Making Sense of Physician Regulatory Risk in the Post-Health Reform Era

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A VARIETY OF FACTORS IS COALESCING ON the state and national levels that have increased the risks to physicians and other health care providers relating to fraud, waste and abuse. Though most enforcement resources are being directed, rightly, at true "bad guys" (providers intentionally defrauding the governmental and private health care payors), the complexity of providing health care in the post-Health Reform era means that even the "good guys" need to apply a level of care to their business dealings that was not required in prior generations. This essay provides a few data points from the most recent governmental initiatives that support this thesis, and highlights some of the evolving trends and areas of risk for physicians in particular.

The Health Reform law, also knows as the **Patient Protection and Affordable Care Act of 2010** [**Pub. L. No. 111-148, 124 Stat. 119 (2010)**] (**PPACA**) went into effect on March 23, 2010, and lawsuits were filed in a number of jurisdictions to repeal the Act almost immediately.[1] While the lawsuits focus on the constitutionality of one key portion of PPACA (Section 1501 (or the "Minimum Essential Coverage Provision")) the broader practical objection has been that Health Reform on a national level will be extremely expensive to deliver. While there are likely too many variables in play for anyone to provide an accurate figure, news sources reported that the estimated cost would be one trillion dollars. While reasonable people may differ, even the staunchest advocates of reform, who expect to see ultimate savings from changes to the insurance and health care delivery systems, acknowledge that there are significant costs to be incurred in achieving the goals of Health Reform.

Where will these funds come from? Though there is little appetite in a still-down economy to raise taxes, there is always room for more fraud busting. The President, speaking to Congress in support of PPACA in the Fall of 2009, stated: "we've estimated that most of this plan can be paid for by finding savings within the existing health care system—a system that is currently full of waste and abuse."[2] Shortly before passage of PPACA, President Obama speaking at a rally in St. Charles, Missouri further underscored the Administration's views of the role of fraud and abuse in the health care system, opining "[i]f we created a Department of Improper Payments, it would be one of the largest agencies in our government."[3] Thus, the Administration is signaling that combating fraud, waste and abuse will be one of the strategies for paying for health care reform. PPACA, itself, included new resources, such as an additional $250 million over six years to fund fraud and abuse enforcement, with another $95 million for **Federal Fiscal Year** (**FY**) 2011 alone.

Governmental fraud enforcement efforts are continuing at an impressive pace. One of the most visible developments has been the Federal HEAT initiative—the **Health Care Fraud Prevention & Enforcement Action Team** (**HEAT**), a joint initiative announced in May 2009 between the **Department of Justice** (**DOJ**) and the **Department of Health and Human Services** (**HHS**) to collaborate on Medicare and Medicaid fraud prevention and prosecutions. Such inter-agency collaboration has been taking place for many years, but the results of late are impressive—with hundreds of arrests in South Florida, Detroit and other targeted areas. On January 11, 2011, the DOJ and HHS issued their annual report[4] for the **Health Care Fraud and Abuse Control** (**HCFAC**) Program, reporting the following highlights of activities during FY 2010:

- $2.5 billion in health care fraud judgments and settlements;
- $2.86 billion received by the Medicare Trust Fund;
- $683.2 million in Federal Medicaid money recovered to the Federal government;
- 1,116 new criminal health care fraud investigations commenced against 2,095 potential defendants;
- 1,787 health care fraud criminal investigations pending against some 2,977 potential defendants (showing that the majority of active cases were filed in 2010)
- 488 cases involving 931 defendants had new criminal charges filed;
- 726 defendants were convicted for health care fraud-related crimes;
- 942 new civil health care fraud investigations with 1,290 civil health care fraud matters pending; and
- 3,340 individuals and entities were excluded from participating in Medicare, Medicaid and other Federal health care programs by the **Office of the Inspector General** (**OIG**).

