

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
*Plan for Retrospective Review of Existing Rules*  
August 22, 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 payment. 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 affordable insurance exchange requirements.

In Executive Order 13563, the President recognized the importance of a streamlined, effective, efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. 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; and
- 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 five principal goals:

- Streamline or eliminate unjustified costs and burdens;
- Increase transparency in the retrospective review process;
- Increase opportunities for public participation;
- Set clear retrospective review priorities; and
- 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.

Among the highlights of this plan are reforms, completed or proposed, that will save hundreds of millions of dollars annually. In a major initiative, for example, CMS has conducted a retrospective review of the conditions of participation it imposes on hospitals to remove or revise obsolete, unnecessary, or burdensome provisions. The goal of the retrospective review is to identify opportunities to improve patient care and outcomes and reduce system costs by removing obsolete or burdensome requirements. *CMS intends to publish a proposed rule on*

*this subject in September 2011 and currently estimates that the revisions may save as much as \$600 million annually and \$3 billion over five years. A related reform from CMS, described in detail on page 16, may save as much as \$200 million. Additionally, CMS has also recently issued a final rule to permit hospitals to use telemedicine to obtain services from a practitioner credentialed at a 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 and, by not requiring providers to be credentialed by every facility in which they are providing a service via telemedicine, it will reduce provider burden. CMS estimates that roughly \$13.6 million in annual net savings to hospitals will result from this initiative, which it published as a final rule on May 5, 2011.*

HHS emphasizes that Executive Order 13563 calls not for a single exercise, but for “periodic review of existing significant regulations,” with close reference to empirical evidence. It explicitly states that “retrospective analyses, including supporting data, should be released online wherever possible.” Consistent with the commitment to periodic review and to public participation, HHS will continue to assess its existing significant regulations in accordance with the requirements of Executive Order 13563. HHS welcomes public suggestions about appropriate reforms. If, at any time, members of the public identify possible reforms to streamline requirements and to reduce existing burdens, HHS will give those suggestions careful consideration.

## **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 has already asked each agency to inventory its existing, significant regulations to provide information that will assist the Department in structuring an ongoing retrospective review process. Specifically, each agency initially reviewed its existing regulations to develop a proposed list of regulations the agency expected to review over the course of the next two years. HHS then took the agencies individual lists to compile the list of regulations proposed for review and identified in this Plan, including the chart of regulations in Appendix A.

Next, HHS will ask agencies to identify those significant regulations that have not been reviewed, but continue to be operational for at least five years since they were originally promulgated. HHS will then set forth a compilation of those potentially outdated regulations for review and identify the review authority (e.g., required by authorizing or other statute, response to citizen petition, pursuant to regulatory review requirements, etc.) applicable to that review. HHS expects to complete this task by the end of December.

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

On an ongoing basis, HHS receives suggestions about what regulations need review and possible change. Many of these suggestions come through correspondence, meetings with stakeholders, town hall meetings, public comment on proposed and final regulations, and other activities. Some of these suggestions resulted in the agency determinations about which regulations would be good candidates for a retrospective review in accordance with this retrospective review Plan. HHS has also received suggestions through public comment on this Plan. Those suggestions were shared with the agencies for consideration when revising this Plan and will be used in future regulatory review and development activities. HHS will continue to receive suggestions through these traditional avenues, as well as through various internet portals as it develops its broader regulatory reform capacity over the next few years.

#### **c. Setting Priorities**

For the initial retrospective review, existing resources do not allow the Department to undertake a detailed analysis on each regulation proposed for review, so

the priority was first, to identify regulations that agencies could easily modify, streamline, or rescind to address regulatory burdens or inefficiencies, and second, to identify regulations that may be ripe for review because of changes in circumstance. These proposed candidates for review were then divided into categories in accordance with the guidelines set forth by the President in Executive Order 13563, including those candidate regulations that:

- Require updating in recognition of changing technology;
- May be revised to reduce the reporting and recordkeeping burdens;
- Can be cleaned up to eliminate outdated provisions; or
- Can be modified to increase flexibility and reduce burdens on states.

