

**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.

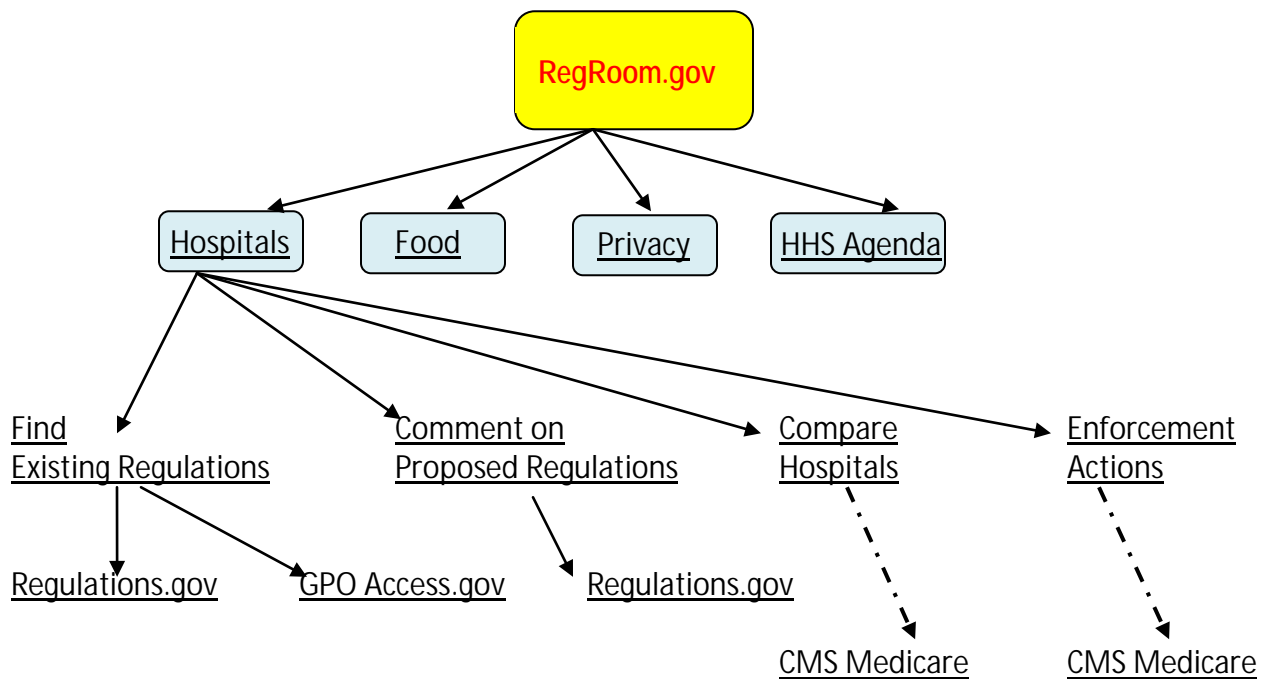
### **b. Increasing Transparency:**

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

APPENDIX A

	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	AHRO	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 AHRO 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.
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.	Published May 11, 2011. Expected to increase access to health care providers and reduce costs. CMS estimates \$13.6 million in net annual savings to hospitals from this initiative.
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.



	CFR Cite	Reference	Agency	Purpose	Impact
3	42 CFR 71.53 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 Final 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.	Published August 1, 2011. Expected to provide flexibility to reduce burdens and costs.
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 disclosures, 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 have an impact on 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	This rule will propose changes to reduce administrative burdens on health plans while still ensuring individuals are notified of material changes to privacy practices.	OCR estimates that this rule will achieve a one-time net savings of \$120 million with an associated reduction of 2 million burden hours. Savings are expected to accrue to both public and private health plans within 60 days of the compliance date of the regulation.
<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. Such flexibility will expand the number of patients receiving this form of treatment and potentially reduce costs associated with drug related crime because more patients are receiving treatment.
<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.
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.

