.
- To base regulation on the best available science.
- To allow for public participation and an open exchange of ideas.
- To promote predictability and reduce uncertainty.
- To identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.
- To take into account benefits and costs, both quantitative and qualitative.
- To ensure that regulations are accessible, consistent, written in plain language, and easy to understand.
- To measure, and seek to improve, the actual results of regulatory requirements.

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

To achieve a more robust and effective regulatory framework, the President has directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. In the President's own words:

"[W]e are seeking more affordable, less intrusive means to achieve the same ends—giving careful consideration to benefits and costs. This means writing rules with more input from experts, businesses, and ordinary citizens. It means using disclosure as a tool to inform consumers of their choices, rather than restricting those choices. And it means making sure the government does more of its work online, just like companies are doing."

"Toward a 21st-Century Regulatory System," *The Wall Street Journal*, Opinion by Barack Obama.

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's retrospective review plan has four goals:

- 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.

While HHS's systematic review of regulations will focus on the elimination of rules that are no longer justified or necessary, the review will also consider strengthening, complementing, or modernizing rules where necessary or appropriate—including, if relevant, undertaking new rulemaking.

## **II. Scope of Plan**

All HHS Operating and Staff Divisions (Agencies) that establish, administer, and/or enforce regulations are included in this plan. These are:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Departmental Appeals Board (DAB)
- Office for Civil Rights (OCR)
- Office of Medicare Hearings and Appeals (OMHA)
- Office of the Inspector General (OIG)
- National Coordinator for Health Information Technology (ONC)
- Assistant Secretary for Health, Office of the Assistant Secretary for Health (OASH)

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 issued.

### **III. Undertaking the Initial Retrospective Review**

#### **a. Taking inventory.**

As the first task in the regulatory review, HHS will ask 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 will identify when its significant regulations were originally promulgated and when they were last modified in any significant way and pursuant to what authority (e.g., required by statute, response to citizen petition, pursuant to regulatory review requirements of prior Administrations, etc.).

#### **b. Using Existing Information on What Agencies Should Review**

Through correspondence, meetings with stakeholders, town hall meetings, public comment on this plan, and other activities, HHS has received suggestions from outside groups about which regulations would be good candidates for a retrospective review and why. As part of the overall reform effort, HHS may determine that an inventory of those suggestions received during the past two years will be helpful to develop a matrix of issues that might be considered in the retrospective review process. Patterns may surface that will give direction to the review process, especially if patterns occur in one information channel about what regulations should be modified that are echoed in other information channels.

**c. Setting Priorities**

Prior to undertaking review of its regulations, each agency will determine what priorities it will use to determine candidate regulations for retrospective review. Because 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. Agencies will review other regulations more thoroughly to determine their regulatory impact according to a predetermined set of criteria aligned with the President's objectives in support of developing a streamlined, robust, and balanced regulatory framework.

**d. Integrating Regulatory Analysis into the Retrospective Review Process**

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 proscriptive activity would achieve the same result.

**e. Evaluating Regulatory Effectiveness**

A good and comprehensive process of retrospective review must contain an evaluation component – a way to evaluate whether the regulation is effective in curbing the behavior it seeks to minimize or in providing incentives for behavior it seeks to enhance. HHS often includes a process for evaluation within a regulation, including two recent regulations:

- Graphic Warning Labels on Cigarette Packs – Integrated into the proposed rule and under consideration for inclusion in the final rule is a process for evaluating the effectiveness of these Warning Labels at conveying the negative health consequences of smoking, delaying the onset of smoking, and ultimately reducing morbidity and mortality from smoking.
- Accountable Care Organizations (ACOs) – Integrated into the proposed rule are ongoing quality and performance measures for health care service providers participating in Medicare as ACOs, against which CMS will evaluate such organizations to help it determine whether the ACO is eligible for shared savings. Additionally, the Center for Medicare and Medicaid Innovation (CMMI) is statutorily required to evaluate its projects, including its testing of alternate payment models other than those outlined in the proposed rule. The vision is that the CMMI may be helpful in identifying alternative payment models as ACO efforts move forward. If successful, these alternatives may be permitted under revised regulations for ACOs.

#### IV. Existing Retrospective Review Requirements

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

- The Regulatory Flexibility Act requires agencies to conduct reviews every ten years of regulations that have a significant economic impact on a substantial number of small businesses.
- Congressional appropriations, on which CMS, for example, is dependent for establishing its reimbursement rates for various providers, as well as frequent amendments to authorization statutes, require review and publication of 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 change.
- Finally, 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.

Over the past several years, HHS agencies have issued a number of final rules as the culmination of a retrospective review. Additionally, HHS agencies are currently reviewing or revising rules within an existing regulatory review framework. For example, FDA has completed the following revisions as a result of its existing retrospective review activities:

- Constituent Materials in Biological Products (2011): The final rule amends the biologics regulations to permit, as appropriate, approval of exceptions or alternatives to the regulation for constituent materials. FDA is taking this action due to advances in the development and manufacture of safe, pure, and potent biological products that, in some instances, render the existing constituent materials regulation too prescriptive and unnecessarily restrictive.
- Safety Reporting for Investigational New Drugs (2010): This final rule is expected to improve the quality of new drug safety reports submitted to FDA. The final rule lays out clear, internationally harmonized definitions and standards so that critical safety information about investigational new drugs will be accurately and rapidly reported to the agency, minimizing uninformative reports and enhancing the reporting of meaningful, interpretable information, thereby enhancing the safety of patients in clinical trials.
- Expanded Access to Investigational Drugs for Treatment Use (2009): This final rule clarified existing regulations and expanded access to investigational drugs for treatment use to improve access for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies.

**V. Initial list of significant rules that are candidates for retrospective review pursuant to Executive Order 13563 over the next two years:**

Appendix A contains a preliminary 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
- NPRMs that may not proceed to final rules
- Interim Final Rules that may be rescinded

The list is only partially complete, as some initiatives have yet to be cleared through the necessary internal review and approval process.<sup>1</sup> Nevertheless, the list provides insight into where the Department will focus its attention over the next two years as it moves forward to implement the retrospective review process.

**Some highlights of HHS retrospective review activities:**

The following information provides a summary of some of the major initiatives the Department is undertaking in response to the President's Executive Order 13563:

**A. HHS Department-wide Initiatives**

**1. Updating regulations in recognition of changing technology.**

**FDA's Bar Code Rule** – FDA has been considering which economically significant rule to subject to a cost-benefit reassessment and has tentatively concluded that the "Bar Code Rule" is the best candidate for this review. The Bar Code Rule dates from February 2004 and requires certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number. The rule also requires the use of machine-readable information on blood and blood component labels.

---

<sup>1</sup> Specific suggestions on candidates for regulatory review submitted by members of the public in response to HHS's request for comment on elements HHS should consider in drafting its plan will be assessed in conjunction with the additional public comments HHS anticipates receiving following the request for comment on this HHS Preliminary Plan, which HHS intends to post by the end of May 2011. HHS intends to complete the final revisions to this Preliminary Plan by mid-August 2011.

Bar codes on drugs allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This new system is intended to help reduce the number of medication errors that occur in hospitals and health care settings. FDA estimated that the bar-code rule, when fully implemented, would help prevent nearly 500,000 adverse events and transfusion errors over 20 years. FDA estimates the economic benefit of avoiding these adverse events to be \$93 billion over the same period.

The goal to the review will be to assess the costs and benefits and to determine if the rule should be modified to take into account changes in technology that have occurred since the rule went into effect.

**Increase Use of Electronic Reports and Submissions** – FDA is embarking on a major campaign to revise its regulations to increase the use of electronic information in the way it conducts business. On its immediate agenda are regulatory revisions to permit electronic submission of clinical study data for drug trials, post-market reporting for drugs and biological products, and registration and listing of drugs and medical devices. FDA is also looking to require electronic package inserts for human drug and biological products.

Similarly, ACF is moving to an electronic information and record management system for its child support program that will ease burdens on and provide greater flexibility to states implementing this program, especially with respect to case transfer among states and tribes. The program will also move to accept electronic signatures to facilitate ease of reporting.

**Use of Telemedicine to Increase Access** – CMS intends to improve access to care for beneficiaries in rural and critical access areas by increasing the ability of a hospital to use telemedicine to obtain services from a practitioner credentialed at a distant hospital by permitting the hospital to accept the credentials of a practitioner credentialed at the distant hospital so long as the distant hospital is also a Medicare participating entity and there is a written telemedicine agreement in place between hospitals. This change will improve the ability of rural and critical access hospitals to provide a broader spectrum of care and services to their patients.