On an ongoing basis, 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. In particular, HHS will emphasize a review of its regulations that will have the greatest potential to alleviate unnecessary burdens and costs or to promote flexibility and create jobs.

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

For those regulations undergoing an extensive and thorough review, the Department will assist agencies in conducting a sound regulatory analysis to determine whether the regulatory activity is meeting the original objectives or whether an alternative, less prescriptive activity would achieve the same result. In the latter case, the Department will explore other alternatives, including the use of guidelines, incentives, public disclosure, and similar non-regulatory measures that might be used to achieve the same outcome as prescriptive regulations. In addition, the Department will also consider how regulations might be designed and written in ways that facilitate evaluation of their consequences and thus promote retrospective analyses and the measurement of actual results. For example, it may consider the use of experimental or quasi-experimental designs, including randomized controlled trials, when promoting the empirical testing of the effects of rules. Two examples are given immediately below.

**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 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.
- Yearly appropriations require review and publication of Medicare 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; and
- 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. 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.

**VI. Some highlights of the initial list of significant rules that are candidates for retrospective review and other activities in response to E.O. 13563:**

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.**

a. **Use of Telemedicine to Increase Access** – CMS provides for access to care for beneficiaries in rural and critical access areas through telemedicine. CMS permits hospitals to use telemedicine to obtain services from a practitioner credentialed at a 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 and, by not requiring providers to be credentialed at by every facility in which they are providing a service via telemedicine, it will reduce provider burden. *CMS estimates that roughly \$13.6 million in net savings will result from this initiative, which it published as a final rule on May 5, 2011.*

b. **FDA's Bar Code Rule** –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 National Drug Code number. The rule also requires the use of machine-readable information on blood and blood component labels.

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 system was intended to 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 prevent nearly 500,000 adverse events and transfusion errors over 20 years. FDA estimated the economic benefit of avoiding these adverse events to be \$93 billion over the same period.

Because the Rule has been in effect for almost eight years, FDA has determined that it is a good candidate for retrospective review to assess the estimated savings and impact on adverse events. The goal of the review will be to evaluate the costs and benefits of the existing Rule and to determine if it should be modified to take into account changes in technology that have occurred since the Rule went into effect. FDA intends to publish by the end of August 2011 a request for comment to initiate the review of this Rule and help FDA evaluate alternative technologies.

c. **Increase Use of Electronic Reports and Submissions** – FDA is embarking on a major campaign to revise its regulations to increase 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.

d. **Aligning the Electronic Health Record Incentive Program with Other Electronic Reporting Systems** – CMS intends to eliminate outdated or redundant quality measures and standardize reporting methods. In particular, CMS is looking at aligning the reporting for electronic prescribing requirements under the electronic prescribing program and EHR Incentive Program in Medicare. This initiative should reduce confusion in the physician community and reduce the reporting and paperwork burdens throughout the industry. *The proposed rule was issued on June 1, 2011, and CMS intends to publish the final rule in September 2011.*

2. **Review reporting, recordkeeping, and other requirements to reduce burdens.**

a. **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.

b. **Revisions to the Health Insurance Portability and Accountability Act Privacy Rule** – OCR is undertaking a number of revisions to the HIPAA Privacy Rule to reduce burden and increase flexibility, while maintaining or strengthening important privacy rights for individuals with respect to their health information. This includes a change to facilitate the disclosure of student immunization records to schools, which will reduce paperwork burden on both parents and health care providers, and help avoid delays in children beginning school. OCR has also proposed changes that would ease burdens on health plans associated with distributing notices of privacy practices, *which could save health plans a total of up to 2,000,000 burden hours and \$120,000,000*, while still ensuring that beneficiaries continue to receive timely notice of material changes to such privacy practices. In addition, in collaboration with CMS, changes are being considered to remove impediments to the ability of individuals to access their own health information held by laboratories.

c. **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.

d. **Eliminate Requirement for Actuarial Reporting for Hospital Pension Costs** – CMS has finalized 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 will relieve hospitals of an unnecessary and burdensome reporting requirement. CMS estimates that hospitals will save \$375,000 annually.

