

# Craig Boyd Garner A Professional Law Corporation

## DON'T FEAR THE FEDERAL REGISTER

**“What is the use of a book,’  
thought Alice, ‘without pictures  
or conversations?’”**

**--Lewis Carroll, Alice in  
Wonderland**

When it comes to federal regulations, there is an unfortunate dearth of illustrations. Instead, promulgation comes solely through the written word, as it did recently on the first business day in June 2013, when the Federal Register published volume 78, Number 108. Born from an act of Congress known as the “Federal Register Act” (49 Stat. 500-503 (July 26, 1935)), the Federal Register will be 78 years old this summer and boasts its own international standard serial number. By its own admission, “[t]he Federal Register provides a uniform system for making available to the public regulations and legal notices issued by federal agencies. These include Presidential proclamations and Executive Orders, federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other federal agency documents of public interest.”

To be sure, regulatory transparency is a fundamental tenet upon which industry leaders must rely, and health care compliance professionals are certainly no exception. In fact, the body of law over which these individuals must take charge is quite the assemblage, and continues to grow at an astounding rate, especially since the passage of the 2010 Affordable Care Act. In a terrain that is often confusing, the Federal Register provides the most reliable roadmap for health care compliance, and the following are some suggestions designed to help keep a compliance program from getting lost:

### 1. Know Your Acronyms

Any meaningful regulation comes with its own, often overwhelming list of acronyms. For example, at the beginning of the 339-page (triple columned) 2013 regulations for the Medicare Hospital Inpatient Prospective Payment Systems, scores of acronyms precede an explanation of Medicare’s future from October 1, 2013, until September 30, 2014. That said, not all acronyms are created equal. Some are of seemingly marginal importance in the context of the regulation, such as “CDI” (*Clostridium difficile*), a severe case of diarrhea caused when an overly aggressive regimen of antibiotics backfires, “NAICS” (North American Industrial Classification System), a system used to distinguish business activity, or “HCFA” (Health Care Financing Administration), the predecessor to the Centers for Medicare & Medicaid Services (“CMS”). Others have merit, but are firmly entrenched in the vocabulary of industry experts, such as “CMS”, “HHS”, “HIPAA” and “OIG”....

### 2. Read the Summaries

While all regulations begin with a basic summary, HHS may employ not only this initial brief, but also a more detailed executive overview, and possibly even a table of contents for its lengthier reports. The summary of the 21-page, April 2013 HHS regulation relating to the Medicare Incentive Reward Program underscores the fact that the Federal Government is focused in its campaign against health care fraud and abuse. Increasing the amount to which an individual may be entitled under this program from no more than \$1,000 to \$9.9 million ruins the chance of a surprise ending for this set of regulations. Likewise, the concise 17-page April 2013 regulation introduced the role of the “navigator”....

### 3. Listen to the OIG

Although the OIG has not officially updated its published guidelines on hospital compliance programs since 2005, when the premier HHS enforcement agency speaks, all compliance officers should listen. In April 2013, the OIG updated its Provider Self-Disclosure Protocol, completely revamping the original guidelines released in 1998. Encouraging “health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs,” the OIG discusses such issues as why disclosure is important, the benefits of self-disclosure, eligibility requirements, and appropriate content. Although only 16 pages long, providers who elect to make a disclosure pursuant to these guidelines would be wise to study this information carefully....



### 4. Never Underestimate the Fine Print; and

### 5. Watch Out for Other Agencies

Last but not least, watch out for other agencies as they dabble in health care, including but not limited to the Department of Labor and the Department of the Treasury.

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## ROADBLOCKS TO REFORM: THE INFLUENCE OF HIPAA AND HITECH

When it comes to health care, our nation has reached a crossroads. President Obama's fledgling Affordable Care Act is a multifaceted, aggressive program designed to overhaul the delivery of health care by effectively restructuring its foundations from the inside out. In doing so, it seeks to reduce the number of uninsured patients who have for so long been a burden to a struggling health care system that must provide medical care as a service while also turning a profit as a business. But such a far-reaching plan has little chance of success if it is forced to evolve while fettered with the restrictions placed upon providers by certain grandfathered programs, most notably the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). As a result, we as a nation must now consider whether the ACA's fundamental mission or patient privacy should rule the day.



Entering its fourth year, the ACA has sharply divided the nation. Detractors paint the program as a misguided crusade of sorts, while supporters welcome what they consider a long overdue attempt to provide care to the millions of uninsured Americans that have for decades taxed the country's emergency departments and strained such government programs as Medicare and Medicaid. The combination of escalating health care costs and the continuous burden placed upon the system by forcing hospitals to swallow the price tag for treating America's uninsured have in a sense given reform the justification to wage war on the cost based health care plans of yesterday, in favor of a more sweeping plan that bases reimbursement on performance and seeks to provide coverage for all. Enacting such a dramatic long-term plan at a time when America's health care system finds itself in such a precarious state has effectively elevated the subject to a matter of national security, and as a result any meaningful response to address this crisis must comport with the actions of a nation in times of war.