	CFR Cite	Reference	Agency	Purpose	Impact
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 to the current provision that, for purposes of determining the time-eligibility period, States' most current reported administrative costs are both inflated by the CPI and adjusted by changes in program participation. The adjustment by changes in participation has not proved useful, over the 20 years that this methodology has been implemented, in projecting administrative costs. HHS will consider options to produce more accurate estimates of State administrative costs.	Changes will streamline and produce more accurate estimates of administrative costs.
<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.	We 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	HIPAA 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
3	45 CFR part 46, 160, 164 and 21 CFR 50 and 56	Protection of Human Subjects in Research (the Common Rule)	HHS with OSTP	The Advance Notice of Proposed Rulemaking seeks public comment related to the ethics, safety, and oversight of human research. Revisions to the Common Rule might enable Institutional Review Boards (IRBs) to better focus their resources on review of research protocols that pose greater than minimal risks to subjects; improve the mechanism for collecting information to evaluate the effectiveness of the research oversight system in protecting human subjects; and facilitate research by reducing unnecessary burdens on institutions and investigators.	Better protection of human subjects who are involved in research, while facilitating, valuable research, and reducing burden, delay, and ambiguity for investigators and research subjects.
<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 CFR 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.
<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.
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	Home Health Agency CoPs Proposed Rule	CMS	Remove unnecessary prescriptive and burdensome requirements to reflect current practice and streamline operations.	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	Remove or revise multiple requirements that are inconsistent with other requirements or impose unnecessary burdens to increase flexibility.	Target to publish the proposed rule is September. Estimated net savings to hospitals could reach at least \$600 million annually; \$3 billion over 5 years.
3	42 CFR 405	Proposed Rule for Non-Hospital Facilities on Provisions to Promote Program Efficiency, Transparency, and Burden Reduction	CMS	Revise or eliminate provisions affecting non-hospital providers that are unnecessary, obsolete, or excessively burdensome.	Target for publication is September 2011. Improved access to care, increased flexibility, better quality and lower costs. CMS estimates the net savings to End Stage Renal Disease facilities, which will be affected most by these changes, could approach \$200 million in the aggregate.
<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.

CFR Cite	Reference	Agency	Purpose	Impact	
3	42 CFR 422 and 423	Contract Year 2012 Part C & D Final Rule	CMS/OS-OMHA	Translating the marketing materials for plan sponsors will result in significant savings to plan sponsors. CMS estimates per contract savings to be \$15,200 for the first year of translation and \$750 for annual updates for each of 305 sponsor contracts. CMS is investigating translating other Part C and D materials into other languages, so that plans need not undertake the translation themselves.	CMS estimates that net savings to plan sponsors could be as high as \$4.6 million for 2012 and \$230,000 for subsequent years.
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
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	CMS began annual rulemaking to promote transparency, enhance beneficiary protections, fine-tune policy, improve CMS oversight of its contracts, and eliminate duplicative and outdated regulations. Both the industry and the advocacy community have been supportive of annual rulemaking as a way of increasing transparency in CMS' policy development process. The industry wants the annual regulations published as early as possible in the year to allow maximum time to implement policy changes prior to the bid submission deadline for the following contract year (first Monday in June).	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 Final Rule	CMS	Removes outdated and unnecessary requirements, including change in ownership regulations and mergers and acquisitions. 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.	Published July 29, 2011. Expected to 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 more closely 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.
6	45 CFR 61	Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers	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 administration 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 by allowing patients' rights information to be given on the day of the services.	\$50 million in savings annually--Savings in patient time of \$35 million; \$17.5 million in savings for providers.
2	42 CFR Part 418	Hospice Wage Index PPS Final 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.	Published on July 29, 2011. Expected to increase flexibility and reduce burdens on hospice services and physicians.

	CFR Cite	Reference	Agency	Purpose	Impact
3	42 CFR Part 416	Physician Fee Proposed Rule	CMS	Remove the new lab signature requirement that the physician sign orders for a clinical lab test. Reduces burden by eliminating unnecessary documentation. The physician, clinical laboratory, and nursing home community perceive the existing requirement to be a significant additional burden; and the clinical laboratory industry believes they will not be paid for many laboratory tests because they do not anticipate full compliance.	Published July 19, 2011. Expected to reduce burdens and increase flexibility.
	42 CFR Part 440	Home Health Face-to-Face Requirement	CMS	Align this requirement for Medicaid with the existing requirement for Medicare that physicians document a face-to-face encounter with the Medicaid beneficiary within certain timeframes.	Published July 12, 2011. Expected to reduce unnecessary burdens of two different requirements. CMS's Office of the Actuary estimates that the net savings from this change will result in savings to Medicare of roughly \$870 million over ten years.
<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.
2	21 CFR 514 21 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.