## **2. Review reporting and recordkeeping requirements to reduce burdens.**

**Streamlining and standardizing data collection for federal HIV programs** – Consistent with the Implementation Plan of the National HIV/AIDS Strategy released last summer, HHS, through its Office of the Assistant Secretary for Health, will convene a working group to consider recommendations for streamlining data collection requirements. To begin, HHS, together with the Department of Housing and Urban Development and the Office of Management and Budget, will consult with State and local health officials and consider changes to lessen grantee reporting burdens. Preliminary conversations with key stakeholders, i.e. the National Association of State and Territorial AIDS Directors, local health officials, local service

providers, and advocates, have taken place regarding the burden of the grant making process, consideration of data sets that have application across several HHS agencies and offices (and potentially across federal departments) that may be aggregated and shared to decrease the repetitious development of similar data for often the same intent. HHS plans to have a draft proposal developed by the end of calendar year 2011.

**Revisions to Health Insurance Portability and Accountability Act** – OCR is undertaking revisions to the HIPAA statute to streamline the process for children to be enrolled in schools, facilitate the ability of individuals to access their own health information, ease burdens on health plans while ensuring that beneficiaries receive notice of material changes to their plans.

**Reduce ACF Reporting Requirements** – ACF is undertaking several initiatives to reduce administrative burdens; reflect improvements in data collection and reporting; and improve consistency with authorizing statutes. Among those are plans to revisit the regulations applicable to the Developmental Disabilities Program in order to provide greater administrative flexibility and improve data collection and reporting and to delete the requirement of quarterly financial reports for Social Services grants.

**Eliminate Requirement for Actuarial Reporting for Hospital Pension Costs** – CMS has proposed in the Inpatient Prospective Payment System rule for 2012 to eliminate the requirement that Hospitals rely on an actuarial determination to report their pension costs. This revision, if finalized in the final rule, will relieve hospitals of an unnecessary and burdensome reporting requirement.

## **B. Cross-cutting efforts within HHS**

### **1. Improving Pre-Market Review for Medical Devices**

In a non rule-making initiative, FDA and CMS intend to pilot a voluntary process for the parallel review of medical devices for marketing (FDA) and national coverage determinations (CMS) that will reduce the total combined time it takes for a medical device to be authorized for sale in the marketplace and then for reimbursement under Medicare. This action will enable providers to know more quickly whether use of a particular device qualifies for reimbursement under Medicare, thereby potentially helping to facilitate patient access to the most up-to-date diagnosis and treatment procedures.

To further efforts to improve pre-market review, the FDA has assessed its process for premarket review of medical devices and established two significant initiatives to improve the agency's medical device premarket review programs. First, FDA is implementing a Medical Device Innovation Initiative to support the development of innovative products by addressing some of the barriers that can impede a product's timely progress to market. Complete information about the Medical Device Innovation Initiative can be found at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHInnovation/default.htm>.



Second, FDA is implementing the 510(k) Plan of Action, which calls for 25 actions during 2011 to improve the most common path to market for medical devices (the 510(k) pathway). These actions will make the 510(k) program a blueprint for smarter medical device oversight; one that drives innovation and brings important technologies to patients. Complete information about the 510(k) Plan of Action can be found at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm>

## **2. ACF-SAMSHA efforts to increase flexibility and reduce burdens on states**

Both ACF and SAMHSA are committed to reducing the administrative burdens on states and their grantees and increasing flexibility in their programs. To that end, they each propose to review regulations to achieve these ends. For example, rules will be reviewed that may:

- Improve and streamline the way states must apply for and report on block grants on mental health and substance abuse prevention and treatment.
- Provide greater flexibility to states in their mandate to provide health insurance to children within its child welfare system by permitting enhanced collaboration with Medicaid and CHIP to create more options for providing that coverage and align medical support enforcement with current healthcare policy.
- Provide greater flexibility to States in implementing the automated child welfare system and enhance child support enforcement by reducing notification requirements among states to free-up resources to pursue enforcement activities.
- Eliminate the ACF requirement to project administrative costs on a variable, rather than fixed basis in order to simplify and reduce the time states are required to invest to determine refugee eligibility.

## **3. Regulations designed to enhance research**

In continuing efforts by the Department to harmonize regulations that apply in the research context, OCR proposed [modifications](#) to the HIPAA Privacy Rule to streamline the research authorization requirements to better align with [the requirements for informed consent under the](#) Common Rule. OCR is working to finalize changes in this area as part of a broader rulemaking that includes final modifications to the HIPAA Rules pursuant to the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act, as well as a final Breach Notification Rule.

In an additional effort to enhance research, NIH intends to review its regulations pertaining to Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects. NIH anticipates that review of this peer review regulation could result in a unified set of peer review regulations for all HHS agencies that would provide greater flexibility and reduce regulatory and administrative burdens.

## **C. Agency-specific Initiatives**

### **1. Regulation of Medical Devices**

Supplementing its non-regulatory activities with respect to medical devices, FDA is also taking steps to reduce the burdens imposed by its medical device regulations. First, FDA is revising its adverse events reporting requirements to convert to a paperless, electronic reporting system. This would help FDA more quickly review these reports and identify emerging public health issues.

Second, FDA intends maintain its ongoing review of classifications of medical devices based on risks to determine whether a particular device can be reclassified to a lower level. FDA anticipates that this ongoing review process will reduce burdens on industry, but maintain the safety and efficacy of the products.

Finally, FDA intends to allow validated symbols in certain device labeling without the need for accompanying English text. The agency believes this change will reduce the burden of having unique labeling requirements for the U.S. market and achieve consistency with labeling requirements for international markets.

### **2. Good Manufacturing Practices and Labeling for Drugs and Food**

In another initiative, FDA is reviewing its current Good Manufacturing Practices (CGMP) regulations, both for foods and drugs. As a primary initiative and pursuant to the Food Safety Modernization Act, FDA will establish preventive controls for food facilities. These new regulations will address and modernize the CGMP for food establishments. Also ripe for this initiative are the CGMP regulations pertaining to pharmaceuticals. These revisions would accommodate advances in technology and control of components. Taken together, FDA anticipates that the revisions would provide greater assurances of safety and quality and address some of the challenges presented by the globalization of the food and pharmaceutical industries.

FDA is also pursuing reviews to revise and update labeling regulations for both food and drugs. As part of its Nutrition Initiative, the agency intends to review and revise the food label regulations to improve and increase the nutrition information available to consumers and help them make better choices about the foods they eat and provide to their families. In a related effort, FDA intends to begin a review of its regulations relating to patient packaging and inserts for pharmaceuticals to determine whether information can be communicated in a more direct and understandable manner.

### **3. Review of Health Professional Shortage Designations**

The Affordable Care Act requires the Secretary to establish a comprehensive methodology and criteria for designating Medically Underserved and Health Professional Shortage Areas through a negotiated rulemaking process. Congress anticipated that use of a negotiated rulemaking process will yield a consensus among technical experts and stakeholders on the methodology for making the designations for these two Areas. The current Health Professional Shortage Area criteria date back to 1978. The current Medically Underserved Area criteria date back to 1975. The review conducted by a Negotiated Rulemaking Committee is currently underway, and the final report is targeted for late Fall 2011. HHS expects that a revised, more coordinated designation methodology and procedure for both designations would, at a minimum, define consistently the indicators used; clarify the distinctions between the two types of designations; and update both types of designation on a regular, simultaneous basis. Consistent with the statute, HHS intends to publish the consensus recommendations of the Negotiated Rulemaking Committee as an Interim Final Rule.

### **4. Conditions of Participation for Hospitals**

In a major initiative, CMS intends to conduct a major retrospective review of the conditions of participation it imposes on hospitals to remove or revise obsolete, unnecessary, or burdensome provisions. Most of the existing hospital requirements have grown up over decades, reflecting new legislation, changes in technology or medical practice, and evolution of the health delivery system. While each of these requirements reflects concerns for improving patient safety or solving problems, their cumulative effect may actually increase burdens on hospitals and health care providers, thereby increasing inefficiency and risk in providing good patient care.

The goal of the retrospective review will be to identify opportunities to improve patient care and outcomes and reduce system costs by removing obsolete or burdensome requirements. Of major concern will be to prevent the elimination or revision of a regulation only to find that the problem it solved resurfaces or that its removal or revision results in unanticipated and more serious outcomes. CMS will proceed with this review carefully, beginning with an internal assessment and then engaging external groups in the process as it seeks to tie burden-reducing steps to outcome-related health and safety reforms.

