Will the health care reform legislation passed in March of this year result in significant costs savings in the delivery of health care?

While that has been touted by some (see, e.g., http://www.newsweek.com/2010/03/20/how-health-care-reform-reduces-the-deficit-in-5-not-so-easy-steps.html), the reality is that today no one knows. Many pieces of the reform consist of directions to the Secretary for Health and Human Services (HHS) to try out new mechanisms for payment for health care. In short, rather than effect an immediate change in the reimbursement mechanisms, Congress has delegated that authority to the agency. For example, one section of the new law requires the Secretary to establish a “value-based” payment system that increases payments to doctors who deliver high-quality care, while lowering payment to those who deliver low-value care. Another section requires HHS to develop a demonstration program to allow certain types of providers to share in cost savings that result from a reduction in hospitalizations. How these various programs will work – indeed, whether they will work at all — is anyone’s guess. As far as their efficacy in reducing costs, the lasting legacy of these reforms simply may be an enormous question mark.

What will the reforms mean for the various sectors in the health industry?

For some, in the short run, the reforms will bring mixed results. Take the pharmaceutical industry, for example. On one hand, the legislation expands the Medicaid programs by raising eligibility and reduces, over time, the so-called “donut hole.” This is the gap in the Medicare Part D coverage for prescription drugs for annual expenditures between $2,250 and $3,600. That hole in coverage assuredly deterred many program beneficiaries from filling some prescriptions. Narrowing the hole will cause a net increase in pharmaceutical sales, as program beneficiaries fill prescriptions they may have previously chosen not to fill. The expansion in Medicaid enrollment also should increase sales.

On the other hand, however, the legislation imposes a series of significant burdens on the drug industry. One burden is a new excise tax that starts at $2.8 billion in 2012 and peaks at $4.1 billion in 2018. Another burden involves a series of disclosure requirements imposed on the industry regarding its business relationships with physicians and teaching hospitals. Effective 2013, not only must each drug company disclose all payments or transfers of things of value to physicians and teaching hospitals, the Secretary of HHS must post this information on a publicly available website in a searchable form. Similar taxes and disclosure obligations will impact the medical device industry.

What do you see as the most significant change?

One aspect of the reform legislation that will have a major impact is the direction to the Secretary to test a pilot project to reimburse for “episodes of care.” For example, when a Medicare Program beneficiary has bypass surgery, that procedure involves pre- and post-hospitalization care in addition to a lengthy period of hospitalization. As currently structured, Medicare Part A pays for the hospital care; Medicare Part B pays for the pre- and post-hospital care; and Medicare Part D covers part of the cost of any prescription drugs the beneficiary takes outside the hospital as pre- or post-follow up care. If the patient
requires skilled post-hospital nursing care in a nursing home, Medicare Part A again covers the cost. The new legislation requires the Secretary to develop methodology for establishing an “episode” for reimbursement for this kind of procedure and the attendant care. While the precise contours of the episode remain to be seen, providers can expect the episode will encompass most, but not all, of the pre- and post-hospital care, and that Secretary will craft a methodology to determine a single payment to cover the episode. Providers should expect that the single payment will be set lower than the sum of the present components, so the overall payment for the episode will (at least in theory) reduce the cost to the program and encourage efficiencies in the delivery of the care.

Without a doubt, such a “per-episode” payment regimen will encourage/force providers to integrate vertically in a single enterprise, or to establish joint ventures and business alliances for the delivery of the “episode” of care. As this new reimbursement methodology is developed and put into practice, I believe it will have a profound effect on the business relationships between doctors, hospitals and their suppliers, including the pharmaceutical and device companies. An additional significant question is whether, in establishing an “episode-of-care” payment, HHS will decide to make that payment to one provider in the chain involved in the delivery of the episode of care. If so, that provider will gain substantial economic power in determining how the money is to be split among the group of providers. It will be important for all providers and suppliers of products to the Medicare program to follow this reimbursement rulemaking process as it develops.

Whether this episode-of-care reimbursement experiment will effect a cost savings for the Medicare program is the billion dollar question for which I do not believe anyone has a clear answer today.

**How will the legislation affect the government’s health care fraud enforcement efforts?**

The government’s enforcement effort has two principal pieces: (1) cases that have both a criminal and civil component; and (2) cases that have only a civil component. Regarding criminal matters, while the legislation clarifies the government’s burden of proof in kickback prosecutions, the law enacts few new criminal statutes. Perhaps of greatest importance are the disclosure requirements that apply to the relationships between physicians and hospitals, on one hand, and drug and device companies on the other. Beginning in 2013, drug and device companies will have to report with considerable detail to HHS all things of value given to providers; the Secretary must post this information, as noted above, on a website. This database will assuredly become a tool for prosecutors and whistleblowers and their attorneys. Indeed, it will permit anyone to assemble data by physician, which will allow ranking physicians and hospitals by monies received from drug and device companies. Certainly, some *qui tam/whistleblower* suits will be brought predicated solely on the results of such data-mining, and drug and device companies can expect an uptick in the filing of false claims act litigation.