## 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, on HHS's preliminary plan. All responses have been forwarded for agency review, but HHS provides the following summary and its response where appropriate in green:

- **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.

**RESPONSE:** At this time, HHS is not defining a specific period for periodic review since appropriate periods may differ depending on the regulation. Instead, HHS will revisit this issue following the reports of the Analytics Team and the Public Participation Task Force and make a determination at that time.

- **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:

- ü 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."
- ü imposed significant implementation burdens;
- ü implicated the protection of confidential information;

- ü were targeted toward the elimination of regulatory duplication or the need to clarify unclear or confusing rules;
- ü Were the subject of advances or changes in technology
- ü may serve either explicitly, or in practice as pilot programs for more expansive regulation or novel regulatory strategies; or
- ü 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.

**RESPONSE:** All of these comments have been passed on to the Analytics Team for its consideration as it develops its recommendations for setting priorities and increasing the robustness of the Department's analytic capacity.

- **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.

**RESPONSE:** Some of these comments are already incorporated into the HHS Plan. For example, HHS intends to increase public access for comment and input in its regulatory activities through the single portal web access button currently under development. With respect to comments on the length of comment period, some agencies already provide for a period of 120 days in many cases. Other regulations that respond to statutory requirements cannot provide for that length of comment period without missing the statutory deadline. In particular, Medicare payment rules that must be promulgated every year have limited public comment periods by necessity, since providers must have sufficient time to plan their potential revenue base for the upcoming year. All other comments have been passed on to the Public Participation Task Force for review as it develops its recommendations for increasing public participation in the review and development of HHS regulations.

- **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 decision-making 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.

**RESPONSE:** All of these comments have been passed on to the Analytics Team for its consideration as it develops its recommendations for increasing the robustness of the Department's analytic capacity, particularly with respect to cost-benefit analysis.

- **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 suggestions, in conjunction with the additional public comment the Department received on the Preliminary Plan, have been forwarded to the appropriate agency for consideration in developing revisions to existing regulations or proposed new regulations. 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.

**RESPONSE:** CMS will be addressing these suggestions in forthcoming regulations as reflected in the Department's Regulatory Agenda for the upcoming fiscal year.

- 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.  
**RESPONSE:** CMS is addressing these suggestions in the forthcoming administrative simplification rules.
  - 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).  
**RESPONSE:** The Department has published an Advance Notice of Proposed Rulemaking on this subject to begin to address this issue.
  - 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.  
**RESPONSE:** These requirements are under review as part of the revisions to Hospital Conditions of Participation, anticipated to be published as proposed new rules in September 2011.
- 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.

## APPENDIX C

### *Public Comments on HHS Preliminary Plan for Retrospective Review of Existing Rules*

Most commenters wrote of general support for the Preliminary Plan.

- “Both Executive Order 13563 and HHS’[s] Preliminary Plan for Retrospective Review of Existing Rules demonstrate a commitment to striking a proper balance when crafting regulations,” one said.

Another “strongly supports the four goals of the HHS retrospective review: transparency, increasing opportunities for public participation, setting retrospective review priorities, and strengthening the analysis of regulatory options.”

But all, of course, had various and varying tweaks they would like to see incorporated in the final version.

More an observation that a suggestion, one commenter observed “the increasingly haphazard manner in which regulatory policies are being issued and the effect that it is having on hospitals’ ability to know what the rules are and where to find them.”

Another noted that “it seems HHS is prioritizing reviews of inefficient paperwork or other reporting burdens,” but “the appeal of these low-hanging fruit should not monopolize the agency’s attention or distract it from other opportunities to use retrospective review to enhance net benefits.”

And a commenter said, “the current [Medicare Secondary Payer] regulation has not been updated in over 15 years,” asserting “the MSP system is not only failing to achieve its objectives, it is actually working against its stated goals. They specifically “urge HHS to include the MSP regulations, 42 C.F.R. Part 411, as well as the sub-regulatory industry guidance, in the list of regulations for retrospective review. The MSP regulations need to be updated for the 21<sup>st</sup> Century.”