### **5. Medicare and Medicaid Alignment Initiative**

CMS has also initiated an Alignment Initiative to identify and address conflicting requirements between Medicaid and Medicare that potentially create barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries. There are tremendous opportunities for CMS to partner with States, providers, beneficiaries and their caregivers, and other stakeholders to improve access, quality, and cost of care for people who depend on these two programs. The goal is to create and implement solutions in line with the CMS three-part

aim, which includes, solutions that advance better care for the individual, better health for populations, and lower costs through improvement. As a first step, CMS has asked for public input to help create a foundation for future collaboration to address the issues. It is especially interested in:

- Ensuring that dual eligible individuals are provided full access to the Medicare and Medicaid program benefits.
- Simplifying the processes for dual eligible individuals to access the items and services guaranteed under the Medicare and Medicaid programs.
- Eliminating regulatory conflicts between the rules under the Medicare and Medicaid programs.
- Improving care continuity and ensuring safe and effective care transitions for dual eligible beneficiaries.
- Eliminating cost-shifting between the Medicare and Medicaid programs and between related health care providers.

#### **6. Streamline Beneficiary Notice Requirements**

Closely related to the Alignment Initiative, CMS intends to review its operations manuals and other documents to coordinate and streamline as many of the Medicare and Medicaid beneficiary notice requirements as possible. This would include an evaluation of the existing notices to see whether they have a positive impact for beneficiaries and, if not, some consideration of alternative approaches.

#### **7. Review of Quality Reporting Requirements**

Moving forward with implementation of retrospective review activities, CMS will also review current and future quality measure reporting requirements to determine whether any measures might be eliminated or revised because they are outdated or redundant and whether standardization of measures might facilitate both the reporting on quality measures and the analysis of those reports. The goal will be to ease the reporting burden to the extent feasible and to develop consistency of reporting across programs.

#### **8. Review Process for Disallowance of State Federal Funds Participation**

Another review CMS will undertake may result in a new rule to implement a new reconsideration process for states when CMS disallows federal funds participation and could lengthen the time states have to credit the federal government for uncollected overpayments, revise repayment installment standards, and clarify certain interest charges for states. This regulation would provide more flexibility and clarification in the redetermination and disallowance process, implement statutory requirements that provide states additional time to credit the federal government for overpayments, and make technical corrections.

## 9. Reducing Obstacles to Access

As it does every year, CMS will review its payment rules for hospitals, physicians, nursing homes, and other health care providers and determine whether there are any regulatory requirements that may be eliminated without sacrificing patient care or safety. For example, CMS has already published a proposed rule for hospice care that would eliminate the requirement that the physician who certified the need for a patient to receive hospice services had to be the same physician to recertify continued need for those services. The proposal would permit a different physician to do the recertification, relieving hospice providers in underserved or rural areas from the onerous same-physician requirement. Similarly, in a recent shift in policy, CMS determined that a requirement that physicians or non-physician practitioners sign off on requisitions for the results of laboratory tests was not necessary and could delay delivery of these results to appropriate health care providers. As a result, CMS has notified providers that it will not enforce the requirement and is in the process of promulgating a new regulation on this provision.

CMS also has approximately 80 additional reform proposals under review and development. CMS plans to present the proposed reforms to HHS leadership throughout the summer of 2011. These reforms will affect hospitals, physicians, home health agencies, skilled nursing homes, hospices, ambulance providers, clinical laboratories, intermediate care facilities, managed care plans, Medicare Advantage organizations, and rural health clinics. While most of these proposals are aimed at reducing barriers to effective patient care, some of them are aimed at transparency objectives—getting more and better online information to the public so that individuals can get the information they need easier and faster to make more informed decisions. CMS will try to complete these first phase reforms by the end of the calendar year.

In phase two, CMS intends to identify additional reforms for implementation next year. CMS will continue to look for ideas from its own staff as well as stakeholders and will use the opportunity in publishing proposed rules to ask the public to identify additional opportunities for regulatory reform. The cumulative effect of removing so many barriers to efficient and effective patient care will be substantial.

**The list of candidate regulations currently proposed for review is at Appendix A.**

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

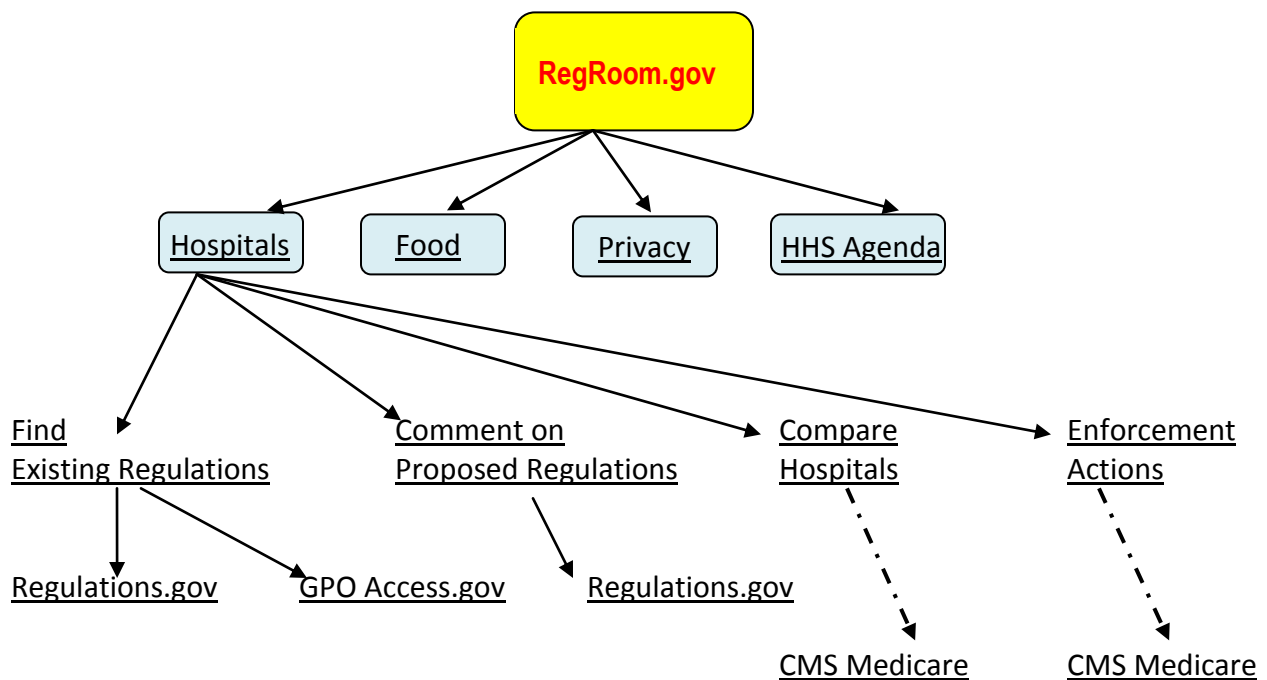
### a. Increasing Transparency:

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 as a whole will inform a proposed regulatory scheme before an agency actually makes decisions about how to proceed with its regulatory 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 essential for businesses, state, local and tribal governments, and the public to understand the basis of a proposed regulatory activity, especially that information on the scientific or evidence based data underpinning the regulation. Among the initiatives HHS will consider to achieve this goal are:

- [HHS RegRoom.gov](http://HHS.RegRoom.gov) – Explore the option of posting on the HHS.gov home page a new button for the HHS RegRoom, a robust, interactive, easy-to-navigate single entry portal from which individuals can readily link to specific regulations, find regulations published as proposed and provide comment, provide input on the review of any existing regulation, read supporting data and other background material, and otherwise participate in the regulatory process. HHS would also post links to its Unified Agenda, as well as information relating to regulatory compliance and enforcement actions, as part of the Department’s response to the President’s January 18, 2011, Memorandum on Regulatory Compliance. The following schematic illustrates how such a button might work.



- Increasing meaningful use of regulations.gov – HHS will work with agencies to increase and improve their use of and links to regulations.gov for the purpose of encouraging public comment on proposed rules and rules subject to retrospective review and for posting more complete supporting and background material on regulations subject to comment. Some agencies already post relevant background information on the regulatory docket; others do not. HHS will work to achieve consistency in the types of documents routinely included in the regulatory docket so that a person has immediate access to that information to inform any comments he or she might consider making. Providing a plain language summary of each regulation listed in regulations.gov if also of major importance. Hyper-technical descriptions of what a regulation does and how it will affect those subject to the regulation and those who are affected by the regulated industry will not increase transparency or public access to the regulatory review process. HHS will provide such summaries in order to foster greater transparency about its regulatory activities.
- Maintaining a single docket for regulatory action – To avoid confusion with multiple docket entries, agencies will be encouraged, to the extent feasible, to use a single Regulation Identification Number to track regulations and one docket to manage the regulatory action. The same docket will include relevant supplemental and background material on quality, science, and other data or information that will help the public become better informed and more readily understand the basis for the review of a regulation or why an agency proposed to change, modify, or propose a regulation.