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

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

In a non-rulemaking 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 payment 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. Each agency proposes 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 the Children's Health Insurance Program to create more options for providing 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

a. Revisions to the Rules Protecting Human Subjects of Research – In a major undertaking, HHS, together with the President's Office of Science and Technology Policy, is leading the effort to review and revise the Common Rule that over 20 years ago established the guidelines for protecting humans when they are subjects of scientific research. A total of 16 federal departments and agencies also follow this rule. It has, however not kept pace with the evolving human research activity, the proliferation of multi-center clinical trials, the expansion of health services research, and the use of advance technologies.

A revised rule could eliminate unnecessary Institutional Review Board reviews and enable them to better focus their resources on review of research protocols that pose greater than minimal risks to subjects. A revised rule might also improve mechanisms for collecting information to evaluate the effectiveness of research oversight systems and facilitate research by reducing unnecessary burdens on institutions and investigators. Revisions could better protect human subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators and research subjects.

HHS published an Advance Notice of Proposed Rulemaking on this topic on July 26, 2011, asking for comment on how HHS might modernize and revise current regulations for protecting human subjects who participate in research to make them more effective. This

ANPRM seeks comment on how to better protect human subjects who are involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. Based on the comments it receives in response to the ANPRM, HHS will proceed to develop and publish a proposed rule for additional public comment.

**b. Modifications to the HIPAA Privacy Rule to Streamline 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. These changes will provide increased flexibility for researchers and reduce paperwork and burden. 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.

**c. Peer Review of Research Grants and Contracts** – 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 will help FDA more quickly review these reports and identify emerging public health issues.

Second, FDA intends to 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.

FDA believes that reducing the burdens imposed by medical device regulations will result in a general costs savings across the board. *Electronic submissions for adverse event reporting will eliminate the need for paper copies and will reduce processing time. Reduced processing time will increase efficiencies.* The regulated industry will benefit by eliminating the cost of paper submissions including delivery costs and the consumer will benefit because FDA will be able to receive, process, and react to submissions of adverse events more quickly and efficiently leading to increased public health benefits.

*Reducing the level of classification where appropriate, while still maintaining safety and effectiveness of certain products will also lower costs.* Industry will benefit because the costs for submissions required to reach the market will be reduced and the consumer will benefit because safe and effective products will arrive in the market place more efficiently.

## **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. This initiative may also include 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, more informed 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.

CGMP regulations, or changes to them, do not generally reduce costs, though there is a presumption of unquantifiable public health benefits from good manufacturing practices. Examples of such benefits include supply chain security for drugs and establishment of preventive controls for food facilities, which improve product safety and reduce the harms associated with poorly manufactured or produced products.

## **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 would 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 has conducted a large-scale 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 over decades, reflecting new legislation, changes in technology or medical practice, and evolution of the health care delivery system. While each of these requirements reflects concerns for improving patient safety or solving problems, their cumulative effect may have actually increased burdens on hospitals and health care providers, thereby increasing inefficiency and risk in providing good patient care.

The goal of the retrospective review is to identify opportunities to improve patient care and outcomes and reduce system costs by removing obsolete or burdensome requirements. *CMS intends to publish a proposed rule on this subject in September 2011 and currently estimates that the revisions may save as much as \$600 million annually and \$3 billion over five years.*

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

CMS has also initiated an Alignment Initiative to identify and address conflicting requirements between Medicaid and Medicare that create potential 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 CMS's three-part aim, comprised of 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

*CMS published the Notice pursuing alignment opportunities on May 16, 2011.* CMS received over 100 responses from beneficiaries, advocates, professional health associations, plans and States on improving care for Medicare-Medicaid enrollees. Section 2602(c) of the Affordable Care Act established specific goals, and the Alignment Initiative has provided an effective means to engage the public and help meet these goals. CMS is currently working through the comments and will be developing a work plan identifying next steps to improve coordination between the programs.

