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K&L Gates LLP

## Health Care Fraud, Abuse and Enforcement

### What's Inside this Newsletter

**Introduction**

Page 2

**Criminal:****Intensified Criminal Focus on Health Care Fraud**

Page 2

Reviews the Department of Justice's intensified focus on health care fraud from a criminal perspective, examines what can be expected going forward and, importantly, what providers need to do to prepare and respond should the government commence an investigation.

**Foreign Bribery:****Feds Promise Prosecution of Improper Payments ...**

Page 7

Discusses DOJ's growing enforcement of violations of the Foreign Corrupt Practices Act in the pharmaceutical and medical device industry in light of Assistant Attorney General Lanny Breuer's statement that the DOJ is 'intensely focused on rooting out foreign bribery' in this area.

**False Claims:****The False Claims Act and Other Enforcement Mechanisms**

Page 11

Reviews recent developments which signal increasing reliance on and use of this critical statute and other enforcement mechanisms against health care providers.

**Civil Litigation – Defense:****The Lessons of Managing Multi-District Civil Health Care Litigation**

Page 18

Discusses lessons learned from and financial benefits to clients of using coordinating counsel in multi-district civil health care litigation.

**FDA Enforcement:****FDA's New Enforcement Paradigm**

Page 19

Examines the FDA's new plans and what regulated companies need to know about its approach.

**Insurance:****Insurance Coverage for the Cost of Investigations**

Page 22

Reviews strategies for maximizing the likelihood of insurance coverage in a health care case.

**Audits:****Responding to Medicare and Medicaid Recoupment Demands ...**

Page 24

Explores strategies for challenging statistical sampling and projection methods in Medicare and Medicaid audits used to recoup alleged overpayments as audits continue to rise in number and frequency.

## Health Care Fraud

This past year brought a reinvigorated emphasis on criminal, civil, and administrative enforcement in the health care area, as significant new government enforcement techniques and policies have been put in place. Federal and state authorities are committed to utilizing these new techniques and policies, in conjunction with those already in existence, to pursue a robust civil and criminal enforcement regime over the health care industry. Health care providers are well advised to keep abreast of current enforcement techniques and trends.

In this edition of the Enforcement Review, K&L Gates' lawyers from a variety of practice specialties draw upon their experience to explain these changes and trends, underscore what can be expected from enforcement in the future and, importantly, explain what participants in the health care system can do to adapt.

Broadly speaking, the health care industry must prepare to be subjected to a far higher level and frequency of scrutiny than has existed previously. The government has directed more enforcement resources at the health care industry; the inevitable result of that focus is more frequent, and likely more aggressive, government enforcement efforts. Matters which were once considered minor regulatory infractions and which were dealt with by the commencement of civil or, at worst, state criminal action may now result in the imposition of increasingly serious penalties, including federal criminal penalties.

The reason is rather plain. With more government dollars focused on rooting out alleged health care fraud and abuse, state and federal agents, civil lawyers, and prosecutors will be searching more diligently for offenses, and will have a strong incentive to find such offenses and justify the extra dollars spent on the effort. In measuring success, the government is notoriously focused on statistics reflecting cases brought, convictions won, and dollars collected. To achieve statistical evidence of the success of this new health care effort, government agencies can be expected to bring more cases.

On the federal side, many types of criminal health care fraud cases result from major investigations which require years of investigative preparation (for example as with cases involving alleged off-label

marketing of pharmaceuticals). Because such cases are slow to develop, statistical results demonstrating the success of the government's new health care fraud effort may be slow in coming. Thus, the need to show immediate, tangible progress can be expected to result in federal agents speeding up cases in the pipeline -- and focusing on more easily provable, less complex offenses. This makes more likely federal criminal prosecutions of health care matters that perhaps were once considered too minor for federal criminal treatment. This is not to suggest that the federal government will cease to initiate more complex, long-term investigations. To the contrary, we believe it will continue to do so. The Department of Justice's (DOJs) recent, record-setting settlement of off-label practices reached by the United States Attorney's Office in Boston against Pfizer in September of 2009 serves to illustrate this point. In addition to these cases, then, industry participants must anticipate that a higher number of cases will be pursued for investigation by federal enforcement authorities arising from matters of lesser scope, as well as by state enforcers. And when they do, serious penalties can be expected.

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## Criminal

### Intensified Criminal Focus on Health Care Fraud

Michael D. Ricciuti (Boston), Steve M. Kowal (Chicago), Floyd R. Hartley (Dallas), and Jeffrey L. Bornstein (San Francisco)

Health care fraud is and will continue to be a growing focus of federal and state criminal prosecutors. Below we outline the reasons for that conclusion and highlight specific approaches we suggest clients consider, particularly where a matter is pending in Massachusetts or one of the other federal districts where there is active criminal health care fraud enforcement.

### The Changed Landscape, 2009 – HEAT and Health Care Fraud Strike Forces

Fraud generally – and health care fraud in particular – is a top DOJ criminal priority. There are many likely reasons for that focus, for example: the Obama administration's drive for health care reform; the increasing economic pressure on Medicare; and the government's estimate of the size of the health care fraud problem (\$60 billion per

year and rising). It is thus unsurprising that DOJ is committed to using criminal approaches (in addition to civil tools) to comprehensively address the problem of health care fraud. Criminal case filings are at an all-time high. As Lanny Breuer, the Assistant Attorney General for the Criminal Division, said in testimony to Congress on May 30, 2009, “[t]he Department’s prosecutions have a clear deterrent effect.”

The renewed coordination between DOJ and the Department of Health and Human Services (HHS) in health care fraud is an outgrowth of the Health Care Fraud and Abuse Control Program (HCFAC), a joint effort directed by the Attorney General and the Secretary of HHS (through its Office of Inspector General (OIG)) to coordinate federal, state, and local law enforcement activity with respect to health care fraud and abuse since the late 1990s. That effort was refreshed in May 2009, when DOJ and HHS announced a new joint initiative to ensure coordination: the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a joint strike force implemented to detect, prevent and prosecute health care fraud. Co-chaired by the Deputy Attorney General and Deputy HHS Secretary, the HEAT Task Force is comprised of top-level law enforcement agents, prosecutors and staff from both Departments and their operating divisions, assisted on a case-by-case basis by Centers for Medicare and Medicaid Services (CMS), investigators from insurance companies, and local law enforcement personnel. The HEAT initiative thus further aims the DOJ and HHS focus on reducing and preventing Medicare and Medicaid fraud through enhanced inter-agency cooperation.

The HEAT Task Force in Washington is supplemented by field-level Health Care Fraud Strike Forces that have been coming on-line since 2007. The Strike Force concept is a familiar one; strike forces have been used for decades to combat organized crime, drug trafficking and terrorism. The Medicare Fraud Strike Forces, like their predecessors, are multi-agency, multi-disciplinary collections of federal, state and local investigators, lawyers and support staff. They use data analysis and community policing techniques to supplement criminal enforcement at U.S. Attorney’s Offices and target emerging or migrating schemes and chronic fraud. The Strike Forces represent a more concentrated criminal, civil and administrative effort

against individuals and health care companies that fraudulently bill Medicare. Since the inception of the Health Care Fraud Strike Force concept two and a half years ago, Strike Forces have been implemented in four phases, corresponding to geographic areas of emphasis. Initially, phase one resulted the establishment of a Strike Force in South Florida. A year later, in May 2008, phase 2 resulted in the establishment of a second Strike Force, focused on fraud in the Los Angeles area. In March 2009, the Strike Force was established in Detroit, followed two months later by implementation of activity in Houston.

The composition of the Houston Strike Force is revealing. It is comprised of agents from the FBI, HHS-OIG, Texas Attorney General’s Medicaid Fraud Control Unit, the Drug Enforcement Administration, Office of Personnel Management’s Office of Inspector General, Office of the Inspector General at the Railroad Retirement Board, and federal prosecutors from the U.S. Attorney’s Office in Houston and the Criminal Division’s Fraud Section. The Strike Force’s multi-agency, federal-state cooperative effort is emblematic of the cooperative approach and high priority being placed on health care fraud enforcement.

DOJ has already begun touting the results of the HEAT Task Force. In June 2009, DOJ brought indictments against 58 defendants in Detroit and eight in Miami; in July, DOJ brought indictments against 32 defendants in Houston. According to government estimates, its Strike Force enforcement initiative has been successful in achieving all-time highs in convictions and recoveries. In 2008, for example, officials from DOJ, the Inspector General for the HHS, and the CMS reportedly cooperated to secure 588 criminal convictions and obtain 337 civil administrative actions against people and organizations alleged to have committed Medicare fraud, and recovered over a billion dollars in health care fraud monies under the False Claims Act. And early indications for fiscal year 2009 reveal that DOJ has already recovered nearly a billion dollars in health care fraud monies and recorded 300 convictions.