**b. 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 and intends to solicit public comment on the complete HHS Preliminary Plan by the end of May 2011.<sup>2</sup> A summary of comments submitted in response to the request for comment on elements to be considered in drafting the plan are at Appendix B. As HHS receives comments on its complete Preliminary Retrospective Review Plan, they will be available for review at the regulations.gov website.

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 and posts them on its website. FDA also issues

---

<sup>2</sup> FDA also has posted a request for public comment on regulations that might be good candidates for review. That notice can be found at [http://www.ofr.gov/OFRUpload/OFRData/2011-10131\\_Pl.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-10131_Pl.pdf).

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.<sup>3</sup>

As another agency with substantial regulatory activity, CMS also seeks input from its regulated community. For example, CMS posts Quarterly Provider Updates on its website so the public and the regulated community are aware of:

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

HHS intends to increase its efforts to promote and develop meaningful public participation. As an initial matter, HHS will establish a Public Participation Task Force including the Assistant Secretary for Public Affairs (ASPA) along with its Director of the Web Communications Division, the Chief Information Officer, the General Counsel's Office, and the Chief Technology Officer, chaired by the Deputy Executive Secretary, 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 CIO and 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. The Public Participation Task Force will report its recommendations to the Deputy Secretary by March 31, 2012.

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

---

<sup>3</sup> <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm251751.htm>



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.
- Involve outside groups who may have not been included in past regulatory review activities through the Offices of External Affairs and Intergovernmental Affairs and other HHS offices to increase the level and diversity of public participation.
- Explore possible collaboration with the Cornell University e-Rulemaking initiative whereby Cornell students and faculty host an interactive blog for public participation and comment on proposed rules. The Department of Transportation is already involved in this initiative.

**c. 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 not 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.

**d. Strengthening Regulatory Analysis**

Agencies already use analytic tools such as cost-benefit or cost-effectiveness analysis, as appropriate, in setting priorities. To buttress those efforts, HHS will ask the Assistant Secretary for Planning and Evaluation (ASPE) 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. ASPE will provide guidance and expertise to help the Department ensure that its regulatory impact analyses are as robust as possible. ASPE is a staff office to the HHS Secretary and independent of operating divisions that draft regulations. ASPE and the Analytics Team will report to the Deputy Secretary by December 31, 2011, on its recommendations for strengthening the HHS analytic capacity for ongoing retrospective reviews and any other matters consistent with this plan.

**VII. Person Responsible for Implementing this Plan**

Dawn Smalls, Executive Secretary

## APPENDIX B

|   | CFR Cite   | Reference  | Agency        | Purpose   | Impact   |
|---|--|--|---------------|---|--|
|   | <b>Department-wide Initiatives</b>                                 |  |               |   |  |
|   | <b>Updating regulations in recognitions of changing technology</b> |  |               |   |  |
| 1 | 45 CFR §§1355.50 – 56  | Statewide Automated Child Welfare System (SACWIS)  | ACF/ACYF/CB   | Grant greater flexibility to States to implement automation that supports their business model; Reduce costs; Reflect changing technology advances; Enable Tribes to implement SACWIS-like systems  | Increased flexibility at reduced costs for title IV-E agencies   |
| 2 | 45 CFR §1351.17  | How is application made for a Runaway and Homeless Youth Program grant?  | ACF/ACYF/FYSB | Update outdated procedures for obtaining announcements and submitting applications.   | Reduce confusion and streamline application process using automation   |
| 3 | 45 CFR Parts 301, 302, 303, 304, 305, 307                          | Efficiency in child support  | ACF/OCSE      | OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.   | OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.   |
| 4 | 42 CFR Part 67   | Health Services Research, Evaluation, Demonstration, and Dissemination Projects; Peer Review of Grants and Contracts | AHRQ          | Update of Regulations [Federal Register Volume 62, Number 52 (Tuesday, March 18, 1997)], pages 12906 - 12914  | Minimal impact; primary purpose is to revise and update this AHRQ Peer Review Regulation   |
| 5 | 42 CFR 37  | Specifications for Medical Examinations of Underground Coal Miners (NPRM, RIN 0920-AA21)                             | CDC           | Modification will allow the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current regulations require the use of film radiography which is being phased out of use at medical facilities in the U.S. | Use of current technology will increase accessibility of services to coal miners. Also anticipate decreased cost for mine operators to obtain modern digital chest images instead of outdated chest x-rays |
| 6 | 21 CFR 310 21 CFR 414 21 CFR 600                                   | Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)    | FDA/CDER      | FDA is revising its regulations to allow mandatory safety reports to be transmitted electronically.   | Would allow FDA to collect and analyze safety reports more quickly and to identify emerging problems faster and disseminate information.   |
| 7 | 21 CFR 314 21 CFR 601  | Electronic Submission of Clinical Study Data (e-CSD)   | FDA/CDER      | FDA is revising its regulations to require submission of data in drug applications in electronic format that FDA can process, review and archive.   | Use of modern technology would increase efficiency and allow for more comprehensive data review.   |
| 8 | 21 CFR 201   | Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (e-Labeling) | FDA/OP        | This rule would require electronic “package inserts” for human drug and biological products.  | Up-to-date prescribing information for healthcare professionals.   |
| 9 | 21 CFR 207   | Electronic Registration and Listing for Drugs (e-DRLS)   | FDA-CDER      | Would convert the registration and listing process to a paperless system, while maintaining an avenue for companies that do not have access to the web.   | Would allow for the utilization of latest technology in the collection of information and improve FDA’s ability to inspect manufacturing establishments.   |

|   | CFR Cite               | Reference   | Agency   | Purpose   | Impact  |
|---|------------------------|---|----------|---|---|
| 10  | 21 CFR 807             | Electronic Registration and Listing for medical devices   | FDA/CDRH | Would convert the registration and listing process to a paperless system, while maintain an avenue for companies that do not have access to the web.  | Would allow for the utilization of latest technology in the collection of information.  |
| 11  | 42 CFR Part 485        | Telemedicine Final Rule   | CMS      | Would allow practitioners in one Medicare participating hospital to provide consultation and services to a patient in another Medicare participating hospital without requiring certification in the second hospital.   | Will increase access to health care providers.  |
| 12  | 21 CFR 4               | Current Good Manufacturing Practices (CGMPs) for Combination Products   | FDA/OC   | Would clarify and codify CGMPs requirements for products that are combinations of drug, device and/or biological products.  | Would provide regulatory clarity for manufacturers of combination products.   |
| 13  | 21 CFR 4               | Postmarketing Safety Reporting for Combination Products   | FDA/OC   | Would clarify that a combination product is subject to the reporting requirements associated with the type of marketing application under which the product was approved.   | Would provide regulatory clarity for manufacturers of combination products.   |
| <b>Review reporting and recordkeeping requirements to reduce burden</b> |                        |   |          |   |   |
| 1   | 45 CFR Parts 1385-1388 | Requirements applicable to the developmental disabilities program   | ACF/ADD  | The original NPRM from June 2008 (to establish long overdue regulations for full reauthorization of the DD Act of 2000) received negative comments. ADD plans to rewrite the package to reduce administrative burden; to reflect improvements in data collection, performance measurement and reporting; and to improve consistency with the statute. | Additional flexibility and reduced administrative burden. Reflect improvements in data collection, performance measurement and reporting. Improved consistency with the statute.  |
| 2   | 42 CFR 34              | Medical Examination of Aliens   | CDC      | NPRM will propose streamlining regulations, updating vaccination requirements and definition changes for drug abuse and drug addiction, revise the scope of the medical examination, and update the list of a communicable disease of public health significance.   | Rule reduces the burden and streamlines the immigration process for both the physicians conducting the medical examinations and the U.S. communities receiving immigrants and refugees.   |
| 3   | 42 CFR 71.53<br>71.53  | Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primates (NPRM, RIN 0920-AA23). | CDC      | NPRM proposes to modify and streamline existing regulations and guidance to reduce administrative burdens for importers of NHPs.  | NPRM proposes to reduce the frequency at which importers of nonhuman primates are required to renew their registrations, and to eliminate quarantine costs for zoo-to-zoo and laboratory-to-laboratory facilities that maintain detailed records. |
| 4   | 42 CFR Part 412        | Inpatient Prospective Payment System Proposed Rule  | CMS      | Currently hospitals must provide actuarial determinations for pension costs and Medicare contractors must review those actuarial reports. Revised reporting could reduce burden by removing the need for an actuarial determination.  | Would provide flexibility to reduce burdens and costs.  |