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More than one commenter suggested the plan should address Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) because the current regulations CMS has issued offer “burdensome, incorrect and unclear guidance.” More specific requests with regard to Section 111 included:

- Give providers sufficient notice and time to adopt changes in requirements.
- Institute reasonable thresholds for the collection of Medicare conditional payments.
- Maintain or increase thresholds for Medicare reporting.

- Act on plans for a user group on mass tort.
- Allow “safe harbor” to RREs/Insurance carriers if the injured person will not provide their Social Security number.
- Lessening penalties for inaccurate reporting.

**RESPONSE:** All of these suggestions have been passed on to CMS for consideration in future rulemaking.

*Medicare Part C & Part D:*

- Reimburse physicians for excessive prior authorizations or ones that are not resolved within a set period of time.
- Prohibit prior authorizations for ongoing drug use by patients with chronic diseases.
- Prohibit prior authorizations for standard/inexpensive drugs.
- Require all plans to use a standard prior authorization plan.

**RESPONSE:** All of these suggestions have been passed on to CMS for consideration in future rulemaking.

*In order to facilitate clinical integration to better serve Medicare beneficiaries:*

- Be sure our anti-trust agencies (DOJ/FTC) provide “user-friendly guidance that clearly explains what issues must be resolved to ensure clinical integration programs comply with anti-trust law.”
- With reference to the Stark Law prohibiting doctors from referring patients to facilities where they have a financial relationship/interest, relax the definition of “financial relationship” because there are “other laws already in place for needed oversight.”
- The Civil Monetary Penalty (CMP) Law should be modernized “to apply only to the reduction or withholding of medically necessary services.”
- Alter or eliminate old anti-kickback laws created to “protect patients and federal health programs from fraud and abuse by making it a felony to knowingly and willingly pay anything of value to influence the referral of federal health program business. Today’s expanded interpretation includes any financial relationship between hospitals and doctors.”
- “[T]he IRS will need to issue an Advisory Information Letter or a Revenue Ruling recognizing that clinical integration programs that reward private physicians for improving quality and efficiency do not violate IRS regulations.”
- More general Medicare/Medicaid barriers, such as the “HIPAA rules generally limiting sharing patient information to providers with whom patients have a direct relationship, unless complex procedures are followed such as obtaining a patient’s permission.”

*Medicare/Medicaid Coordination:*

- “Establish clear standards... that differentiate between the Medicare responsibilities in an episode of care and the Medicaid coverage obligations.”
- “Modify third-party liability regulations to require that states utilize the most cost effective method for recovering payment for dually eligible patients.”
- “Medicare and Medicaid claims submission should be combined with initial billing to Medicare and transfer billing of remaining non-covered care to the respective state Medicaid program.”
- “Require States to recoup incorrect payments from the Medicare program rather than the provider.”
- “States should be permitted to coordinate with Medicare through a claims sampling approach.”

**RESPONSE:** CMS has already embarked on an Alignment Initiative, designed to better coordinate Medicare and Medicaid. All of these suggestions have been passed on to CMS for consideration as it implements this Initiative.

*Physician Face to Face Encounters:*

- The Patient Protection and Affordable Care of 2010 includes rules/restrictions for Medicare payments for home health services “having a face-to-face encounter with the patient prior to certifying the need for care.”  
**RESPONSE:** CMS is revising the face-to-face requirement with respect to home health services.
- “Repeal the current regulation with its burdensome documentation requirement.”
- “Issue a regulation that allows home health agencies to supplement the current certification language with a physician attestation statement of the date that a face to face encounter occurred and that the finds of the encounter support the need for home health services.”
- “Publish model documentation forms for voluntary use.”
- “Eliminate the regulatory requirement for a narrative regarding why the patient meets Medicare coverage standards.”

**RESPONSE:** CMS will be promulgating a regulation to address conditions of participation requirements for a variety of Medicare providers, including home health agencies. CMS will be considering these comments as it develops this regulation.

*Provider Enrollment, Chain, and Ownership System (PECOS) enrollment:*

- “Amend the ordering/referring physician to comply with the statutory requirement of ordering/referring physician in Medicare, not PECOS.”