### **The Pfizer and Harkonen Cases**

In September 2009, Pfizer, through its Pharmacia & Upjohn Co. subsidiary, reached a civil and criminal settlement and agreed to plead guilty to allegations of off-label marketing. Pfizer agreed to pay \$2.3 billion to the government, which represents the largest health care fraud settlement in history. Of the total amount Pfizer paid, \$1.195 billion, the largest criminal fine ever imposed, was to settle allegations stemming from the marketing of Bextra and \$1 billion, the largest civil fraud settlement ever, was to settle civil False Claims Act actions arising from the marketing of Bextra and three other drugs, Geodon, Zyvox and Lyrica.

According to the information filed in Boston, Pfizer's corporate predecessor, Pharmacia, was charged with off-label marketing of Bextra for unapproved uses in unapproved doses, despite the Food and Drug Administration's (FDA) specific refusal to approve Bextra for some of the marketed uses. The information alleged Pharmacia's marketing practices were reviewed at the highest corporate level. DOJ also targeted Pharmacia's marketing efforts through advisory boards of doctors, consultant meetings, and physicians who agreed to become advocates for Bextra. In addition, DOJ alleged that Pharmacia's funding of purportedly independent continuing medical education (CME) program had as a stated purpose the dissemination of messages promoting Bextra for unapproved uses. Pharmacia allegedly did this by incorporating CME planning into its market messaging strategy for Bextra; the government contended that Pharmacia used slides developed by advertising agencies for CME purposes, thereby merging its marketing and CME functions.

Significantly, in published comments, the government noted that one reason it exacted a record-setting settlement in this case was because Pfizer had been prosecuted previously. This was Pfizer's fourth settlement of charges of illegal marketing since 2002. Acting United States Attorney for the District of Massachusetts, whose office spearheaded the investigation and the federal district where the plea and sentencing took place, noted that "[a]mong the factors we considered in calibrating this severe punishment was Pfizer's recidivism."

Of course, the Pfizer case had been in the works during the Bush administration, and likely was largely concluded during it. Nevertheless, it has been widely celebrated by the Obama administration to emphasize its focus on health care fraud. Indeed, the announcement of the settlement was not made in the District of Massachusetts, but rather at DOJ in Washington, D.C., ensuring that the case would receive widespread publicity.

Of further note is the conviction in San Francisco of W. Scott Harkonen, the former CEO of the biotech firm InterMune, involving charges of wire fraud (he was acquitted of felony misbranding of a drug). Although Harkonen's trial has not been the subject of significant nationwide publicity, it is significant for individuals in the health care industry. It is not common for pharmaceutical fraud cases to make it to a jury trial. And in the Harkonen case, the government not only pursued prosecution of an individual executive, but did so where the executive had left the company long ago and where the company separately entered both a deferred prosecution agreement and corporate integrity agreement with the government.

Nevertheless the government pursued Harkonen for wire fraud and felony misbranding. Harkonen was the CEO of InterMune and a member of its Board of Directors from 1998 to 2003. In August of 2002, InterMune issued a press release about a clinical trial of its Actimmune drug, which had been approved for treatment of two rare childhood diseases, heralding its success in treating a more common lung disease called "IPF." At that time, InterMune was still attempting to secure FDA approval of Actimmune for treating IPF (which approval was never obtained). After InterMune's press release, however, the government contended that the company grossly misstated the clinical trial data and directly contradicted guidance Harkonen had just received from the FDA. In 2006, InterMune signed a deferred prosecution agreement (DPA) in which, among other things, it agreed to pay nearly \$37 million to resolve criminal charges and civil liability. InterMune also entered a 5-year corporate integrity agreement (CIA) with the OIG for HHS.

The government has expansive power to pursue health care executives for fraud, but rarely does so; attorneys involved in the case thus reportedly believed the company's deal would effectively end the criminal probe. Despite the fact that he left

InterMune in 2003, and that InterMune entered into a DPA with DOJ in 2006 and a CIA with the OIG, on March 18, 2008, the U.S. Attorney's Office for the Northern District of California proceeded to indict Harkonen on wire fraud and felony Food, Drug, and Cosmetic Act charges for his role in the creation and dissemination of allegedly false and misleading information about the efficacy of Actimmune. And in a relatively rare development, the pharmaceutical fraud case against Harkonen advanced to a jury trial in August.

The prosecution pursued two theories: first, the government contended that Harkonen promoted and caused the promotion of Actimmune as a safe and effective treatment for IPF despite the lack of FDA approval (so-called off-label marketing); and second, prosecutors asserted that Harkonen caused the issuance and distribution of a false and misleading press release regarding the efficacy of Actimmune. While Harkonen responded that the press release was true, the government claimed the Actimmune clinical trial actually failed, contrary to InterMune's press release and subsequent related communications with pharmacies and physicians. Further, the prosecutor's opening statement accused Harkonen of putting profits ahead of truthfulness, a theme repeated in many of the government's health care fraud prosecutions for its resonance with jurors.

Insofar as the criminal charges are concerned, the Harkonen case was typical of the type of charges DOJ and OIG have pursued in off-label marketing cases. But Harkonen is notable for what its circumstances may portend: an increased willingness to pursue prosecution of individuals involved in health care fraud. DOJ's press release announcing the indictment, for example, quoted the Special Agent in Charge of the FDA's Office of Criminal Investigations in the Washington Field Office, Kim Rice, on precisely that point:

*Pharmaceutical executives who promote drugs using false and misleading information should not be allowed to hide behind a corporate shield.*

*Pharmaceutical companies do not run themselves, and those who engage in criminal conduct will be held personally accountable.*

### What Can Be Expected Now?

A few thoughts about how to navigate these increasingly treacherous waters:

First, **focus on prevention**. Health care companies are well advised to ensure that compliance efforts are state-of-the-art. Where deficiencies result from instances of wrongdoing by low-level employees, the company itself can also be charged under expansive corporate *respondeat superior* principles. Under those principles, a company may be held criminally liable for the acts of its agents committed within the scope of their duties and intended, at least in part, to benefit the corporation, which is defined very broadly. However, whether DOJ elects to charge a corporation is a matter of discretion. Exercise of that discretion depends upon an analysis of the factors under DOJ's Principles of Federal Prosecution of Business Organizations (the "Principles") found in the United States Attorney's Manual, the guidebook utilized by DOJ. In exercising that discretion, DOJ rewards companies that take compliance seriously; that actively root out violators by thoroughly investigating and responding to allegations of wrongdoing; and that even make disclosures of potential violations to DOJ.

Second, **if the government is at the doorstep, carefully consider presenting to the government those factors which support a non-prosecution outcome**. The commencement of an investigation does not mean that a criminal prosecution and large payment to the government are inevitable. Even when some problematic conduct has occurred, it is possible for the corporation to avoid government enforcement activity. Of course, every investigation is different, and the factual background can be crucial. But it is important to understand that the government can be persuaded by a company or its counsel to close an investigation without enforcement activity. The defense should work toward that goal from the very early stages of the investigation.

Undoubtedly, representing a company in an investigation of possible FDA violations poses some significant challenges. The statutory scheme affords the government enormous discretion. It defines a series of "prohibited acts" in very broad terms. The commission of any of those prohibited acts can support a prosecution for a misdemeanor

offense, even without proof of knowledge or bad intent. A more serious felony conviction does require a demonstration of intent to defraud or mislead, but even that level of intent can be inferred from circumstantial evidence that is subject to sharply differing interpretations.

This degree of discretion can lead to inconsistent applications of statutory and regulatory requirements. Conduct that previously was ignored by the government or addressed through regulatory warnings can be used to support a criminal investigation and prosecution. Also, the investigating agencies contribute to the defense challenge. Many investigations are initiated and pursued aggressively by FDA's Office of Criminal Investigations (OCI). These agents do not operate under the direction of the various FDA district offices. Rather, OCI enjoys a parallel report relationship to the Office of Regulatory Affairs. Thus, FDA's regulatory policy and OCI's enforcement efforts are not necessarily coordinated. The OCI offices are located in numerous cities around the country, and the agents often initiate investigations by contacting the local U.S. Attorney's Office. This type of semi-independent operation can result in a haphazard decision to commence an investigation. Although these decisions have important ramifications for the companies involved, they may not always be guided by consistent policy considerations. Changes in the FDA's enforcement policies and focus are another factor. Since the agency effectively is the client of the prosecuting office, these policy directions can substantially affect prosecutorial decisions.