|  | CFR Cite                                  | Reference   | Agency        | Purpose  | Impact  |
|--|---|---|---------------|--|---|
| 5  | 45 CFR 164.512                            | Disclosures of Student Immunization Records to Schools under the HIPAA Privacy Rule   | OCR           | Better facilitate the disclosure of student immunization records to schools in states that have school entry laws  | Will facilitate these public health disclosurers, reduce burden on parents and health care providers, and help avoid delays in children beginning school  |
| 6  | 45 CFR 164.528                            | HIPAA Privacy Rule Accounting of Disclosures Requirements   | OCR           | Improve the workability of current disclosure requirements and better balance the burden to regulated entities with the benefit to individuals   | Will provide the individual with information about those disclosures that are most likely to impart the individual's legal and personal interests, while reducing administrative burden on regulated entities |
| 7  | 45 CFR 164.520                            | HIPAA Privacy Rule Requirements on Health Plans to Re-Distribute to Individuals Their Notices of Privacy Practices When Material Changes are Made | OCR           | Reduce administrative burden and cost  | Will reduce administrative burden on health plans while still ensuring individuals are notified of material changes to privacy practices  |
| <b>Reviewing regulations to "clean up" or eliminate outdated provisions.</b>   |   |   |               |  |   |
| 1  | 45 CFR Part 1370                          | Family Violence Prevention and Services Programs  | ACF/ACYF/FYSB | Rescind the requirement to publish quarterly funding opportunity announcements in the Federal Register and revise regulations to bring them into conformity with the reauthorized Family Violence Prevention and Services Act  | Clarity of programmatic operating procedures  |
| 2  | 45 CFR § 400.11(c)                        | Award of Grants to States   | ACF/ORR       | Delete reference to financial status reports being required quarterly for Social Services grants; Add language to require annual reporting for Social Services grants with the flexibility for ORR to request financial status reports more frequently in accordance with Part 92. | Reduces burden on states by decreasing frequency of reporting unless a specific need surfaces.  |
| 3  | 42CFR8                                    | Opioid Treatment Facilities   | SAMHSA        | Review requirements that methadone clinics are to follow and credentialing agencies are to follow in credentialing such programs.  | Provide more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction.  |
| <b>Cross-cutting agency efforts within HHS</b>                                 |   |   |               |  |   |
| <b>ACF-SAMSHA efforts to increase flexibility and reduce burdens on states</b> |   |   |               |  |   |
| 1  | 45 CFR Parts 301, 302, 303, 304, 305, 307 | Efficiency in child support   | ACF/OCSE      | OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.  | OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.  |

|   | CFR Cite                                  | Reference  | Agency   | Purpose  | Impact   |
|---|---|--|----------|--|--|
| 2 | 45 CFR Part 302                           | Efficiency in child support                                      | ACF/OCSE | OCSE is drafting an NPRM which increases statutory state law exemption approval periods from three to five years   | Provides relief to states by decreasing the frequency with which states have to request an extension of an approved state law exemption.   |
| 3 | 45 CFR Part 303                           | Efficiency in child support                                      | ACF/OCSE | OCSE is drafting an NPRM which updates case closure criteria to increase state flexibility and facilitate effective case transfer between states and tribes.   | States will have greater flexibility to close unenforceable cases and redirect resources to more productive efforts. States will also have a process by which cases can be closed and transferred to a tribal child support program.     |
| 4 | 45 CFR §§302, 303, 308                    | Strengthen medical support in the child support program          | ACF/OCSE | OCSE has a statutory responsibility to secure private or public health care coverage for each of the children in its caseload and to enforce court orders that require parents to obtain health care coverage. Previously, OCSE provided guidance to states providing them the option to define medical support to include private health insurance as well as Medicaid, CHIP, and other state coverage plans; however, to provide states with greater flexibility OCSE is revising the regulations, providing state child support agencies with the flexibility to pursue options such as enhancing collaboration with Medicaid and CHIP (OCSE-AT-10-10). | Medical support requirements will be reconciled with the health insurance reform legislation, and will substantially improve children's health care coverage and reinforce parents' shared responsibility for their children's coverage. |
| 5 | 45 CFR Part 303                           | Efficiency in child support                                      | ACF/OCSE | OCSE is drafting an NPRM which discontinues the mandate for States to notify other States involved in enforcing a support order when they submit an interstate case for offset. States referring past-due support for offset will notify any such other State involved in enforcing the debt only when they receive the offset amount from the United States Treasury States.  | States will not be inundated with unnecessary information and will ultimately save both time and resources   |
| 6 | 45 CFR Parts 301, 302, 303, 304, 305, 307 | Efficiency in child support                                      | ACF/OCSE | OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.  | OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.   |
| 7 | 45 CFR §400.211(a)(5)                     | Methodology to be used to determine time-eligibility of refugees | ACF/ORR  | Modification is needed to reduce the administrative burden on States in projecting the variable portion of administrative costs. Deleting the requirement to project variable administrative costs (which has proven to be time consuming without producing better projections) and relying on fixed costs, simplifies this process.   | Project administrative costs with a less time consuming approach for states.   |

|                                    | CFR Cite       | Reference   | Agency   | Purpose  | Impact   |
|------------------------------------|----------------|---|----------|--|--|
| 8                                  | 45CFR96        | Substance Abuse Prevention and Treatment Block Grant and Community Mental Health Services Block Grant | SAMHSA   | To create additional flexibility for States, eliminate requirements no longer in statute, change requirements in light of current knowledge of substance abuse prevention and treatment, and bring the program into the post health reform era.<br>Will include regulations on the CHS BG which has not had any since its creation to facilitate communications and cooperative efforts on behalf of substance use and mental illness in State.  | Will represent significant but necessary changes, States will benefit from additional flexibility, provides some structure for States in seeing this program in the light of health reform.<br>Is expected to add cooperative efforts on behalf of agency working on mental and substance use disorders. |
| <b>Enhancing Research</b>          |                |   |          |  |  |
| 1                                  | 42 CFR 52h     | Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects  | NIH      | This regulation is already followed by other DHHS sister entities, so modifying and streamlining this rule could lessen regulatory burden and provide greater flexibility across the Department. Additionally, there appear to be opportunities for reducing administrative burdens. For example, revising definitions of conflicts of interest for peer reviewers could provide flexibility in constituting review panels and lessen administrative burden. Revising review criteria could provide greater flexibility in evaluating applications and make them applicable to other types of applications in addition to those for research projects. This is important given NIH's development of new types of initiatives in response to the changing nature of science for which the criteria specified in the current regulations are not optimal. Revising the regulations to allow for a pre-screening process could reduce the toll on the system. | It is reasonable to expect that regulatory review of the peer regulations could result in a unified set of peer review regulations for all HHS agencies that provides greater flexibility and reflects reduced regulatory and administrative burdens.  |
| 2                                  | 45 CFR 164.508 | HIPPA Privacy Rule Authorization Requirements for Research  | OCR      | Streamline the HIPAA research authorization process and harmonize with the Common Rule's informed consent requirements   | Will provide increased flexibility for researchers, reduce paperwork and burden, and harmonize with other research rules   |
| <b>Agency-Specific Initiatives</b> |                |   |          |  |  |
| <b>FDA Medical Products</b>        |                |   |          |  |  |
| 1                                  | 21 CFR 803     | Electronic Medical Device Reporting   | FDA/CDRH | Would convert adverse events reporting of medical devices to a paperless system.   | Would allow paperless reporting of adverse events  |
| 2                                  | 21 CFR         | Down-classifications of Medical Devices (various)   | FDA/CDRH | Review classifications of medical devices to determine if down-classification (i.e., move to a classification with less stringent requirements) is appropriate.  | Regulate based on risks and reduce regulatory burden.  |