These figures represent enforcement efforts against all types of providers. The OIG and other enforcement entities continue to pursue their investigations and audits of physicians and others. The OIG's 2011 Work Plan presents to the industry some of the top issues the OIG will study in the coming year. For physicians, the Work Plan includes risks associated with (among others):

Place-of-service errors;

- Coding and payments for **evaluation and management** (**E&M**) services;
- E&M payments during the "global surgical" period;
- Payments for Part B imaging services and other diagnostic tests;
- Sleep studies;
- Compliance with Medicare's "Assignment" rules; and
- Payments for services ordered by "excluded" providers.

What types of initiatives new should physicians expect? There are several ranging from delays and changes in enrollment in the Federal health care programs, new fraud investigators, restrictions on the ability to profit from ancillaries and tighter enforcement statutes to enhanced personal liability. The following paragraphs summarize a number of these developments.

Enrollment Restrictions

Much of the Government attention has been correctly focused on keeping criminal elements out of the Medicare and Medicaid programs. A variety of provisions in PPACA are designed to help HHS combat fraud, waste, or abuse through the enrollment or revalidation processes. The law contains a number of new tools that are likely to be targeted at certain "high risk" categories of providers and suppliers in particular home health and durable medical equipment. Abuse in these areas has been a key target of the Federal HEAT initiative, discussed above. Because abuse in DME and home health sectors has been such a focus of attention, PPACA now requires that physicians must have face-to-face encounter with a patient prior to certification for home health services or DME, and only Medicare-enrolled physicians may order DME or certify home heath services.

Changes in the area of enrollment and screening included different levels of screening will vary among categories of providers and suppliers, such as license checks, fingerprinting, criminal background checks, multi-state database inquiries, random or unannounced site visits, or other appropriate screening technologies. Certain types of providers and suppliers may be subject to a temporary "provisional period" (30 days to one year). During this "provisional period" the provider or supplier may be subject to enhanced oversight, prepayment review, prepayment caps. Enrollment applications will now require disclosures of affiliation with providers that have uncollected debt, or who have been suspended or excluded from participation. The Act also allows for enhanced civil money penalties for providers making false statements in enrollment the process. What this all means for physicians likely is more delays, hassles and claims interruption when bringing on new physicians or when changing practice settings. On the whole, however, most physicians will welcome any efforts to keep the unscrupulous and corrupt providers out of the market.

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Mandatory Compliance Programs

Compliance programs have been recognized as valuable internal tools to prevent overbilling or other regulatory violations. These programs, though lauded by prosecutors and providers alike, have historically been voluntary. The OIG published a Compliance Program Guidance document for Individual and Small Group Physician Practices on October 5, 2000[5] with the OIG's recommendations for how physicians should set up a voluntary compliance program in their offices. After PPACA, these voluntary programs will be mandatory. All providers and suppliers as a condition of enrollment in Medicare, Medicaid, and/or CHIP must implement compliance programs subject to a variety of requirements the **Centers for Medicare and Medicaid Services (CMS)** will impose by regulation. As of this printing, CMS has invited comments but not outlined the mandatory terms of such programs.[6] It is unknown whether smaller physician groups will be asked to undertake significant efforts in this area. Nevertheless, the advantages to physician groups of establishing a compliance program now are many, including an enhanced ability to detect and prevent violations—not to mention the ability to earn favor in the eyes of a prosecutor or regulator if an investigation is undertaken against a physician group that has an effective compliance program. Medical staff education around office-based compliance programs has been ongoing in Rhode Island and likely will increase as physicians recognize the need to implement such programs in their practices.

Enhancements to the False Claims Act and the Anti-Kickback Statute

PPACA (and prior statutes) introduced changes to several of the key enforcement—including the most important law, the **False Claims Act (FCA)**. The FCA is valuable to the government because it includes the opportunity for treble damages plus $11,000 per claim penalties. In addition, the FCA permits private "whistle-blower" or *qui tam* plaintiffs to bring cases in the name of the government and recover a share of the reward. The changes to the FCA were designed to (1) make it easier to prove a violation against a provider and (2) encourage *qui tam* law suits. PPACA weakens the so-called "public disclosure bar" by restricting scope of information considered "publicly disclosed" and, therefore, unable to support a *qui tam* case and expanding definition of "original source," thus permitting many additional private plaintiffs to bring cases under the FCA.