**RESPONSE:** This suggestion has been passed on to CMS for consideration in future rulemaking.

*Outcome and Assessment Information Set (OASIS) Assessments:*

- "OASIS imposes a substantial burden on home health agencies" in the form of massive paperwork requirements.
- "Require the collection of OASIS items for Medicare fee for service patients only."

**RESPONSE:** This suggestion had been passed on to CMS for consideration in future rulemaking.

*Nursing Assessment Requirement:*

- "Allow the therapist or nurse to conduct a start of care assessment in multi-discipline cases."

**RESPONSE:** This suggestion has been passed on to CMS for consideration in future rulemaking.

*Home Health Aide (HHA) Supervision:*

- "Eliminate the current supervisory regulation."
- "Focus aide supervisory requirements on the aide, not the patient."
- "Allow HHAs to establish policies for frequency of aide supervision based on the aide's skills, experience, and past performance."
- "At a minimum require supervision of every aide every sixty days in at least one home while the aide is performing patient care."
- "Allow LPNs/LVNs to supervisor home health aides."
- "Allow therapist to perform aide supervision as appropriate."

**RESPONSE:** All of these suggestions have been passed on to CMS for consideration in future rulemaking.

*Interpreter Services:*

- "Re-estimate provider's actual cost to implement [rules in translation requirements] and establish requirements based on provider size."
- "Translate any CMS model document into languages where there are 100 or more persons residing in the country."
- "Allow providers to use family members and friends as interpreters."
- "Develop resources for providers including affordable telephone translation services, computer driven voice, and written translator programs."
- "Eliminate the requirement for translators to have training in medical terminology."

**RESPONSE:** All of these suggestions have been passed on to CMS for consideration in future rulemaking.



*Beneficiary Notices:*

- "Allow home health agencies to combine several notices into a single form."
- "Eliminate the signature requirements where they exist."
- "Allow all notices to be made by phone and then mailed to beneficiaries."

**RESPONSE:** All of these suggestions have been passed on to CMS for consideration in future rulemaking.

*Therapy reassessments:*

- "Amend the regulation to require regular reassessment... to provide for regular and ongoing redetermination of medical necessity for continued therapy services and oversight of care by a qualified therapist."

**RESPONSE:** This suggestion has been passed on to CMS for consideration in future rulemaking.

**A long list of individual suggestions and considerations all of which were forwarded to CMS for consideration as it develops future rulemaking:**

Many regulations requiring a "physician" to perform procedures or at least supervise them are called unnecessary by commenters because oftentimes the work can be done just as easily by Certified Registered Nurse Anesthetists (CRNAs) and other Advanced Practice Registered Nurses (APRNs).

Similarly, this commenter wrote that current regulations, 42 CFR part 482.52(a)(4) requires unnecessary supervision by an "operating practitioner or an anesthesiologist" upping costs by increasing staff members but not safety. This commenter summed up these particular concerns by, "suggest[ing] that all regulations and interpretive guidelines issued by CMS be reviewed with the intent of removing restrictions concerning anesthesia services provided by nurse anesthetists."

"Unfunded mandates" such as translator services were cited by more than one commenter, noting that required "medical translator services are costly, and neither Medicare nor Medicaid compensates."

"[T]hree out of five physicians selected their top regulatory grievances [in an AMA survey] to be associated with unfunded mandates" found in current regulations.

Reduce overlapping documentation/certification.

Update and increase the Medicare Economic Index (MEI).

Coordinate all codes, quality measures, operating rules, feedback reports and timelines associated with the Physician Quality Reporting System.

Review evaluation and management (E & M) visit guidelines to accurately reflect providers' work.

Update Medicare regulations that "were developed decades ago within the context of cost-based reimbursement."

"Regulation should be cost effective," establishing "a safe haven for innovation and encourag[ing] the pursuit of excellence."

Be careful that laws/regulations do not impede progress improving patient care.

Electronic Health Records (EHR) were created and incentives offered to encourage their proliferation, but one commenter called the process "overly complex and confusing," saying that in order to make EHR a really successful national program it will require "[s]implified regulations."