Despite these challenges, counsel can have, and historically has had, substantial success in persuading the prosecuting offices – both U.S. Attorney's Offices and the DOJ – to refrain from prosecution. Several factors appear key to these successful efforts:

- **Be mindful of the differences between regulatory enforcement and criminal prosecution.** In some instances, defense counsel concentrate only on the regulatory compliance aspects of the investigation and neglect to address concerns related to the exercise of reasonable prosecutorial discretion discussed above.
- **Seek an opportunity to make a presentation directly to the senior decision makers in the office contemplating a prosecution.** A presentation to the government's investigating team will not likely be sufficient to convey the defense position to those who will make the final decision.
- **Focus on policy concerns.** Prosecutors make take a different strategy than FDA's past approaches under similar circumstances. In many instances, FDA's own guidance documents can be used by a company's counsel to demonstrate to prosecutors that similar or even more egregious conduct has been addressed through less onerous enforcement. This information will help to promote an independent review by the prosecuting office.
- **Conduct a reliable internal investigation.** An effective presentation must be supported by thorough internal investigation to assemble the factual information the government may very well have ignored. Often, the government will have compiled information drawn from several isolated events, and will conclude that bad intent is demonstrated. The defense must provide the information that places these events in the proper context, and that will undermine the conclusion the government seeks to draw.
- **Address the Principles.** The defense presentation must address the factors outlined in the Principles. Often, a thorough review of the facts in the context of these Principles will demonstrate the government's inability to comply with important provisions.
- **Address lack of intent.** A decision to prosecute – rather than merely pursue regulatory remedies – usually depends on the government's assessment of intent. The defense must be prepared to address that issue directly. Conduct that is the product of a bad intent will incense the government; conduct that is motivated by benign intent will be viewed differently. In either instance, however, the effect on patients may very well have been the same. Thus, development of the full factual record is crucial to place the conduct – and the intent that motivated that conduct – in the proper perspective.

- **Address other enforcement mechanisms.** For a company, the Principles require the identification of a reason to prosecute that would not be adequately addressed through other types of enforcement. Because of the wide range of enforcement remedies available in FDA-related matters, there often is a substantial basis to contend that prosecution is unnecessary. Moreover, in some situations it may be possible to argue that a prosecution will undermine incentives to pursue effective corporate compliance programs, and therefore actually undermine overall enforcement efforts.
- **Consider speaking with Main Justice.** The decision of the U.S. Attorney's Office or the litigating office of DOJ may not be determinative. In some instances, it may be possible to secure a meeting with senior DOJ representatives at "Main Justice," the Justice Department's headquarters in Washington, D.C. – particularly if there is a factual basis to contend that important policy considerations are implicated. Senior officials may not be as invested in the potential prosecution as the investigating office, and therefore may be more willing to review the issue from a fresh perspective.

One final point: Presentations to the government in the context of a potential criminal case are far different from negotiating a civil settlement with a private party or engaging in other business meetings. Critically, such presentations require a far higher level of candor than companies often expect.

**Candor is crucial** – not only will DOJ expect it, but companies should expect that any lack of candor will be penalized by DOJ, often harshly, and thus undermine the company's effort to avoid prosecution.

### *Foreign Bribery*

## **Feds Promise Prosecution of Improper Payments in Foreign Sales of Pharmaceuticals and Medical Devices**

Matt T. Morley (Washington, D.C.) and Suzan Onel (Washington, D.C.)

In remarks on November 12, 2009, Assistant Attorney General Lanny Breuer made clear that the DOJ is "intensely focused on rooting out foreign bribery" in the pharmaceutical and medical device industry. Noting that roughly one-third of U.S. pharmaceutical industry sales occur outside the United States, Mr. Breuer observed that this business carries with it particularly high risks of running afoul of the Foreign Corrupt Practices Act (FCPA), which prohibits improper payments to foreign officials in connection with business transactions. The full text of Mr. Breuer's remarks can be found at <http://www.justice.gov/criminal/pr/speeches/2009/11/11-12-09breuer-pharmaspeech.pdf>

Companies are often unpleasantly surprised to learn how broadly these restrictions apply, as the FCPA defines a "foreign official" to include not only persons who act on behalf of governments and government agencies, but also officials and employees of government-controlled entities. Some "foreign officials" may be obvious, said Mr. Breuer, "like health ministry and customs officials." "But others may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities." In many instances, as Mr. Breuer pointed out, "nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing" of a pharmaceutical product or medical device will involve a "foreign official" within the meaning of the FCPA.

Commenting further in another speech on November 17, Mr. Breuer observed that "the depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates, in our view, a significant risk that corrupt payments will infect the process."

Mr. Breuer also repeated what other DOJ officials have been saying in recent months – that in addition to vigorous prosecution of companies that violate

the FCPA, senior executives will be held accountable (see the Harkonen discussion above). In Mr. Breuer's view, "effective deterrence requires no less. Indeed, we firmly believe that ... culpable individuals must be prosecuted and go to jail where the facts and the law warrant."

### **Why the pharmaceutical and medical device industry is at high risk for FCPA violations.**

As Mr. Breuer's remarks aptly point out, potentially improper payments pose a particularly significant risk for pharmaceutical and medical device companies, given that they are likely to have a relatively greater number of contact points with foreign government officials than do many other industries. Most companies doing business abroad need government approvals in order to open offices, to obtain permits and licenses, and to import goods. While pharmaceutical and medical device companies have these same needs, they also market products that generally require regulatory approvals before they can be sold, sometimes after intensive testing that may be redundant of tests already conducted in other countries. Additional approvals may also be required regarding product pricing and medical insurance reimbursements.

Although these risks are significant – violations of the FCPA can carry both civil and criminal sanctions – companies can substantially reduce their risks of running afoul of the law by taking some relatively simple steps. By identifying their risks in this regard, and developing policies and procedures to mitigate them, companies can reduce both the likelihood of a violation and the potential consequences of any violation that may occur in spite of the company's best efforts.

In recent years, many companies, including a disproportionately high number in the pharmaceutical and medical device industry, have found themselves enmeshed in federal law enforcement investigations, apparently as a result of confusion about the scope of the FCPA's prohibitions. In particular, three aspects of the law may easily be overlooked.

1. **Doctors and hospital administrators can be "government officials."** As Mr. Breuer suggests, it is not always obvious who is a "government official" under the FCPA. For

purposes of the FCPA, the term includes not only regulatory, judicial and law enforcement personnel, but also officers and employees of government-owned enterprises – even where they are engaged in ordinary commercial or professional activities, and even if they are not considered to be government officials under local law. In many countries around the world, government control of medical facilities and related businesses is common, and payments to persons associated with those entities may violate the FCPA.

2. **The FCPA reaches all over the world.** U.S. authorities have extremely broad jurisdiction under the FCPA. It applies to everything that a U.S. company, citizen or permanent resident does, regardless of where in the world they do it. It also applies to actions that take place in the United States, or which have even a slight connection to U.S. commerce – such as fund transfers, fax transmissions, or telephone conversations in furtherance of an improper payment. U.S. law enforcement officials have been aggressive in their interpretation of the jurisdictional scope of the statute and have initiated prosecutions against non-U.S. individuals and business entities in certain cases despite the attenuated nature of their contacts with the United States.
3. **Sales incentives may be considered to be bribes.** The FCPA prohibits not only outright bribery, but the provision of anything of value, directly or indirectly, in exchange for business or any sort of improper advantage. This means that practices that may be accepted in the private sector, such as incentives provided to encourage customers to purchase products, can run afoul of the FCPA if provided to persons employed by institutions controlled by a local or national government. As Mr. Breuer put it, the types of payments that violate the FCPA "are not any different than the items of value that would violate the Anti-Kickback statute if given within the United States."

### **Federal law enforcement is "intensely focused" on the issue.**

Over the past five years, more than half a dozen pharmaceutical and medical device companies have settled civil charges with the SEC or criminal

charges with the DOJ in connection with alleged improper payments abroad. The ways in which payments were alleged to be made differed in each case – including briefcases filled with cash, purported “charitable donations,” and lavish “study trips” to Las Vegas and Miami. But the context was essentially the same in every case: payments were made to doctors or purchasing officials of state-owned hospitals to induce the hospitals to purchase the company’s products.

