



# Client Alert



Contact Attorney Regarding  
This Matter:

R. Michael Barry  
404.873.8698- direct  
404.873.8699 - fax  
[michael.barry@agg.com](mailto:michael.barry@agg.com)

Arnall Golden Gregory LLP  
Attorneys at Law

171 17th Street NW  
Suite 2100  
Atlanta, GA 30363-1031  
404.873.8500

2001 Pennsylvania Avenue NW  
Suite 250  
Washington DC 20006  
202.677.4030

[www.agg.com](http://www.agg.com)

## **HHS Issues Plan for Retrospective Review of Existing Rules— Includes Proposed Changes by CMS, OCR and FDA**

On January 18, 2011, President Obama issued Executive Order 13563 in which he directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those that can be eliminated as obsolete, unnecessary, burdensome or counterproductive or that can be modified to be more effective, efficient, flexible and streamlined. Obviously, the impact of this Executive Order was far-reaching. Within the Department of Health and Human Services (HHS) alone, 16 separate agencies are targeted, including but not limited to the following:

- Agency for Healthcare Research and Quality (AHRQ);
- Centers for Disease Control and Prevention (CDC);
- Centers for Medicare & Medicaid Administration (CMS);
- Food and Drug Administration (FDA);
- Health Resources and Services Administration (HRSA);
- Indian Health Services (IHS); and
- Office for Civil Rights (OCR).

HHS issued its Preliminary Plan on May 18, 2011, and the final Plan was issued on August 22, 2011. The Plan includes the results of HHS's review of regulations and related proposals intended to reduce costs and improve efficiency. Some highlights of the Plan include the following:

### **1. Revisions to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule**

OCR proposes changes to the Privacy Rule to reduce burdens, while also enhancing flexibility and strengthening of privacy rights. The proposal includes changes to enhance the disclosure of student immunization records to schools; and the introduction of changes that would allow individuals increased access to their own health information that is held by laboratories.

### **2. Improving Premarket Review for Medical Devices**

The FDA and CMS intend to pilot a voluntary process for the parallel review of medical devices for marketing and national coverage determination. The objective of both these agencies is to reduce the time that it takes for a device to be authorized for sale and to enable providers to quickly determine whether the use of a device qualifies for Medicare reimbursement.

### **3. Review of HPSA and MUA Designations**

In response to the Affordable Care Act's requirement that the Secretary establish a methodology for designating Medically Underserved Areas (MUA) and Health Professional Shortage Areas (HPSA), HHS expects to publish a final rule in late autumn 2011. The criteria currently used to define HPSA and MUA date back to 1978 and 1975, respectively. The new rules are expected to provide consistency, clarity and a means for regular updates.

### **4. Revisions to the Conditions of Participation for Hospitals**

Based upon a comprehensive review of the Hospital Conditions of Participation, CMS intends to issue significant revisions. CMS intends to publish its proposed rule in September 2011 and expects that the plan will save \$600 million annually and \$3 billion over five years.

The full text of the *HHS Plan for Retrospective Review of Existing Rules* (August 22, 2011) can be found by clicking [here](#).<sup>1</sup>

<sup>1</sup> <http://www.hhs.gov/open/execorders/13563/index.html>

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