|    | CFR Cite  | Reference   | Agency          | Purpose  | Impact   |
|----|---|---|-----------------|--|--|
| 3  | 21 CFR 814  | Revision of Device Premarket Approval Regulations (21 CFR 814.39); Special PMA Supplement Changes Being Effectuated             | FDA/CDRH        | Remove duplicative requirements  | Streamline and clarify regulatory requirements.  |
| 4  | 21 CFR 882  | Revise 21 CFR 882.5975 referencing device classification for dura mater, now regulated as an HCT/P                              | FDA/CDRH        | Clarify classification of dura mater.  | Clarification of regulatory status   |
| 5  | 21 CFR 351 21 CFR 360 21 CFR 371                      | General Hospital and Personal Use Devices; Issuance of Draft Special Controls for Infusion Pumps                                | FDA/CDRH        | Based on an analysis of death and serious injury reports submitted to FDA, the agency is establishing special controls to provide reasonable assurance of safety and effectiveness of these devices. | Increased safety for patients.   |
| 6  | 21 CFR 801  | Use of Symbols in Device Labeling   | FDA/CDRH        | Allow validated symbols in certain device labeling without the need for accompanying English text.   | Reduce burden of labeling requirements by permitting harmonization with labeling for international markets   |
| 7  | 21 CFR 10 21 CFR 314 21 CRF 600 21 CFR 601 21 CFR 606 | Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products   | FDA/CDER        | FDA is revising certain definitions and reporting requirements based on recommendations of the ICH.  | Revise reporting requirements and times to enhance the quality of safety reports received by FDA.  |
| 8  | 21 CFR 201 21 CFR 606                                 | Bar Code Rule for Drugs   | FDA/CDER & CBER | FDA is conducting a retrospective economic review of an economically significant regulation.   | Assess costs and benefits to determine if rule should be modified to take into account changes in technology that have occurred since the rule went into effect. |
| 9  | 21 CFR 210 21 CFR 211                                 | Amendment to CGMP regulations for Finished Pharmaceuticals (Pharmaceutical CGMP for the 21st Century--Phase 2)                  | FDA/CDER        | FDA is revising its CGMP regulations to accommodate advances in technology and to harmonize with the other International standards.  | Flexibility and harmonization for pharmaceutical industry.   |
| 10 | 21 CFR 210 21 CFR 211                                 | Amendment to CGMP regulations—Components  | FDA/CDER        | FDA is revising its CGMP regulations to address control of drug components.  | Provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.                                      |
| 11 | 21 CFR 314  | Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets | FDA/CDER        | FDA is revising its existing regulations to implement provisions of the FDA Amendment Act.   | Clarify certifications needed when filing petitions related to generic drug applications.  |
| 12 | 21 CFR 201 21 CFR 208                                 | Patient Labeling for Drugs (Patient Package Inserts and Medguides)  | FDA/CDER        | TBD  | TBD  |
|    |   |   |                 |  |  |
|    | <b>FDA Foods</b>                                      |   |                 |  |  |
| 1  | 21 CFR 101  | Food Labeling (Nutrition Initiative)  | FDA/CFSAN       | Revising and updating food labeling regulations to make nutrition information on packaged food label more useful to consumers.   | Improving nutrition information will help consumers make better dietary choices.   |



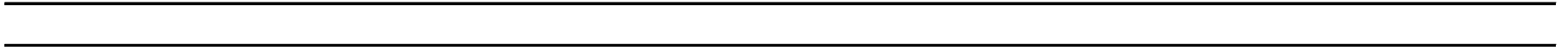
|   | CFR Cite  | Reference  | Agency      | Purpose  | Impact   |
|---|---|--|-------------|--|--|
| 2   | 21 CFR 110                                      | Preventive Controls (Modernization of Current Food Good Manufacturing Practice Regulations)  | FDA/CFSAN   | In recognition that existing food GMP rules are inadequate, the Food Safety Modernization Act requires FDA to establish preventive controls for food facilities.   | Reduced illness and death from food-borne illness.   |
| <b>CMS Conditions of Participation</b>                  |   |  |             |  |  |
| 1   | 42 CFR Part 484                                 | HHA CoPs Proposed Rule   | CMS         | Remove unnecessary prescriptive and burdensome requirements.   | Increase the amount of time clinicians can spend with patients and lessen time on paperwork. |
| 2   | 42 CFR Part 482                                 | Hospital CoPs Proposed Rule  | CMS         | To reduce burdens and increase flexibility.  | Increase flexibility and lower costs.  |
| 3   | 42 CFR 405                                      | Other facility CoPs  | CMS         | Reduce unnecessary administrative burdens and increase access to care.   | Improved access to care, increased flexibility, and lower costs.                             |
| <b>CMS Review of Appeals process and ALJ provisions</b> |   |  |             |  |  |
| 1   | 42 CFR 405.720 and 722                          | Reconsiderations and Appeals Under Medicare Part A; Hearing; right to hearing.   | CMS/OS-OMHA | Clarify and streamline appeals procedures.   | Eliminate confusion and unnecessary duplication.   |
| 2   | 42 CFR 405.855                                  | Appeals Under the Medicare Part B Program; ALJ hearing   | CMS/OS-OMHA | Clarify and streamline appeals procedures.   | Eliminate confusion and unnecessary duplication.   |
| 3   | 42 CFR 422 and 423                              | Contract Year 2012 Part C & D Final Rule   | CMS/OS-OMHA | Translating the marketing materials will significantly drop the approximate cost of initially translating materials to \$3,304 and the cost of annually updating to \$165 per plan. CMS is investigating translating other Part C and D materials into other languages, so that plans need not undertake the translation themselves. | Substantial  |
| 4   | 42 CFR Part 498                                 | Appeals Procedures for Determinations that Affect Participation in the Medicare Program and for Determinations that Affect the Participation of ICFs/MRs and Certain NFs in the Medicaid Program | DAB         | Remove references to determinations by OIG because superseded by 42 CFR Part 1005  | Eliminate confusion  |
| 5   | 42 CFR 430.2; 42 CFR 457.230; 45 CFR 1355.30(c) | Other applicable Federal regulations; FFP for State ADP expenditures; Other applicable regulations.  | DAB         | Remove outdated references to 45 CFR Part 74 to make regulations consistent with 2003 changes. Public assistance grants to states are now subject to 45 CFR Part 92. See 68 Fed. Reg. 52844 (Sep. 9, 2003).  | Avoid disputes about what requirements apply   |

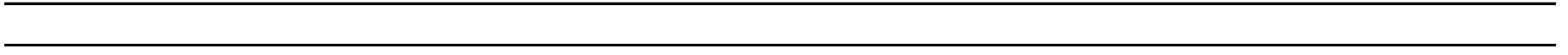
|   | CFR Cite   | Reference  | Agency | Purpose  | Impact  |
|---|--|--|--------|--|---|
| 6   | 42 CFR Part 498.83(d)  | Departmental Appeals Board action on request for review.   | DAB    | Remove outdated reference to Public Health Service and revise to state that "review will be conducted by a panel of at least <i>three</i> members of the Board, designated by the Chair or Deputy Chair," as intended.               | Avoid confusion and possible procedural challenge   |
| 7   | Various provisions under Titles 42 and 45 of CFR (e.g., 42 CFR 457.206@) | Administrative appeals under SCHIP.  | DAB    | Remove outdated references to "Departmental Grant Appeals Board" and replace with "Departmental Appeals Board"   | Eliminate confusion   |
| 8   | 42 CFR Part, 488 Subpart C   | Survey Forms and Procedures  | DAB    | Superseded by 42 CFR Part 488, Subpart E   | Eliminate confusion   |
| <b>Other Reviews Consistent with 13563</b>                          |  |  |        |  |   |
| <b>Reconsideration of Need for Final Rule consistent with 13563</b> |  |  |        |  |   |
| 1   | RIN 0920-AA31  | Possession, Use, and Transfers of Select Agents and Toxins (SARS-Cov and Chapare Virus)  | CDC    | Will merge with Biennial Review of List of Select Agents and Toxins (RIN 0920-AA34).   | More efficient rulemaking   |
| 2   | RIN 0920-AA04  | Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices                      | CDC    | Review of comments to the NPRM indicates that additional analysis is needed to assess the economic impact of its proposed rule. CDC plans to withdraw the proposed rule and consider possible alternative approaches                 | Existing regulations will enforce quality assurance and administrative provisions while it explores alternative approaches.   |
| 3   | RIN 0920-AA36  | Amendments To Establish Wildland Firefighting Protection Performance Requirements for Approval of Respiratory Protective Devices | CDC    | Respiratory Protection requirements were established in a national consensus standard, NFPA 1984, published March 2011. This NFPA standard requires NIOSH certification for respirators fulfilling the requirements of the standard. | NIOSH is considering the possibility of not publishing this Final Rule. Instead NIOSH will rely on the NFPA standard (which requires NIOSH certification) as it provides expected levels of respiratory protection. |
| <b>Increasing Transparency consistent with 13563</b>                |  |  |        |  |   |
| 1   | 42 CFR 422 and 423   | Contract Year 2012 Part C & D Final Rule   | CMS    | This process improves transparency by introducing a formal notice-and-comment process for annual policy changes.   | Increase transparency   |