In many of these cases, senior corporate executives appear to have been unaware of improper payments made at the direction of lower-level personnel, in remote foreign operations, who may have viewed the payments as customary or otherwise necessary to the performance of their responsibilities. In many instances, the payments were made through foreign subsidiaries, sales agents, or other intermediaries. The FCPA and federal criminal law principles, however, contain very broad provisions for vicarious liability, holding companies responsible for the actions of such lower-level employees, even if those actions were unauthorized. The FCPA also makes both companies and individuals responsible for actions taken by third parties on the company’s behalf, whether or not authorized, if someone in the company knew of the violation or if the circumstances suggested a high likelihood that a violation would occur.

Mr. Breuer has warned that “our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in your industry.” In fact, the targeting of the pharmaceutical and device industries has been well publicized by U.S. law enforcement officials for several years, and is part of a broader FCPA enforcement effort by both the SEC and the DOJ. Indeed, both agencies continue to describe FCPA enforcement as a priority, and recent statistics confirm that this is not idle talk. These agencies brought 38 actions in 2007, and 33 more in 2008. These efforts were capped over the past year by a settlement with Siemens, A.G., which paid over \$1.6 billion in fines, penalties and disgorgement to U.S. and German authorities in December 2008, and another settlement with both KBR, Inc. and Halliburton Co., which paid a combined total of \$579 million in fines and penalties in February 2009. A number of individuals have been sentenced this year to jail terms for FCPA violations, and others are

awaiting sentencing. Beyond this, companies charged with FCPA violations may also suffer considerable reputational damage, along with restrictions on their ability to export goods or to participate in U.S. government programs, including Medicare and Medicaid.

Moreover, it is not only the United States taking action against international bribery. Over the past decade, most other developed nations have adopted statutes similar to the FCPA or promulgated even broader antibribery laws. These laws are being more vigorously enforced around the world and in some cases expanded. One recent case, which included alleged payments in connection with the sale of medical equipment, involved not only U.S. authorities but vigorous efforts by German prosecutors as well. In the United Kingdom, reform of existing bribery laws is underway, and lawmakers are expected to create a new offense for the failure to prevent bribery by a company, which would address a company’s negligence in failing to do enough to stop people working on its behalf from paying or promising or offering a bribe in connection with its business. Under the proposed law, adequate compliance procedures would provide a defense for the company, except in the case of misconduct by senior management.

### **Developing an FCPA compliance program.**

Although U.S. law does not expressly require companies to have an FCPA compliance program, in practice U.S. law enforcement policies – including the federal sentencing guidelines and DOJ’s Principles of Federal Prosecution of Business Organizations – create powerful incentives for every company involved in international commerce to take meaningful steps to prevent improper payments. For those that do so, the consequences of a violation, if one occurs, are likely to be less severe: penalties may be lessened and in some cases, prosecution of the company may be avoided altogether. By contrast, the failure to have a program may exacerbate the consequences of any violation that comes to the attention of the authorities.

Even though no organization can prevent every unauthorized action by its personnel or by third parties acting on the company’s behalf, the risks of legal liability can be significantly reduced through a

well-designed FCPA compliance program. In this regard, there are several steps, which can be relatively simple and inexpensive, that every company operating internationally should consider.

- **Assess the magnitude and nature of your particular risks by identifying the points of contact between your company and foreign government officials.** Each company has a unique set of circumstances in which it deals with government officials. Understanding when and where those interactions occur is the starting point for assessing the company's corruption risks. In addition to employees of state-owned hospitals, as noted previously, persons involved in the conduct or evaluation of clinical trials and research may pose similar risks.
- **Evaluate and assure the sufficiency of your policies and procedures to mitigate the risks identified.** Effective compliance programs often include:
  - A prohibition of improper payments.
  - Controls over gifts and entertainment.
  - Due diligence procedures to evaluate the legitimacy and reputation of third parties that may act on the company's behalf (such as agents, consultants, and other intermediaries) and joint venture partners. As noted above, these parties can create FCPA liability for you, even if you don't know that they are acting improperly.
  - Contractual provisions to require third parties not to make improper payments, and providing for mechanisms to monitor and audit compliance, and to terminate the relationship in the event such payments are made.
  - Due diligence in the merger and acquisition context to ensure that potential anticorruption problems are identified and evaluated prior to consummating any transaction and assuming successor liability for corrupt payment problems.
- **Be sure that relevant company personnel understand your policies.** A written policy alone is unlikely to be effective unless it is effectively communicated to employees and reinforced with periodic training that assures their understanding.
- **Set the proper tone from the top.** As with any other corporate directive, an FCPA policy will be taken seriously only if supervisory personnel show, by words and actions, that the policy is important and must be followed. A clear tone at the top should be conveyed by the chief executive and repeatedly reinforced throughout the organization.
- **Check to assure that the policies and procedures are being followed.** Monitoring and auditing compliance with policies and procedures is essential. This often includes mechanisms for accumulating and reviewing certain types of payments and expenditures, such as gifts, entertainment expenses, and payments to consultants; annual certifications of compliance by relevant personnel; and internal auditing of selected accounts, such as employee reimbursements and promotional and marketing expenses.
- **Follow up on "red flags" and take remedial steps as needed.** If potential corrupt payment issues arise, companies must be prepared to take prompt action and make appropriate inquiry into the situation. If a problem is found to exist, companies are expected to take steps both to correct it and to prevent a similar recurrence. In many law enforcement actions, the severity of sanctions appears to have been greatly increased by a pattern of failing to respond to repeated indications that improper payments were being made.
- **Keep your board of directors informed.** Federal guidelines provide that, for a compliance program to be considered "effective", a company's board must exercise reasonable oversight of the program's implementation and effectiveness. Case law holds that, while corporate directors cannot be required to guarantee the effectiveness of corporate compliance programs, they must assure that a reasonable system exists in order to meet their fiduciary duty of good faith to the corporation. *See, e.g., Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

Federal officials have made it abundantly clear that they are devoting considerable effort to identifying and prosecuting improper payments to foreign officials, particularly in connection with the sale of pharmaceuticals and medical devices. Companies can avoid a host of unpleasant consequences by devoting efforts now to assess their risks and take appropriate steps to control them.

### *False Claims*

## **Developments in False Claims Actions**

Robert J. Sherry (Dallas), Mary Beth F. Johnston (Research Triangle Park), Paul W. Shaw (Boston), Darlene S. Davis (Research Triangle Park), and Amy O. Garrigues (Research Triangle Park)

On May 20, 2009, President Obama signed the Fraud Enforcement and Recovery Act of 2009 (“FERA”), which significantly expanded potential liability under the civil False Claims Act, 31 U.S.C. §§ 3729 et seq. (“FCA”). Given a health care provider’s daily exposure to FCA risk, these changes will surely have a dramatic impact on the health care industry in particular. Most notably, a health care provider may now find itself expressly subject to liability if it retains an overpayment from Medicare; if it retaliates against an independent contractor; or if, as a subcontractor, it causes another entity to submit a false claim to the government.

In addition to FERA, the federal government has also demonstrated a heightened focus on efforts to combat fraud and abuse in 2009 by establishing HEAT (discussed above), and by implementing the Recovery Audit Contractor (“RAC”) Program in full force across the nation. While expanding its enforcement activities, the government has, at the same time, appeared to limit options for providers seeking to self-disclose certain regulatory violations. The recent Self-Disclosure Protocol letter from the Office of Inspector General of the Department of Health and Human Services indicates that its Self-Disclosure Protocol is no longer available to providers who are solely reporting violations under the federal physician self-referral law, 42 U.S.C. § 1395nn (“the Stark Law”). The government also has set a settlement floor for claims related to the federal anti-kickback statute (“AKS”). All of these

recent actions emphasize the importance that health care providers should place on conducting routine internal audits, refunding payments when appropriate, and continuing to ensure that their compliance programs are robust.

### **Federal False Claims Act Changes**

Significant changes and expansions to the FCA for health care providers include the following:

- Specifying “retention of overpayments” as a source of liability;
- Adding “contractors or agents,” in addition to employees, as individuals who may bring a retaliation claim;
- Allowing the government to add new claims and relate back to the date of the relator’s filing;
- Expanding persons liable under the FCA to include those who make or cause a false statement or record to be made that is “material” to a false claim;
- Clarifying that a false claim submitted to an agent of the government may create FCA liability; and
- Allowing the Attorney General to delegate authority to issue civil investigative demands (CIDs) and to share information obtained in response to a CID with relators if “necessary” to an FCA investigation.