With respect to the civil component of criminal matters, and purely civil enforcement cases, the legislation shifts the balance of power in false claims act litigation to government and whistleblowers. Congress substantially modified certain aspects of the False Claims Act that companies have been effectively utilizing to minimize or terminate False Claims Act exposure.

In my opinion, companies should expect increased health care fraud enforcement for the foreseeable future, with the potential for an uptick when the information that various sectors must disclose becomes available to government investigators and the *qui tam* bar.
What do you see as the greatest area of concern for the executives who manage our health care clients?

I am most concerned about the government’s push to prosecute corporate executives for misdemeanor violations of the Food Drug and Cosmetic Act (the FDCA) under the Responsible Corporate Officer doctrine. In a felony prosecution under the FDCA, for example, the government must prove beyond a reasonable doubt that a defendant acted with the “intent to defraud or mislead.” In contrast, in a misdemeanor prosecution predicated on the Responsible Corporate Officer doctrine, the government has only to prove that the defendant shared a responsibility in the business process that resulted in the unlawful conduct. In short, no proof of intent is required; indeed, in the 1970s, the Supreme Court affirmed the misdemeanor conviction of the president of a large food distributor with 874 outlets and 16 food warehouses because of the adulteration of food at two warehouses.

What makes the present trend so ominous is the power of the Inspector General for HHS to exclude individuals who have been convicted of misdemeanors from further participation in federal health care programs. Such exclusions can effectively end one’s career. On March 4, 2010, Margaret Hamburg, Commissioner of the Food and Drug Administration, informed United States Senator Charles E. Grassley that the FDA was going to “increase appropriate use of misdemeanor prosecutions” in order “to hold responsible corporate officials accountable” for violations of the FDCA. Lewis Morris, general counsel to the Inspector General, more recently warned: “We are going to start to use [authority under the Responsible Corporate Officer doctrine] in the appropriate circumstances to get high-level executives out of companies, so that the company has a better shot at changing its behavior, so that it does not become a recidivist.” Morris added: “It’s our expectation that in the next several months you will begin to see the fruits of that new strategy.” And, the HHS Office of Inspector General already has acted as Morris has warned. Three high-level executives of one pharmaceutical company pled guilty in 2007 to a single misdemeanor violation of misbranding a drug, in violation of the FDCA. The government stipulated that none of the executives had any personal knowledge of the criminal conduct. Nevertheless, the Inspector General determined to exclude each for 20 years. While the administrative process has reduced those exclusions to a dozen years and the executives are challenging their exclusions in court, if you are a 55-year-old pharmaceutical company executive, a twelve-year exclusion wipes out the rest of your career.

I personally think there is great potential for the Responsible Corporate Officer misdemeanor prosecutions to be unfair and heavy handed. In my opinion, use of the doctrine is bad public policy, particularly in prosecuting corporate executives (1) where no lower level employees have been convicted of felonies under the Food Drug and Cosmetic Act or (2) where the government cannot prove that the executive was aware that adulterated or misbranded drugs or devices were being distributed by employees under his or her supervision. The deck will be somewhat stacked in the government’s favor — as it will not have to prove any criminal intent on the part of the defendant, just that he or she stood in responsible relation to a public danger. However, existing case law supports a vigorous defense, including on constitutional grounds and on grounds of objective impossibility (that, objectively, it would not have been possible for the charged corporate officer to have prevented the conduct) on behalf of an accused executive, particularly those who manage vast corporate enterprises with widespread operations involving many products.

How does the current environment impact corporate compliance programs?

If they do not have robust corporate compliance programs, all clients in this industry should work expeditiously to assure the efficacy of their programs. Amendments to the federal sentencing guidelines for corporations, which should take effect in November, will reward organizations with effective programs whose leadership (i.e., the chief compliance officer) reports to the board of directors and/or the CEO. Companies also should be moving to bolster their auditing and monitoring programs, both to test the effectiveness of their compliance programs and to demonstrate, in the event of an investigation, that the company has more than a paper program. Periodic risk assessments, as called for in the 2006 amendments to the U.S. Sentencing Commission guidelines, also should be conducted and the results reviewed with senior management to identify opportunities for improvement. Prosecutors are growing increasingly sophisticated about such issues, and if companies hope their compliance programs will be a mitigating factor when prosecutors exercise their discretion, the company will need to demonstrate the program was comprehensive, robust and effective.