#### **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 has undertaken will result in a new rule to implement a new reconsideration process for states when CMS disallows federal funds participation and will 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 should 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. *Additionally,*

*the regulation will provide savings to states as they can spread their repayment to the federal government over a longer period of time. The proposed rule for these new repayment options published on August 3, 2011.*

#### **9. Promoting Efficiency, Transparency, and Burden Reduction**

CMS will propose reforms in Medicare and Medicaid regulations to increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or divert activities away from providing high quality patient care. The proposed rule will eliminate or modify many existing requirements imposed on health care providers. Slated for inclusion in this reform are:

- Existing rules relating to the list of operating room emergency equipment that must be available in an ambulatory surgery center and a duplicative infection control program requirement for those facilities;
- Rules barring reenrollment for failure to respond to requests for information; rules governing deactivation of providers and suppliers; and
- Permitting greater flexibility for meeting the conditions of participation for Intermediate Care Facilities for the Mentally Retarded.

Other changes to eliminate redundant or unnecessary rules are also contemplated. *CMS estimates that the total savings from these reforms could approach \$200 million CMS intends to publish the proposed rule in September 2011.*

#### **10. 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 final rule for hospice care that would eliminate the requirement that the physician who performs a face-to-face encounter be the same physician to certify continued need for those hospice 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, CMS determined that a previous regulation requiring that physicians or non-physician practitioners to 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 has approximately 80 reform proposals under review and development. CMS plans to present the proposed reforms to HHS leadership throughout the summer of 2011. These reforms may 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 barriers to efficient and effective patient care will be substantial.

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

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

As noted, Executive Order 13563 calls not for a single exercise, but for “periodic review of existing significant regulations,” with close reference to empirical evidence. The Department invites public suggestions about appropriate reforms at any time and will give them careful consideration.

### **a. Streamline or eliminate unjustified costs and burdens:**

The overarching goal of ongoing retrospective review is to streamline regulations the Department promulgates and to eliminate unnecessary, costly, or burdensome regulations wherever possible. Particularly in the current economy, regulations that interfere with the ability of industry to responsibly carry out production of goods and services in response to consumer demand and to create jobs in the process are unproductive. On the other hand, this Department has a mission and responsibility to protect public health and safety and this mission and responsibility must take priority. It is only by maintaining a robust and healthy workforce and citizenry that the nation’s economy will grow and prosper. This Department will continue to be sensitive to the need to promote the economic health of the nation without sacrificing the health and welfare of the American people.