### **Overpayments**

Of all the recent FCA amendments, none is more troubling to health care providers than the changes to the “reverse false claims” provision regarding “overpayments.” Previously some affirmative act, such as creating a false record or the submission of a false statement, was required to be liable under the FCA. As amended by FERA, the FCA now specifies that liability attaches to any person who “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government.” “Obligation” is defined to include “the retention of any overpayment.” As FERA did not substantially revise the definition of “knowingly,” however, it continues to include acting in deliberate ignorance or reckless disregard of the truth or falsity of information and does not require proof of specific

intent to defraud. Accordingly, the retention of an overpayment, if there is a legal obligation to repay it, may cause liability under the FCA.

It is fairly common for health care providers to receive payments from federal health care programs that may in whole or in part constitute “overpayments,” however defined. Accordingly, the amendments to the FCA raise but fail to answer a number of open questions. What is considered an “overpayment”? What constitutes a legal “obligation” to refund an overpayment? How often does a health care provider have to check for overpayments? How quickly must an overpayment be refunded to avoid improper retention? When has there been knowing concealment?

This revision to the FCA subjects a provider that fails to refund an overpayment to treble damages as well as up to \$11,000 per improperly retained overpayment. These changes also appear to lead to greater opportunities for *qui tam* relators to bring lawsuits, and to potential referrals to the Office of Inspector General (“OIG”) and the Department of Justice from Medicare and Medicaid contractors, if an audit or investigation discloses the existence of overpayments that were not refunded on a timely basis.

Accordingly, we recommend that health care providers ramp up their routine audits of their documentation, billing and reimbursement practices and conduct appropriate internal review and due diligence. If audits reveal overpayments received from Medicare or Medicaid, regardless of the cause of such overpayment (*e.g.*, a billing error, a lack of appropriate documentation supporting a specific bill, or a violation of the Stark Law), providers should refund monies to avoid further damages and penalties under the revised FCA.

### Retaliation

The FCA, as amended, also now allows an “employee, contractor or agent” to bring a retaliation action under the FCA if discriminated against in the terms and conditions of employment because of lawful acts taken to stop a violation of the FCA. Interestingly, while the statute was amended to add “contractor or agent” and to remove that the discrimination must be “by the employer,” the statute still includes that the discrimination must be in the “terms and conditions of employment.” It is

not clear how this would apply to an independent contractor. Ultimately, however, these changes appear to open the door to potential lawsuits by management companies, vendors and physicians and other individuals who are independent contractors (and not employees) of health care providers. In doing so, the legislation appears to reverse established precedent across a number of circuit courts that the FCA retaliation provision applies only to the employer-employee relationship.

Protected conduct under the FCA has also been expanded to include any lawful act to stop one or more violations of the FCA. It is therefore no longer specifically tied to bringing an action under the FCA, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under the FCA. Thus, protected conduct may very well be held to include actions that are not readily foreseeable in the day-to-day operations of a health care provider.

### Statute of Limitations

Pursuant to the newly adopted legislation, the FCA now also provides for the tolling of the statute of limitations in certain instances. If the United States chooses to intervene in an FCA lawsuit, then it can file its own complaint or amend the relator’s complaint to clarify or add any additional claims. If such claims arise out of the conduct, transaction, or occurrences set forth in the prior complaint, then any such additional pleading by the government will relate back to the original date that the relator filed the initial lawsuit.

### RAC Audits

#### Analysis

Providers can expect to see an increase in Medicare audits as the RAC program continues to be implemented. Those who have not yet undergone a RAC audit should identify high-risk services and develop a process to prepare for and respond to a RAC audit. (Later in this Newsletter, Raymond Pepe discusses what to do when confronted with a RAC audit based on statistical sampling.) The look-back period for claims is three years, and audits will not be conducted on claims paid before October 1, 2007.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 required that the Centers

for Medicare and Medicaid Services (“CMS”) initiate a pilot program to evaluate the use of RACs in identifying and correcting underpayments and overpayments under Medicare Parts A and B. California, Florida and New York were chosen as the initial three states for the three-year demonstration project, with an additional three states (Massachusetts, South Carolina and Arizona) were added in 2007. The pilot program ended in March 2008. As of March 27, 2008, RACs had corrected more than \$1.03 billion in Medicare improper payments. Approximately 96 percent (\$992.7 million) were overpayments collected from providers, while the remaining 4 percent (\$37.8 million) were underpayments repaid to providers. A significant majority of overpayments (85 percent) were collected from hospitals related to inpatient services, likely reflecting the higher rate of return that results from auditing hospital claims. It is noteworthy that of the \$828.3 million reported by CMS to have been improperly paid to hospitals during the demonstration, about 36 percent was due to incorrect coding and 41 percent was due to the service being rendered in a medically unnecessary setting (*i.e.*, the beneficiary needed care but did not need to be admitted to the hospital to receive that care).

The Tax Relief and Health Care Act of 2006 requires that CMS expand the RAC pilot program to all states by January 1, 2010.

RAC audits are not intended to replace audits by other Medicare contractors, but rather to create an additional level of review. RACs are guided by the same Medicare policies and rules to identify improper payments as the Medicare claims processing contractors, are required to use clinical staff such as nurses when conducting medical reviews and are required to engage a medical director. In instances where there is no Medicare policy, the RACs review claims based on accepted standards of medical practice at the time of claim submission. Unlike other Medicare contractors, RACs are paid on a contingency basis; that is, they retain a portion of the sums recovered as overpayments or underpayments. Consequently, there is concern that these contractors will have a financial incentive to find improper payments.

RACs are allowed to use their own claims selection methodology and analyze claims using their own proprietary techniques to identify those that contain

errors. These techniques may include data mining techniques and reports issued by the OIG, Government Accountability Office (“GAO”) and Comprehensive Error Rate Testing (“CERT”) Program. In the case of clear improper payments, the RAC contacts the provider to either collect any overpayment or pay an underpayment. This process is called an “automated review” and, according to the RACs, is used only when an improper payment is obvious on the face of the claim (*e.g.*, a claim for two colonoscopies for the same patient, on the same day, at the same hospital) or when a written Medicare policy or coding guideline exists and precisely describes the coverage conditions. In the case of claims that *likely* contain errors, the RAC requests medical records from the provider in order to further review the claim. This process is called “complex review.” These two review processes are similar to those employed by the Medicare claims processing contractors to identify improper payments.

To prevent duplication of efforts, RACs are instructed to audit claims that were not previously identified by the DME Medicare Administrative Contractors (“MAC”) MACs, which include carriers, fiscal intermediaries and durable medical equipment regional carriers. These claims include: (1) post-payment medical reviews already in progress; (2) claims subjected to complex pre-payment medical review; (3) claims involved in a fraud/benefits integrity review in progress; and (4) claims related to a law enforcement investigation. However, a recovery by a RAC does not preclude the Secretary of the Department of Health and Human Services or the Attorney General from investigating and prosecuting allegations of fraud and abuse arising from an overpayment.

Once a RAC makes a determination regarding a claim, it issues a results letter setting forth its findings. At this point, providers have a 15-day period in which to discuss these findings with the RAC and provide any additional information. The RAC will then issue a demand letter setting forth the amount of the overpayment or underpayment and the provider’s appeal rights. Providers are entitled to appeal any negative determinations to their MAC within 120 days of the claim adjustment and the MAC must respond to the re-determination request within 60 days. If a provider wishes to appeal this re-determination, subsequent appeals

process steps would include a reconsideration submitted to a Qualified Independent Contractor (“QIO”) within 180 days, an appeal to an Administrative Law Judge (“ALJ”) within 60 days of a denied reconsideration by the QIO, an appeal to the Medicare Appeals Council within 60 days of the ALJ’s decision, and as a final step, an appeal to a federal district court.

Providers who have not yet undergone a RAC audit should develop a process to prepare for and respond to a RAC audit. The AHA and other industry groups recommend the following process:

- Conducting a self-assessment to identify error-prone claims identified by the RACs. This may be done internally by a RAC interdisciplinary team or an outside consultant;
- Educating physicians and other providers on the top admission and documentation problems identified by the RAC self-assessment;
- Developing a list of particularly error-prone diagnosis-related groups (“DRGs”) and implementing a correction plan;
- Identifying individuals who will be involved in overseeing any RAC audits. Such individuals may include the corporate compliance officer, the medical records director, officials responsible for reimbursement issues and any other individuals responsible for coding and billing compliance;
- Training these individuals on the RAC audit process, including what to expect if the organization is audited and how to respond appropriately;
- Determining where medical records are stored and how they can be accessed if located off-site, and ensuring that such records are accessible in a timely manner; and
- Reviewing OIG work plans for a period of three years from the date RAC audits are scheduled to begin in your state. This can help in identifying the areas most likely to be targeted by the RACs and ensuring that future coding in these areas is correct.