Physicians have long known that the Federal and Rhode Island Anti-Kickback Statutes prohibited knowingly paying or soliciting any remuneration with the intent that it cause the physician or other provider to refer a patient for a Medicare, Medicaid or other federal or state health care program service. *Medicine & Health/RI* has included articles over the years designed to help physicians navigate the law and the many exceptions and regulatory "safe harbors" that define illegal conduct from acceptable business arrangements. Concerned that case law had been too lenient on providers, Congress in PPACA amended the law to state that a person "need not have actual knowledge of this section or specific intent to commit a violation of this section." This was intended to eliminate the "*Hanlester* defense" named after one of the first major Anti-Kickback cases, *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). Additionally, PPACA added new language to assure that claims billed for items or services resulting from a violation of the Anti-Kickback Statute constitute

false claims under the FCA. Physicians should remain vigilant about financial dealings with other health care providers as well as drug and device companies to be sure that they do not get ensnared in an Anti-kickback prosecution.

Stark Law Changes

There were several changes to the Physician Self-Referral or "Stark" law that will be important to physicians. One of the most immediate Stark changes for physicians is a new documentation requirement for the use of the "In-Office Ancillary Services" exception. This exception allows physicians to provide needed ancillary services in their office and refer patients for those services. Under the new requirement, as interpreted by CMS,[7] physician, ordering certain MRI, CT, and PET scans must inform patients in writing that they may obtain service from an alternate supplier and include a list of suppliers furnishing same service in area around the physician's office. These new forms have been required as of January 1, 2011.

CMS now has the authority to settle and compromise Stark Law violations. Historically, there have been few avenues to bring voluntary disclosures of Stark violations to the attention of the government without having to repay 100% of the Medicare referrals associated with the financial relationship. This draconian result was particularly unfair as the Stark Law (unlike the Anti-Kickback Statute) discussed above, has no "intent" standard, thus making inadvertent contracting errors as serious as intentional violations. Until 2009, physicians, hospitals and others could bring Stark violations to the attention of the OIG through its self-disclosure protocol, but the OIG recently announced that it would no longer accept "Stark-only" disclosures (*i.e.,* violations without "colorable" Anti-Kickback violations). Under PPACA, providers and suppliers may enter into a **Self-Referral Disclosure Protocol (SRDP)** with CMS for Stark violations and negotiate a settlement below the 100% severe penalty. There have been few settlements under the SRDP as of this printing, so the metrics CMS is using are not yet well known. However, the agency is considering:

- The nature and extent of "illegal or improper practice"
- Timeliness of disclosure;
- Cooperation in providing additional information;
- Litigation risk; and
- "Other factors."

Finally, PPACA ends the debate on whether to permit the expansion of physician-owned hospitals. While not prevalent in New England and Rhode Island, other regions of the country experienced great competition coming from physician-owned hospitals against the community hospitals. After the change in the law, a moratorium on new physician-owned hospitals applies to any hospitals without a Medicare provider agreement as of Dec. 31, 2010. Existing physician-owned hospitals can no longer increase capacity or the percentage of physician ownership or investment after March 23, 2010. There are limited exceptions available for hospitals that treat the highest percentage of Medicaid patients in the county, or that have a high Medicaid percentage and are located in high-growth, underserved areas.

Mandatory Refund and Reporting of Overpayments

Overpayments can be caused by any number of factors—and sometimes it is highly questionable whether a specific payment is an overpayment at all. This is due to the complexity of the billing rules, uneven guidance from payors, and significant "gray areas" in interpretation of these rules in the context of medical records, diagnoses, and clinical practice. In the past, many health care attorneys saw no express duty to refund innocent overpayments discovered after payment. The DOJ and CMS disagreed, and alleged that "wrongful retention" of an overpayment was illegal. Two significant legislative changes, including both PPACA in 2010 and the 2009 **Fraud Enforcement and Recovery Act (FERA)** amendments, materially improved the government's hand in this area. These laws expressly reference improper retention of overpayments as the basis for a FCA prosecution. PPACA heightened this risk by imposing an express duty to refund and report Medicare and Medicaid overpayments by *the later* of 60 days after the overpayment is "identified" or the date cost report is due (for cost reporting providers). And the failure to report and return the overpayment exposes the provider to liability under the FCA.