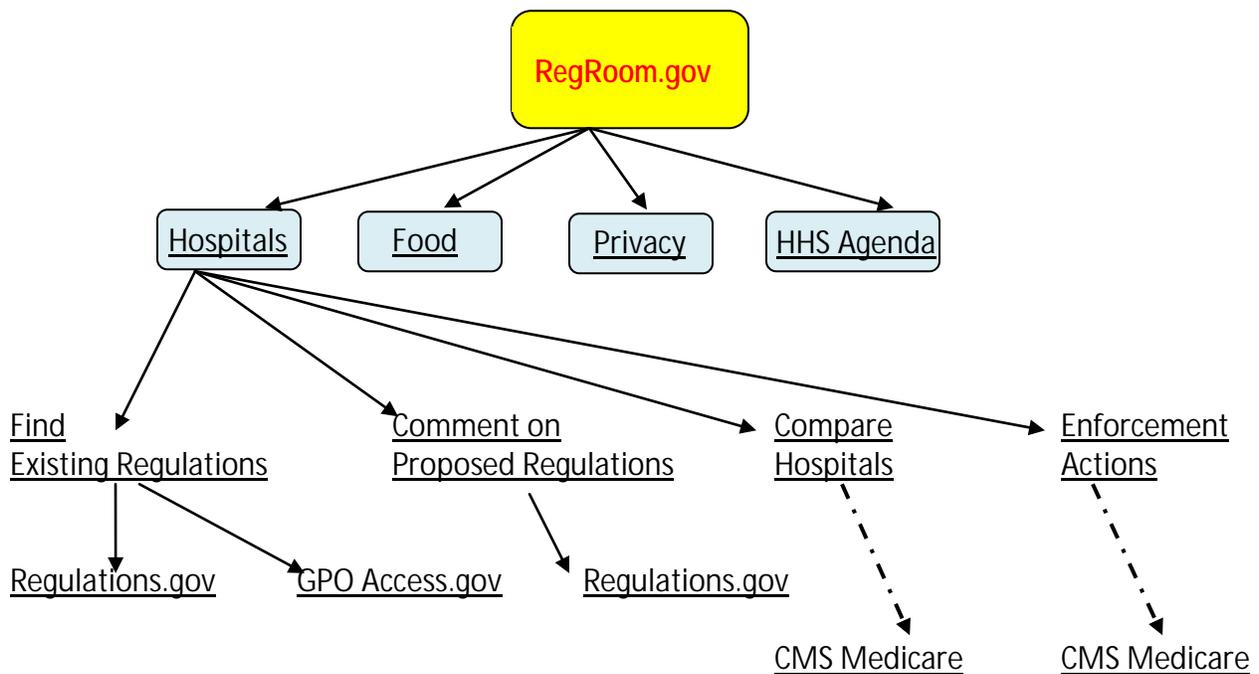
### **b. Increasing Transparency:**

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 – 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 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 is 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 plain language 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.

c. **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 additional public comment on the complete HHS Preliminary Plan. A summary of comments submitted in response to the requests for comment on elements to be considered in drafting the plan are at Appendix B and on the complete HHS Preliminary Plan are at Appendix C.

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 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>1</sup>

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<sup>1</sup> <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm251751.htm>

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. The Task Force will 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 these technologies to great advantage. Other agencies can usefully enhance the regulatory review and development process by increasing 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 geared toward increased public participation and transparency in the ongoing review of regulations throughout the Department. These principles will help agencies think about innovative ways to involve interested parties in the retrospective review process so they can more easily react to and benefit from the comments, arguments, and information of others as they refine their own comments. Among the principles to be considered are:

- Active engagement with thought-leaders through meetings and sponsored listening sessions on specific regulatory reform proposals. Thought-leaders might include the regulated community, affected groups, academics, and public interest groups, as well as 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.

#### d. 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.

Several commenters stated strong views about the guidelines for selecting candidate regulations subject to review. Some suggested that review should occur only after sufficient time has elapsed for meaningful evaluation of a rule's performance or whether changed circumstances, scientific advances, or technology warrant review of a rule. Others suggested fixed time periods for review ranging from every four to every 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. While agencies did not necessarily factor in the length of time a regulation has been in effect in developing the list of initial candidates for review, HHS will take these suggestions into account as it moves forward with its ongoing retrospective review process.

Fundamentally, however, retrospective review priorities are 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; and
- Whether there are significant, unresolved issues with implementation or enforcement
- 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.

e. **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. To assist with this, HHS agencies will share online both internally and with stakeholders and the public prior regulatory impact analyses and evaluation studies pertaining to HHS regulatory requirements.

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. Public commenters also suggested 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 federal and state agencies. As a staff office to the HHS Secretary and independent of operating divisions that draft regulations, ASPE is well positioned to assist with this effort. 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.

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

Dawn Smalls, Executive Secretary