### Self-Disclosure Protocol

Earlier this year, the OIG recently released An Open Letter to Health Care Providers, limiting the ability of providers to utilize the Self-Disclosure Protocol. Providers who discover compliance problems that implicate only the Stark Law without “colorable” anti-kickback violations can no longer raise them to the OIG through the self-disclosure process. Additionally, the OIG is mandating a minimum settlement of \$50,000 to resolve self-disclosed kickback concerns.

Thus, while facing increased scrutiny and potential liability from both the government and *qui tam* relators alike, health care providers seemingly have one less avenue for approaching the government to resolve potential Stark or AKS (if the settlement is less than \$50,000) liability that they identify through their own internal compliance efforts. Ultimately, in light of all of these activities, health care providers should ensure that their compliance programs are effective and that, in particular, they have systems in place to identify any overpayments or other violations, to timely refund overpayments, and to thereby minimize their exposure under the False Claims Act.

### Analysis of the Changes Made to the False Claims Act

#### The Federal Civil False Claims Act Generally

The FCA continues to be a major weapon in the federal government’s arsenal to combat alleged procurement fraud. A continuing drumbeat about procurement and health care fraud in the last several sessions of Congress has generated several FCA reform proposals and amendments to the FCA. As the reader likely is aware, the FCA, prior to the recent amendments, prohibited a variety of conduct involving false claims, false statements and, generally, the receipt of government money based on prohibited conduct.

From the perspective of a government contractor, FCA cases are big business for the federal fisc. DOJ secured \$1.34 billion in FCA settlements and judgments in the fiscal year ending September 30, 2008. This brings total recoveries since 1986, when Congress substantially amended and strengthened the FCA, to more than \$21 billion.

Yet, Congress is dissatisfied with the current scope of the FCA, particularly in light of three recent federal court decisions interpreting the FCA. The FERA, signed by President Obama on May 20, 2009, substantially amended the FCA and will have a major impact on government contractors. One FERA amendment to the FCA is intended to legislatively overrule the Supreme Court's unanimous decision in *Allison Engine Co. v. United States ex. rel Sanders* ("Allison Engine") by removing the "intent" requirement to get a false or fraudulent claim paid. Under the language of FERA, a false statement or record need only be "material to a false or fraudulent claim." This change created by FERA is retroactive to June 7, 2008 – the same week of the *Allison Engine* decision. FERA redefines the term "claim" to include transactions in which government funds are directly or indirectly at issue, and imposes FCA liability to cover any situation where money or property is to be spent or used on the government's behalf or to advance a government program or interest. FERA thus expands liability to indirect recipients of federal funds by eliminating the so-called "presentment" requirement and therefore effectively overrules prior law on this point.

FERA also expands the reverse false claims provision by adding a new definition of the term "obligation," potentially making the knowing retention of an overpayment a violation. The FERA amendments also create some procedural changes in the way FCA cases are investigated and litigated. First, if the government elects to intervene in an FCA action and its claim arises out of the same conduct, transactions or occurrence set forth in the *qui tam* complaint, then the government's pleading will relate back to the filing date of the original *qui tam* complaint. Second, the Attorney General has the power to delegate the authority to issue CIDs and to share materials derived from the CIDs with relators, thereby potentially allowing relators, with no specific knowledge of the alleged fraudulent conduct, to use CID materials to satisfy the requirements of Rule 9(b) or to expand a complaint.

Both the House and the Senate have proposed legislation amending the FCA. The proposed amendments encompass some of the changes incorporated by FERA and expand FCA liability by narrowing the public disclosure and original source provisions and allowing government employees,

both current and former, to file *qui tam* suits in certain situations.

In short, FERA is sure to stimulate increased activity in the FCA arena. While many of the FERA amendments are sure to be challenged in the courts, the breadth of FCA claims is likely to expand, resulting in a new intensity in enforcement activity. The current environment not only has generated proposed federal FCA amendments, but also has implications for state and local contractors as well. This latter concern can be traced back several years to the passage of the Deficit Reduction Act ("DRA").

### Continuing Impact of the DRA

President Bush signed the DRA into law in February 2006. The goal of the DRA was to save \$40 billion over five years by, among other things, slowing the growth in spending for Medicare and Medicaid. The real impact of the DRA, however, may be the creation of additional state FCAs and (as described later) the education of a potential new class of whistleblowers.

Section 6031 of the DRA provided a financial incentive for states to enact FCAs to pursue remedies for the submission of false or fraudulent claims to state Medicaid programs. Section 6031 took effect on January 1, 2007. Under this incentive program, the state is entitled to 10 percent more than its normal share of any amounts recovered under a state action brought under such a law. In order to qualify for this program, though, the state FCA must meet certain identified requirements. The state law must:

1. Establish liability for false or fraudulent claims described in the federal FCA with respect to any expenditures related to state Medicaid plans described in Section 1903(a) of the Act;
2. Contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the federal FCA;
3. Contain a requirement for filing an action under seal for 60 days with review by the State Attorney General; and
4. Contain a civil penalty that is not less than the amount of the civil penalty authorized under the federal FCA.

Under the DRA, HHS OIG, in consultation with the U.S. Attorney General, must determine whether a state's FCA meets the statutory requirements. The OIG published a notice in the Federal Register on August 21, 2006, that set forth the OIG's guidelines for reviewing state FCAs. The guidelines set forth the procedure that states must follow to request an OIG review of their laws to determine if the requirements are met.

To date, twenty states have submitted their FCAs to the OIG for review. Fourteen states have laws that have been approved by the OIG – California, Georgia, Hawaii, Illinois, Indiana, Massachusetts, Michigan, Nevada, New York, Rhode Island, Tennessee, Texas, Virginia and Wisconsin. Because California's FCA statute ("CFCA") emulates the federal FCA, and because of the relative dearth of CFCA precedent, California courts frequently employ federal FCA case law to interpret the CFCA.

As could be expected, many of the states currently without FCA statutes, including some that have had their proposed FCA statutes rejected by the OIG, are scrambling to draft and pass legislation meeting the standards set forth by the OIG to qualify for the 10 percent incentive. Eight states have legislation for new FCAs pending. Florida and New Mexico also are considering bills to amend their FCAs to address the issues raised by the OIG. Given the current enforcement environment and the federal incentive, it is likely that additional states will embark on the introduction or passage of false claims legislation.

The continued publicity attendant to federal FCA legislative and litigation activities – coupled with the impact of the DRA – has created an entirely new set of challenges and concerns for public sector contractors and health care organizations. In this environment, states (and, in some cases, whistleblowers acting on behalf of the states) increasingly are better postured to pursue state FCA litigation.

The creation and amendment of state FCAs allows the states to recover not only in situations involving state funds, but also situations involving mixed funds of state and federal money, such as Medicare, Medicaid, and Federal Aviation Administration funds. In light of the creation of state FCAs, there are a growing number of parallel claims, originating in federal court under the federal FCA and accompanied by a state FCA claim.

It can be safely concluded, however, that despite the prospects of OIG approval or disapproval, states are rushing to enact new or revised FCAs -- both of a general nature and relating specifically to Medicaid fraud. As of this writing, it appears that thirty states have some form of FCA statute. Nine of those have been enacted in the last two years. Additionally, the cities of New York, Chicago, and Washington, D.C. have similar statutes in place. Twenty-five of these states have *qui tam* provisions, and each allows the relator to share in any recovery obtained to varying degrees. Remarkably, California, Montana and Nevada allow for a relator to share in recovery up to 50 percent depending upon the circumstances of the case. All of the states that have *qui tam* provisions allow political subdivisions to intervene and litigate as co-plaintiffs with the relators in their FCAs or to monitor the cases if they choose not to intervene.

As suggested above, the subject matter of existing state FCA laws varies. Seventeen of the state false claims statutes with *qui tam* provisions apply to any type of false claim against the state, while eight states have statutes with *qui tam* provisions that are specifically limited to health care or Medicaid fraud only. Tennessee and New Mexico are the only states with both a general provision and a separate health care-specific statute.