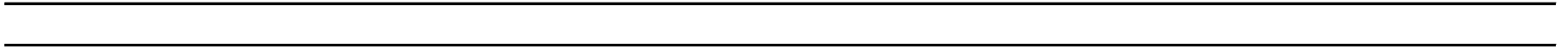
|   | CFR Cite                            | Reference   | Agency   | Purpose   | Impact  |
|---|-------------------------------------|---|----------|---|---|
| 2   | 42 CFR Part 441                     | Home and Community Based Services Waivers   | CMS      | The provision is unnecessary or obsolete because it hinders State Medicaid programs from designing waivers based on functional need and prevents States from consolidating waiver services to multiple target groups. The consolidation of waivers reduces the administrative costs to States for management and oversight, and potentially offers a better tool for State allocation of scarce resources across multiple target populations. | Reduced administrative burdens and costs to states and better tools for states to use in administering the program.   |
| 3   | 45 CFR 60 and 61                    | Merger of the National Practitioner Data Bank for Physicians and Other Health Care Practitioners with the Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers | OIG/HRSA | Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61  | Merging the Data Banks reduces burdens on users by eliminating the need for users to follow two different regulations and pay two separate fees to obtain information; Eliminates OIG and DOJ oversight of the HIPDB. |
| <b>Other Activities consistent with 13563</b> |                                     |   |          |   |   |
| 1   | 42 CFR Part 412                     | Inpatient Rehabilitation Facility Prospective Payment System Proposed Rule  | CMS      | Removes outdated and unnecessary requirements   | Reduce burden and increase flexibility.   |
| 2   | 21 CFR 606 21 CFR 630               | General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification   | FDA/CBER | FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.   | Fulfill requirements of Regulatory Flexibility Act.   |
| 3   | 21 CFR 203 21 CFR 205               | Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures   | FDA/CDER | FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.   | Fulfill requirements of Regulatory Flexibility Act.   |
| 4   | 21 CFR 1002 21 CFR 1010 21 CFR 1040 | Laser Products; Amendment to Performance Standards  | FDA/CDRH | Amending the performance standards for laser products to achieve closer harmonization with the International Electrotechnical Commission (IEC) standards.   | Would harmonize with the IEC and reflect current advances in science.   |
| 5   | 21 CFR 203 21 CFR 205               | Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures   | FDA/CDER | FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.   | Fulfill requirements of Regulatory Flexibility Act.   |

|                                     | CFR Cite                           | Reference   | Agency              | Purpose  | Impact  |
|-------------------------------------|------------------------------------|---|---------------------|--|---|
| 6                                   | 45 CFR 61                          | Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers | OIG/HRSA            | Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61   | Cost savings for organizations and practitioners who have the authority to obtain HIPDB; Time saving for reporters and queries of the Data Bank information; Eliminates OIG and DOJ oversight of the HIPDB. |
| 7                                   | 31 CFR Part 33 and 45 CFR Part 155 | State Innovation Waivers under Section 1332 of the Affordable Care Act  | CMS (with Treasury) | HHS and Treasury jointly-issued a proposed rule allowing States to apply for a waiver of certain statutory requirements of the Affordable Care Act. The waivers will be known as State Innovation Waivers and would promote state flexibility in designing "health care solutions that work best for them." This effort is consistent with E.O. 13563.   | Increase flexibility for States.  |
| <b>Other CMS Rules under Review</b> |                                    |   |                     |  |   |
| 1                                   | 42 CFR Part 416                    | Ambulatory Surgical Centers (ASC) Conditions for Coverage: Same-Day Services Final Rule   | CMS                 | Reduce burden on ASCs and improve timeliness in access to care.  | Improve patient care and reduce burdens on providers and patients.  |
| 2                                   | 42 CFR Part 418                    | Hospice Wage Index PPS Proposed Rule  | CMS                 | The current requirement states that the physician who conducts the face-to-face visit with a Medicare hospice patient prior to recertification must be the same physician who completes the recertification. This may risk access to care for patients in areas of physician shortages, and is burdensome for hospices to implement, given the difficulty some hospices have in obtaining physician resources. | Increase flexibility and reduce burdens on hospice services and physicians.   |
| 3                                   | 42 CFR Part 419                    | Outpatient PPS Proposed Rule  | CMS                 | Revise supervisory requirements.   | Increase flexibility.   |
| 4                                   | 42 CFR Part 416                    | Physician Fee Proposed Rule   | CMS                 | Reduces burden by eliminating unnecessary documentation.   | Reduce burdens and increase flexibility.  |
| 5                                   | 42 CFR Part 412                    | IRF PPS Proposed Rule   | CMS                 | This action will help CMS better meet changing patterns of demand for IRF services. CMS gets numerous questions from providers regarding the interpretation of these requirements because they are difficult to interpret and are repetitive. CMS also believes that these requirements are outdated and are no longer necessary.  | Reduce confusion and eliminate outdated requirements.   |
| <b>Other FDA Rules under Review</b> |                                    |   |                     |  |   |
| 1                                   | 21 CFR 558                         | Veterinary Feed Directives  | FDA/CVM             | Improve efficiency of the process for veterinarians to issue feed directives.  | Streamlined VFDs will assist veterinarians and medicated feed manufacturers.  |

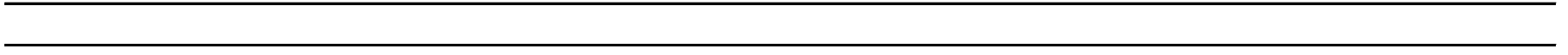
|   | CFR Cite                 | Reference  | Agency  | Purpose   | Impact   |
|---|--------------------------|--|---------|---|--|
| 2 | 21 CFR 514 21<br>CFR 510 | New Animal Drugs—Records and Reports concerning experience with approved drugs and medicated feeds | FDA/CVM | Reviewing regulations to determine how to clarify, streamline, and harmonize.         | Aligning with international standards and clarifying requirements will result in improved reporting by sponsors. |
| 3 | 21 CFR 58                | Good Laboratory Practice for Nonclinical Investigations  | FDA/OC  | Review standards for nonclinical investigations to determine how best to update them. | Update standards for nonclinical investigations.   |

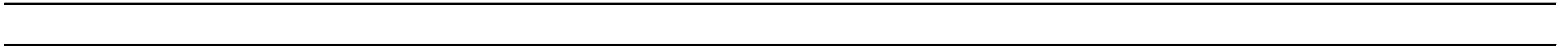


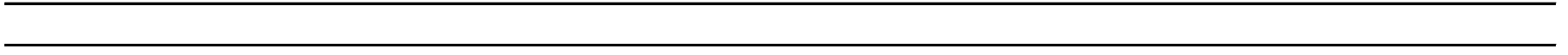


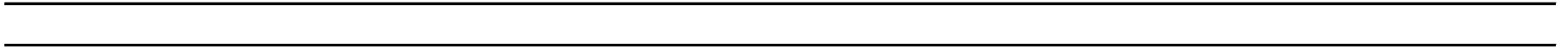












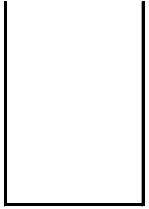
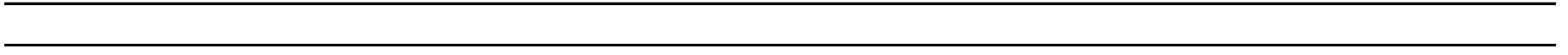
---

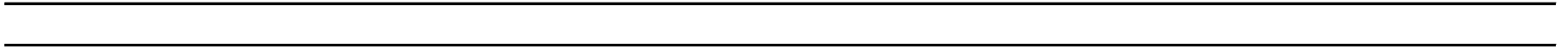
---

---

---

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |







|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

The image displays a grid with 10 columns and 12 rows. The grid is defined by black lines. The first two rows are partially cut off on the left side. Starting from the third row, there are three red horizontal lines positioned between the black grid lines. This pattern of three red lines between black lines repeats for the next two rows, then for the next two rows, and finally for the last two rows of the grid.





|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |



A 13x13 grid is shown. The grid consists of 13 columns and 13 rows. A thick red horizontal line is drawn across the grid, passing through the middle of the 6th row from the top. The grid lines are black and the background is white.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

A grid consisting of 13 columns and 10 rows. Two horizontal red lines are drawn across the grid. The first red line is positioned between the top row and the second row. The second red line is positioned between the third row and the fourth row.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |







|  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |









|  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |





|  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

## APPENDIX B

### SUMMARY OF PUBLIC COMMENTS

HHS posted a request for comment in the Federal Register on April 23, 2011, asking for comment on how it should structure its retrospective review plan and prioritize regulations for retrospective review. By the close of the comment period on May 12, 2011, HHS had received 21 comments on specific elements and priorities, to be incorporated into HHS's preliminary plan, including the following:

- **Schedule for Ongoing Review.**

Commenters offered a number of suggestions for the timeframe for periodic review ranging from every four to 10 years. One commenter cautioned that HHS should be careful not to schedule the review of existing rules so early as to reduce the ability or incentive for the industry to adapt.