This change in the law requires immediate action by physicians and other providers. In particular, office staff need to be trained to know when an overpayment has been "identified" and to bring this promptly to the attention of someone with the authority to evaluate whether the overpayment is real and take the required steps. There are also some important undefined elements of the law, including when an overpayment is "identified," what level of certainty or confidence is required, and the actual processes required.

Physician Payment "Sunshine"

Discussed for many years by Senator Charles Grassley and debated in a number of states (including Rhode Island), physician financial relationships with drug and device companies is now regulated on both the state and Federal levels. These so-called "sunshine" laws are motivated by the concern that gifts and payments by manufacturers to physicians may lead to conflicts of interest and improperly influence physicians in their drug or device prescribing decisions. These laws do not prohibit physician involvement in research and education with industry, but they impose various new compliance requirements on these relationships, and also require public disclosure of arrangements that previously were treated as confidential. A number of states, including Massachusetts, Maine and Vermont, passed local laws. Some states, like Massachusetts and Vermont ban "gifts" and require disclosure of financial relationships on state website.

PPACA now federalizes this area, requiring "transparency reports" of payments by "applicable manufacturers" of a drug, device, biological, or medical supply. These reports will begin on March 31, 2013 and will disclose to HHS payments or other transfers of value to a physician or "teaching hospital." Reports will contain the physician and teaching hospital names and business addresses, dates and amounts of payments, and description of the nature of payment. Disclosure of some confidential information relating to clinical trials will be permitted prior to FDA approval/clearance or four years. There

are minimal exemptions for the reports. Payments of less than ten dollars each, up to $100 aggregate, educational materials, evaluation units of devices, discounts and rebates, expert witness fees and a few other arrangements do not require disclosure.

Expansion of the "RAC" program and other new auditors

Physicians doing Medicare work in Massachusetts, New York, California and Florida are familiar with the **Recovery Audit Contractor** (**RAC**) program. This program engages contingency Fee "bounty hunter" contractors to find overpayments in Medicare parts A and B. This Medicare RAC program commenced as a demonstration in three states, but expanded nationally in 2009. The results of the contingency fee model have been so successful (a good "return on investment" according to CMS) that Congress has now further expanded RAC to Medicaid as well as Medicare parts C and D. Thus, Rhode Island physicians must be prepared for requests for charts and demands for overpayment refunds from Medicare and Medicaid. Failure to respond to these contractors will result in automatic overpayment demands.

The RACs join an alphabet soup of other auditors physicians may encounter, including **Zone Program Integrity Contractors** (**ZPIC**), encompassing what was handled by **Program Safety Contractors** (**PSC**), and **Medicaid Integrity Contractors** (**MIC**). These auditors are an overlay on the existing apparatus of inforcement and investigation by the OIG, **Medicaid Fraud Control Units** (**MFCU**), DOJ, and State Attorneys General. For physicians, this requires a greater familiarity with who is out there, what they are looking for, and what rights you have when they are asking questions.

Individual Liability

Most of the attention in health care enforcement cases has been on recovering overpayments and imposing other financial penalties. Though personal criminal or civil liability has always been a risk, it has not been a central element of the fraud and abuse enforcement regime. This may be changing, based on activities like the HEAT initiative, discussed above, and increasingly strong rhetoric from the DOJ.

References

1. See, e.g., *Virginia ex. rel. Cuccinelli v. Sebelius*, 702 F.Supp2d 598 (2010).
2. H9390 Congressional Record—House (September 9, 2009)
3. Full text of speech (3/10/2010) downloaded from http://www.mainjustice.com/2010/03/10/obama-speech-on-health-care-waste-and-fraud/ (February 21, 2011).
4. Downloaded from http://www.oig.hhs.gov/publications/docs/hcfac/hcfacreport2010.pdf (February 21, 2011)
5. 65 Fed. Reg. 59434.
6. 75 Fed. Reg. 58204 (September 23, 2010)
7. 75 Fed Reg. 73443-73447 (Nov. 29, 2010)

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