### **Section 6032 of the DRA – The Education Requirements**

The DRA also created substantial additional burdens for health care organizations. Section 6032 of the DRA requires large health care organizations that receive \$5 million or more in annual Medicaid reimbursement to educate employees about certain fraud and abuse laws and the whistleblower protection provisions in those laws. The companies must adopt written policies for all employees, contractors, and agents that:

1. Provide detailed information about the FCA and comparable state statutes, including the whistleblower protection provisions in those laws;
2. Include detailed descriptions of the company's policies and procedures for preventing fraud and abuse; and
3. Update employee handbooks to describe the rights of employees to be protected as whistleblowers and restate the company's

policies concerning false claims laws and the company's internal process for preventing fraud and abuse.

Compliance with Section 6032 is required for the company to be eligible to receive Medicaid payments. Failure to comply may result in the forfeiture of all Medicaid payments during the period of noncompliance. The true danger of failing to comply exists in the threat that the government may assert that a company's knowledge (or imputed knowledge) of its noncompliance with Section 6032 makes its Medicaid claims false and subject to penalties under the FCA.

### Recent Health Care-Related FCA Cases of Note

**Parallel Federal and State Medicaid FCA Claims: *State of Texas ex rel. Ven-a-Care of the State of Texas ex rel Ven-a-Care of the Florida Keys Inc. v. Abbott Laboratories Inc., Travis Co. Dist Ct. (Cause No. D-1-GV-04-01286)***

*Abbott Laboratories* is an example of the multitude of FCA claims involving alleged illegal drug pricing schemes by pharmaceutical companies. State and federal laws require that drug manufacturers report the prices at which they sell their products to various providers, including pharmacies, wholesalers and distributors. State Medicaid programs use this pricing information to estimate the costs Medicaid providers pay to acquire the drug manufacturers' products. Medicaid providers bill the state-run programs for these costs, plus dispensing fees, and Medicaid reimburses the providers. When manufacturers report inflated prices to the state programs, these taxpayer-funded programs overpay providers for the drugs. The difference between what a provider actually pays to purchase a drug and what is reimbursed by the program is called the "spread."

In *Abbott Laboratories*, the Texas Attorney General alleged that the company violated the state FCA by purposefully 1) reporting false and inflated prices to Texas Medicaid, as well as to third-party price reporting services, in order to create enhanced spreads; 2) creating spread sheets showing pharmacies how much more profit they could make when purchasing one product over another; and 3) tying sales personnel compensation to success in marketing the spread. The alleged scheme prompted

providers to favor Abbott over other manufacturers and inflated the company's profits.

Abbott Laboratories settled the case for \$28 million, with \$7.6 million payable to each of the State of Texas (plus attorneys' fees and costs) and the federal government. The relator's share was \$2.8 million, plus attorneys' fees and costs. The Texas Attorney General's office has executed drug pricing scheme settlements with numerous pharmaceutical companies, including Schering-Plough/Warrick Pharmaceuticals in May 2004 for \$27 million, Boehringer Ingelheim/Roxane Laboratories in November 2005 for \$10 million, and Baxter Healthcare Corp. in June 2006 for \$8.5 million.

**Strict Pleading Requirements – Materiality: *United States ex rel. Kennedy v. Aventis Pharmaceuticals, Inc., et al.*, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008)**

In *Aventis*, the relators brought *qui tam* claims on behalf of the United States and the State of Illinois, under § 3730(b) of the federal FCA and the Illinois Whistleblower Reward and Protection Act, against Aventis Pharmaceuticals, Inc. The relators were former Aventis sales representatives and alleged that Aventis marketed its drug Lovenox for off-label uses, thereby inducing doctors and hospitals to submit fraudulent Medicare reimbursement claims to the United States government and the State of Illinois. The relators claimed Aventis purposely ordered its personnel to mislead doctors regarding the approved and safe uses of Lovenox.

Aventis argued that none of the charges for Lovenox identified by the relators qualified as a false claim because individual prescriptions are immaterial to the amount paid by the government for the treatment of a given patient. According to the defendant, Medicare and Illinois Medicaid both reimburse hospitals for inpatient services under a prospective payment system that provides fixed payments based on the diagnosis related group code ("DRG") assigned to each patient.

The district court agreed with Aventis and dismissed the relators' FCA claims because the complaint failed to identify itemized off-label uses that were paid for by federally funded health care programs. The district court stated:

The off-label uses of Lovenox charged on a patient's bill did not cause the

government to pay any more money than it would have paid had the charges not been included in the bill. Under the applicable law and regulations, the government paid the hospitals according to the previously determined DRG rate, which has nothing to do with the particular drugs prescribed or used in the patient's treatment. Under the circumstances, the allegedly false claims do not meet the Seventh Circuit's materiality requirement, because there is no causal relationship between the alleged falsehood and amount the government paid.

Because the individual charges for Lovenox on patient bills were immaterial to the government's Medicare/Medicaid reimbursement decisions, they could not serve as the basis of FCA liability.

### Conclusion

The DRA dramatically increases the stakes for government contractors and health care organizations. Numerous states have enacted, revised, or proposed FCAs in the wake of the DRA. This trend will continue. The educational requirements of the DRA also create the prospect for more state FCA activity. Given the increased Congressional, state and local focus on procurement fraud issues, health care organizations and contractors both should be wary of what the next few years may hold.

### *Civil Litigation - Defense*

## The Role of Coordinating Counsel in Defending Complex Cases

Michael DeMarco (Boston) and David Glynn (Boston)

As a result of DOJ's newer policy to federally pursue smaller, less egregious, health care fraud cases, and the widening of the net that will entail, companies will find themselves more frequently involved as the subject of investigations or defendants in lawsuits with multiple other companies in their industry for similar, if not identical, practices. The old adage of "safety in

numbers" does not apply in these situations, unless everyone has a common understanding of the defense, which is not as simple to achieve as it may sound. As a practical matter, these types of actions may be brought simultaneously, or over time, against individual companies in different jurisdictions, or they may be brought in one action against multiple co-defendants. In either case, many, if not all, defendants are likely to engage different defense counsel and to have limited insight into the company-specific facts that their co-defendants see as most relevant to the case. In such circumstances, companies face the risk, if not certainty, of inadvertently taking, or being blindsided by, contrary legal or factual arguments. The preventive remedy against that risk would be for the companies to agree at the early stages to engage one counsel, or a small number of counsel, to coordinate a defense.

The role of the coordinating counsel is not to represent all of the defendants or to argue on behalf of all of the defendants. Indeed, that scenario is highly unlikely due to legal conflicts and allegiances of companies to their trusted counsel. Rather, the role of the coordinating counsel is to ensure that all defense counsel are brought under one umbrella in order to devise a mutually applicable defense to the claims that are common among all defendants and ensure that any defense by individual defendants to unique claims does not compromise the common defense. Typically, the role of the coordinating counsel is framed by a joint defense and common interest agreement entered into by the parties, pursuant to which the parties agree to work cooperatively to defend the case with respect to common issues. Based on the scope of that agreement, coordinating counsel's role may range from simply bringing defense counsel together to discuss legal strategy to establishing a cost-sharing system for discovery, or to appearing in court as a "single voice" of the defense on common issues. Regardless of the level of control given to coordinating counsel by the parties, its presence is a strategic imperative in any multi-defendant litigation.

K&L Gates has experience as coordinating counsel in major multi-district health care litigation cases that have involved consolidated actions of class-action lawsuits, federal whistleblower actions, and lawsuits brought by the attorneys general of

multiple states. In such cases, liaison counsel takes on the role of coordinating the parties' individual counsel to ensure that similarly-situated defendants present a unified defense and avoided taking positions that would compromise fellow defendants. Moreover, where coordinating counsel has experience in the relevant district court, with local plaintiffs' counsel and with others involved, coordinating counsel can help to guide the parties through the process of often cumbersome complex litigation practices and procedures.