- **Process for Setting Priorities.**

Commenters suggested requiring each agency to develop a ten year strategic plan to identify the regulations, policies, and related guidance and procedures that will be reviewed, using the advice and counsel of a panel of topic experts and representatives of principal stakeholders. Commenters also recommended that the retrospective review be undertaken by a team independent of the staff responsible for the rule during the proposal stage. One commenter suggested that agencies should not limit the scope of their retrospective review plans to promulgated rules, recommending that the review also include decisions to deregulate, denials of public petitions for regulation, and significant areas of inaction. Commenters recommended prioritizing rules for which retrospective review would be most valuable and that agencies establish clearly articulated criteria that will assist interested parties anticipate which rules an agency is likely to review. Several commenters suggested specific criteria for setting priorities, including significant regulations that:

- ✓ were related to a significant change in circumstance so that another opportunity is not provided "for interested groups to rehash arguments and facts presented during the initial notice and comment rulemaking process."
- ✓ imposed significant implementation burdens;
- ✓ implicated the protection of confidential information;
- ✓ were targeted toward the elimination of regulatory duplication or the need to clarify unclear or confusing rules;
- ✓ Were the subject of advances or changes in technology
- ✓ may serve either explicitly, or in practice as pilot programs for more expansive regulation or novel regulatory strategies; or

✓ do not add value or enhance accountability.

Commenters recommended that as agencies gain experience with retrospective review and develop best practices over time they should update and improve their retrospective analysis guidelines and share any best practices with other agencies in the federal and state bureaucracies.

Although the request for comment did not specifically solicit comment on the scope of the preliminary plan, several commenters urged the Department to include guidance documents, particularly those that have been issued to provide interpretation of regulations, and an assessment of paperwork burdens as part of the retrospective review.

- **Public Participation.**

Several commenters supported HHS's goal of using new technologies to increase public participation in its rulemaking, but cautioned that these efforts should not replace the formal public comment requirements of the Administrative Procedures Act.

Commenters recommended that the agency notify the public when it is considering selecting specific rules for retrospective review and when it initiates the retrospective review process, as well as what action it intends to take as a result of the review. Commenters urged the Department to consult with outside experts when setting review priorities. Other commenters urged greater consultation with stakeholders or established working groups, prior to sending a regulation or guidance document for review to the Office of Management and Budget, and the creation and use of more specialty-tailored listservs.

Several commenters suggested greater use of town hall meetings and other public forums during the informal rulemaking process; however other commenters cautioned against the use of town hall meetings, noting that town hall meetings that are not purposeful or do not provide adequate advance information are not meaningful. Suggestions also include surveying stakeholders to determine whether the goals of a regulation and/or policy are being met and whether modifications could reduce the administrative and financial burdens of a regulation while still achieving its original objectives. Another commenter suggested establishing an online tool or an email address for the public, to flag existing rules that have become outdated or need to be modified.

With respect to the time afforded for public comment, one commenter suggested extending the comment period for all rules to 120 days. Other commenters supported a phased comment period, in which the agency could make an initial request for comments on a proposed rule, organize and

summarize those comments by topic, and then publish that summary asking for additional comments on the proposal.

- **Analysis of Costs and Benefits.**

Several commenters emphasized that HHS already has the tools in place to appropriately analyze costs and benefits, including the issuance of a Request for Information as an initial step to seek input on how a particular statutory requirement can best be implemented; and urged the use of surveys and studies to evaluate the potential impact of regulatory initiatives. One commenter also recommended that accounting mechanisms be built into new regulations as a means of reducing costs and improving the quality of subsequent retrospective reviews. One suggestion for recommendations on how to do so included the guidelines outlined in the European Commission's Impact Assessment Guidelines.

One commenter recommended that attention also be paid to the distributional impact of regulations, arguing that in addition to the aggregate costs and aggregate benefits, the distribution of those costs and benefits is relevant to decisionmaking as well. Commenters also recommended that the full range of distributive impacts should be addressed, rather than focusing exclusively on the impacts to a single community, like small businesses.

Other commenters urged specific recommendations to reduce burdens; for example, one commenter urged HHS to consider a special category or exemption, like the exemptions afforded small businesses, for research contracts or for institutions of higher education, hospitals and other non-profit organizations that fall under the uniform administrative requirements for grants and agreements.

- **Coordination with Other Departments.**

Commenters strongly supported efforts to consider the combined effects of regulations, and urged greater coordination among federal agencies and the agencies of HHS in their rulemaking. Several commenters offered specific suggestions where greater coordination would be beneficial, including several that are included in the initial list of candidate regulations appended to this plan including: the coordination of reporting metrics, reporting periods, and reporting mechanism across programs.

## **SPECIFIC SUGGESTIONS FOR CANDIDATE RULES TO REVIEW**

In addition to providing responses to the questions posed, a number of commenters also took the opportunity to suggest specific candidate regulations for retrospective review. These regulations will be reviewed and considered in conjunction with the

additional public comment the Department expects to receive on the Preliminary Plan. Specific Regulations nominated as candidate regulations for retrospective review, include:

- Requirements to provide translators for Medicare and Medicaid patients with hearing impairments or limited English proficiency.
- Integration and coordination of reporting requirements for overlapping incentive programs, such as the Physician Reporting system (PQRS), e-prescribing, and meaningful use of electronic health records.
- Streamlining of claims review by multiple contractors including Medicare Parts A and B Recovery Audit Contractors, Medicare Administrative Contractors, Medicaid Integrity Contractors, Comprehensive Error Rate Testing Contractors, and Zone Program Integrity Contractors, which were presented as often redundant.
- Expedited implementation of ACA's administrative simplification provisions relating to the standards and operating rules for the electronic exchange of information that are intended to address patient eligibility and financial responsibility; timely acknowledgement, response, and status reporting consistent with a transparent claims and denial management process; and the description of administrative data that inform physicians when a service has been denied and the reason for the denial, efforts that could significantly reduce the administrative complexity of the claims processing cycle.
- Review of the pre-Authorization requirements for drug and Medicare Advantage plans
- Review of Emergency Medical Treatment and Labor Act (EMTALA) requirements
- Review of Medicare documentation requirements
- Updates to the Medicare Economic Index (MEI)
- Review of the prohibition on the use of consultation codes in favor of lower valued visit codes
- Improvements to the Medicare Enrollment Process
- Improvements on the timeliness of PQRS Feedback Reports to allow physicians to assess their reporting and performance status in time to revise their reporting practices to be a successful participant.
- Improved education and outreach to physicians about new requirements
- Suggestions for cross Department collaboration between CMS and DEA to secure a change in DEA policy to allow nurses at long term care facilities to act as agents of physicians in communicating with pharmacists.
- Coordination of the regulation developed by HHS, Department of Labor, and the IRS relating to Wellness Programs, with overlapping guidance on the same subject by the Equal Opportunity Commission.
- Coordination of the CDC select agent regulation with the Department of Agriculture select agent program.
- Coordination of Privacy Act requirements with the "Common Rule."



- Harmonization of the human subjects protections between the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA)
- Elimination of the Health Insurance Portability and Accountability Act (HIPAA) requirements from research, or suggestion to harmonize HIPAA regulations with OHRP regulations.
- Review of Expanded Form 1099 reporting requirements for an assessment of whether additional requirements create additional burden.
- Modification of requirements on sub-recipient monitoring so that grantees are no longer required to monitor sub-recipients who regularly receive federal awards.
- Alignment of regulations of the Office of the National Coordinator (ONC) with other HIPAA and ACA requirements.
- Review of requirements related to Medicare's Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) Adjustment, including Medicare policies of counting resident time for DGME and IME payment purposes; cost reporting required by GDME and IME-related information hospitals; and the IRIS system.
- Requirements under the current Conditions of Participation that require all verbal orders to be dated, timed, and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient to authenticate the order.
- Requirements for participation in Medicare's Provider Enrollment and Chain Ownership (PECO) system for all services
- Call for additional flexibility in physician self-referral regulations
- Call for greater flexibility in OIG regulations so that they incorporate changes occurring in the health care system.
- Reduction of requirements that are duplicative of the A-133 audit as required under the Single Audit Act.
- The prohibition of voluntary committed cost sharing across the Federal government and create a mandatory cost sharing exemption for research universities.