Many commenters cited excessive provider reporting and information gathering as a significant burden, with one urging "CMS to align the measures used for various Medicare programs whenever possible to reduce [the] provider reporting burden."

Many outdated Medicare regulations need to be updated/eliminated.

There are too many program integrity audits, with one commenter saying "the flood of new auditing programs, such as the introduction of Recovery Audit Contractors (RACs)," is increasingly unmanageable and redundant.

"CMS's condition code 44 rule is unworkable and in need of modernization," and should be simplified.

The Clinical Laboratory Improvement Amendment (CLIA) should be updated because penalties for minor infractions can be too severe.

Review "all Medicare regulations that should have been amended based on the statute and legislative intent of Section 1861(g) of the Social Security Act (SSA)."

Review and revise the multiple procedure payment reduction (MPPR) policy for outpatient therapy.

Update Medicaid rules to mandate that occupational therapy services should “only be delivered by a qualified occupational therapist (OT) or an occupational therapy assistant (OTA) under appropriate supervision.”

Carefully monitor regulations of the Affordable Care Act (ACA) to ensure interagency cooperation.

Work with the Office of Management and Budget (OMB) to generate quality assessments of the costs and burdens of new regulations.

Greater emphasis on the development of regulations so there is less need to review and alter them in the future.

Prioritize reviews of regulations that impose “significant administrative and financial burdens.”

Set up a transition plan for the Medical Loss Ratio (MLR) to “provide a better glide path to the 2014 insurance market reforms.”

Streamline redundant and overlapping health information privacy rules.

An undue burden is placed on the property-casualty insurance industry “by administrators who have demonstrated a lack of understanding of the industry.”

Research training and certification programs required annually can be reviewed and in many cases changed to re-training/re-certification every two years.

HHS should alter requirements that “animal care and use protocols be reviewed every three years and replace it with a requirement to match the period of time of the animal protocol to the length of the grant.”

“Regulatory actions that seek to improve the Medicare physician payment system must adequately reimburse medical practices for services. Excessive penalties and onerous thresholds damage the stability of incentive programs and stall the adoption of health information technology.”

“Eliminate a redundant Medicare system and standardize provider credentialing through adoption of the Council for Affordable Quality Healthcare [CAQH] Universal Provider Datasource [UPD] currently used by private sector payers and state Medicaid programs.”

“It is imperative that CMS work to better integrate and align Physician Quality Reporting System (PQRS) requirements with the requirements of other Medicare quality reporting initiatives.”

“Timely and meaningful feedback and assistance with identifying and correcting unsatisfactory reporting throughout the year is critical.”

“Standardiz[e] exceptions and eliminat[e] seemingly conflicting requirements placed on healthcare providers.”

“[2003 and 2005 HIPAA security regulations] have proven sufficient...Additional onerous and costly requirements serve only to impede the cost-effective provision of quality care.”

“[W]e continue to be concerned with the lack of pilot testing prior to national implementation of complex and costly new standards such as HIPAA Version 5010 and ICD-10.”

“HHS has empowered numerous contractors to interact with and audit healthcare providers...[our] members continue to report inconsistencies in the guidance given by various contractors, delays in correspondence on the part of contractors and continued confusion about the contractors’ specific identity and authority...We urge the agency to ensure that all its auditors perform their duties consistently and transparently to maximize provider understanding and compliance with government requirements.”

“Review limited English proficiency and hearing impaired translator mandates and consider potential unintended consequences.”

“Any standards from an outside standards development organization that is to be incorporated into a FDA rule or guidance to the same federal notice and comment processes and other requirements of the Administrative Procedures Act (APA). Similarly, directives applicable to the development of federal rules should be followed prior to adopting these outside organizations’ standards.”

“When FDA develops proposed rules and guidance, take into consideration the effects on the entire drug supply chain system.”

Review the “therapy incident-to” rule. “The regulations disallowed Medicare Part B payments to be made for outpatient rehabilitation therapy services provided as incident to services when furnished by...health professionals who did not meet certain qualifications....[We believe the rule is] flawed and the imposition of the therapy restriction continues to harm patients by limiting access to much needed therapy services.”

“[T]he proliferation of new burdensome, and in some cases unnecessary, regulations imposed on home health agencies have put a strain on their financial and human resources.”