As in any war, tactical decisions must be made about where and when to strike, and certain basic individual liberties may come into question as focus shifts to the priorities of the country as a whole. History provides plenty of examples from which society can gauge the purported need to temporarily rescind fundamental rights as a means to protect the sovereign nation. Ocean vessels were outright seized during the Civil War, Cuban ports were obstructed during the Spanish-American War, American citizens of Japanese ancestry were subject to detention and relocation during the Second World War, and more recently, the passage of the *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001* (also known as the "Patriot Act") issued what some consider to be questionable changes to the Constitution, sacrificing individual privacy in the name of public safety. While the casualties from reform's war on behalf of health care bear no resemblance to recent conventional campaigns, it is not too soon for the United States to take drastic measures as a means to resolve the conflicts found at the heart of her slowly evolving new health care program.

When considered from this vantage point, the fundamental premise entrenched within HIPAA and HITECH represents an overwhelming restriction of the ability of health care reform to succeed, as the combined programs prevent the ACA from developing into maturity. Although HIPAA's early provisions in many ways mirror the spirit of the ACA by protecting health insurance coverage for workers who lose their jobs, its evolution and partnership with HITECH have established national standards for the delivery and sharing of patient health information, the violations of which often lead to Draconian stipulations. The result has been a massive, often crippling price tag for providers, who must adopt new systems and work practices in order to comply or risk incurring civil money penalties ranging from hundreds to millions of dollars.

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Whether necessary or not, there has been a fundamental shift in the overall expectation of privacy since September 11, 2001. Perhaps it is time for the Federal Government to create a similar paradigm in health care. While the need to protect patient privacy remains extremely important, the ways in which compliance is enforced do nothing short of crippling the power of providers as they focus on their primary goals of ministering to today's patients while keeping their doors open to serve the patients of tomorrow. In the modern age of reform, the provision of medical care must be administered with a view toward the future, lest the providers themselves become extinct. To successfully do so in the current health care climate calls for a sacrifice of equal measure.

## NAVIGATING THE RAPIDS OF HEALTH CARE REFORM WITHOUT A PADDLE

**“The only fence against the world is a thorough knowledge of it.” – John Locke, philosopher (1632-1704)**

*In its bid to restructure the nation’s health care system, the 2010 Patient Protection and Affordable Care Act (the “ACA”) has created both challenges and opportunities in the areas of corporate compliance, governance and risk communities. In three short years, myriad regulatory clarifications have swollen this 906-page statutory giant into a 70,000-page behemoth whose might has been enough to overcome the judicial and electoral challenges of 2012, eliminating any doubts as to whether reform is here to stay.*

*At its core, the ACA means different things to different people. Patients typically focus on the promise of new guarantees and protections for health insurance for the populace, as well as the penalties for those who remain without coverage. But the ACA has also captured the attention of health care providers as they shift from a formerly cost-based system toward one that gauges success or failure primarily on patient experience. Even the insurance industry must yield to the new law and wend its way through a changing landscape complete with medical loss ratio requirements, the end of lifetime limitations, challenges to any increase in premiums over a certain percentage, and the soon to be introduced Health Insurance Exchanges.*

*While the infusion of elements such as innovation, preventative care and overall wellness provide the Federal Government with a new and as yet untested backup plan to ensure the success of health care reform, plenty of room still exists within the ACA to combat health care fraud, abuse and waste. The False Claims Act stands at the forefront in the government’s battle to preserve the integrity of health care resources, although the law has evolved considerably since first signed into effect by President Lincoln in 1863. By ensuring the legacy of the FCA for future generations, however, the ACA has also created several compliance risks for companies across the nation.*

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## TAXING HEALTH CARE REFORM

*For almost 60 years, April 15 has meant “Tax Day,” or the day when individuals must submit their income tax returns to the Federal Government. The Sixteenth Amendment to the United States Constitution establishes Congressional “power to lay and collect taxes on incomes, from whatever source derived, without apportionment among the several States, and without regard to any census or enumeration.” Three years since its passage, the Affordable Care Act (ACA) has become inextricably connected to the laws of federal taxation. The following list sets forth some key points of intersection:*

### **Disclosure or Use of Information by Tax Return Preparers**

Medical Loss Ratio (MLR)	Health Insurance Premium Tax Credit
Reporting Employer Provided Health Coverage in Form W-2	Individual Shared Responsibility Provision
Net Investment Income Tax	Health Coverage for Older Children
Additional Medicare Tax	Excise Tax on Indoor Tanning Services
Minimum Value	Adoption Credits
Small Business Health Care Tax Credit	Medicare Shared Savings Program
Health Flexible Spending Arrangements	Transitional Reinsurance Program
Medical Device Excise	Qualified Therapeutic Discovery Project Program
Group Health Plan Requirements	Annual Fee on Healthcare Providers
Employer Shared Responsibility Payment	Tax-Exempt 501(c)(29) Qualified Nonprofit
Patient-Centered Outcomes Research Institute	Health Insurance Issuers
	Retiree Drug Subsidies

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