Some of the lessons K&L Gates attorneys have learned as coordinating counsel include:

- Coordinating counsel is critical to ensure that counsel for all of the defendants are communicating with each other to agree on how to present common facts and both joint and individual legal arguments, so as to avoid inadvertently compromising the position of other defendants.
- There are significant cost and efficiency benefits to coordinating a common defense early on in the litigation to avoid duplication of effort among defendants.
- Coordination of the defense can help facilitate case management by assisting the court in structuring the case in a rational and effective way. For example, in some cases, the defendants have been able to provide guidance to the court on which defendants shared similar products or used similar marketing practices and, thus, on how to assign the defendants into manageable groups for discovery, motions practice and trial.
- Coordination of the defense helps to facilitate settlement, by offering a coordinated position to the plaintiff or prosecutor, thus making discussions manageable and facilitating contribution to a global settlement.
- Based on the experience of K&L Gates attorneys as coordinating counsel in past cases and the lessons learned in that role, we would recommend that companies adopt a proactive strategy and bear in mind the following three key points to prepare themselves if and when they are faced with a complex, multi-party health care litigation:

1. Ensure that your general counsel has heightened awareness of the lawsuits or investigations in which your competitors, suppliers, or similarly situated companies in your industry are involved, particularly those initiated by DOJ. Further, ensure that your general counsel is staying abreast of the industry practices and which practices DOJ is presently focused on. This will give the company warning of potential hot button issues as well as allow the company to prepare for a knock at the door.
2. Ensure that you have access to outside counsel with experience, if not a physical presence, in the geographic markets in which you operate or make sales, as these are the jurisdictions in which you are likely to be challenged.
3. Ensure that you have access to outside counsel with experience in complex commercial litigation, white collar criminal defense and, ideally, in defending against class-action litigations.

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### *FDA Enforcement*

## **FDA's New Enforcement Paradigm – From the Slow-Roaster to the Microwave**

Rebecca L. Dandeker (Washington, D.C.)

With a Democratic President and a Congress controlled by the Democratic Party, many government agencies have perceived a "mandate" to increase enforcement efforts against the business community. The FDA is no exception. On August 6, 2009, at a program sponsored by the Food and Drug Law Institute in Washington, DC, newly confirmed FDA Commissioner Margaret Hamburg, M.D., addressed a group of food and drug attorneys, members of regulated industry, and consumer organization representatives. The subject was FDA's expansion of enforcement priorities under the Obama Administration. Her stated goal was to lay out a plan for maximizing FDA's existing enforcement tools and authority. The overall message was that FDA would be speeding up its activities. If past actions were perceived to be "slow" due to the agency's careful and deliberate

approach to enforcement, future actions would be swift and aggressive.

During her presentation, Commissioner Hamburg discussed what she believes constitutes an effective FDA enforcement regime, which would have four co-existing priorities. The agency must be: (i) **vigilant**, using its current surveillance tools to identify and resolve problems more effectively; (ii) **strategic**, prioritizing and targeting significant problems sooner; (iii) **quick**, responding to egregious and serious violations more rapidly; and (iv) **visible**, publicizing FDA's enforcement activities earlier to discourage others in industry from committing similar violations. Five weeks later, Commissioner Hamburg addressed the Regulatory Affairs Professionals Society in Philadelphia and asserted that effective, visible and rapid FDA enforcement is "good for" the regulated industry. She is quoted as stating that "an effective enforcement strategy creates public confidence in FDA oversight, which in turn keeps trust in the safety of FDA-regulated products from eroding." She announced the following six steps, which are being immediately implemented by FDA, to address what some FDA critics had described as "past enforcement deficiencies." Analysis of these actions is presented immediately after each of the FDA's "new" enforcement steps.

1. **Establish a Post-Inspection Deadline** – Following a facility inspection resulting in findings of significant noncompliance, industry will have no more than 15 days in which to respond before the FDA will move ahead with a warning letter or other enforcement action.

FDA has in the past requested a 15-day response to inspectional correspondence, but the request was informal and routinely extended. Now the request is formal (published as a Notice in the Federal Register) and the deadline will be enforced. The problem with this timeline is that it is very short – which may not be readily apparent on the surface. If inspectional findings truly represent "significant noncompliance" (which is undefined), then the company's efforts to correct the deficiencies will usually take 6 to 18 months. Identifying the necessary corrective actions can scarcely be accomplished in 15 business days, let alone drafting and finalizing a responsive letter to a government agency. Consequently, FDA-regulated industries will

have to determine how to submit a written answer that is swift, but that also meets FDA's expectations (expanded over decades) for containing complete, systems-wide, top-down, and detailed corrective and preventive actions. This will be no easy task.

2. **Faster Issuing of Warning Letters** – A streamlined warning letter review policy that limits FDA's in-house lawyers' review to significant legal issues only.

With FDA's in-house lawyers as a conduit, warning letters were considered to contain a well-vetted enforcement "message," but they took a long time to be issued. By cutting out the legal review function, the time between allegedly violative action and warning letter issuance will be much shorter. But the FDA has issued warning letters in this fashion before with unfortunate results. Previously, it led to district-by-district fiefdoms with little to no consistency across the country. As a result, a nation-wide company could get an FDA warning letter at its facility in California for conduct that was expressly permitted by an FDA inspector at its New Jersey facility. Achieving "compliance" under such a fickle regime involves guesswork and expense, and does nothing to "protect the public health" (FDA's mission) or gain public trust. And with "speed" as FDA's goal, there is little incentive for FDA's compliance officers at "headquarters" in Maryland to step in and mediate such district-wide inconsistencies as they have in the past.

3. **Enhance FDA's Existing Relationships with its Regulatory Partners** – By enhancing FDA's existing relationship with local, state, and international partners, the agency hopes to strengthen its risk control and enforcement capabilities.

We have seen this already in the form of subpoenas, investigations, indictments and other enforcement actions by state regulatory agencies, state attorneys general, and sister federal agencies such as the Centers for Medicare and Medicaid Services, the Consumer Product Safety Commission, the Department of Veterans Affairs, and the Drug Enforcement Administration. These additional "police" have

other state and federal statutes and regulations to enforce. Thus, companies must be vigilant to understand and ensure compliance with many sets of rules. This is not a change, of course, but such a coordinated increase in inter- and intra-governmental cooperation means that enforcement actions will be more frequent, with one act of non-compliance potentially generating several inquiries from different avenues.

4. **Prioritize Enforcement Follow-Up** – After issuing a warning letter or initiating a major product recall, FDA will move faster to assess industry response and compliance.

This is probably good news for companies that have fast-acting change-control and compliance capabilities, so long as they “get it right” the first time. For companies with an extensive hierarchy or slow-moving decision-making processes, however, their reactions and responses may not be timely enough to avoid additional enforcement action. Moreover, “follow-up” might be better phrased as “subsequent enforcement,” since Dr. Hamburg wants to limit the back-and-forth discussions between regulators and companies and instead favors strong FDA action rather than deliberative “agreements.” In place of a second warning letter would be seizures, injunctions, civil fines and even criminal penalties.

5. **Increase Enforcement Readiness** – This will allow the agency to act swiftly and aggressively when needed to prevent potential public health risks.

Some companies have experienced this already and, unfortunately, their perspective might be that FDA is embarking on a cowboy culture – shoot first and ask questions later. When the mantra is “swift and aggressive,” science can get sacrificed on the altar of speed. If FDA’s science is debatable, or even flat-out wrong, the agency may change course later but by then it is too late. The damage has been done, and a company’s reputation, partnerships and market share often cannot be regained. When the underlying scientific issues are complex, a “deliberative” and “careful” government agency is a positive thing, regardless of timeframes.

6. **Implement a Formal Warning Letter “Close-Out” Process** – Following receipt of a warning letter and an agency inspection confirming that the identified problems have been resolved, FDA will issue a formal “close-out” letter indicating that the identified violations have been successfully addressed. FDA intends to post “close-out letters” on its website.

Again, this sounds like a good idea. But with FDA resources running perpetually low, the agency “close-out” timelines are likely to be very long – too long to be of use to industry members who lose consumers and reputation in days. A close-out letter that gets issued 12 to 18 months after a warning letter is not that helpful. Nonetheless, we have seen many companies hit hard after a warning letter by secondary entities: investors, customers, and partners who cancel contracts, cancel financial offerings, and take their business elsewhere due to the “taint” associated with FDA’s statement on non-compliance. Consequently, many companies will find it useful to have a close-out letter in hand to pacify future vendors, customers, and Wall Street. Let’s just hope that FDA is prepared for the onslaught of requests for close-out letters that it will receive. A description of the Warning Letter Close-Out Program is already posted on FDA’s website, applicable to letters issued after September 1, 2009.

So what can the FDA-regulated industries do to prepare for this ramped-up enforcement? One response may be to put more money and employee resources into compliance, now. Make sure that your company fully understands and is complying with FDA’s requirements. Conduct internal audits and identify areas of concern before FDA turns its attention to your company. Later, if FDA takes action against your company or products, move swiftly to address the issues – in hours, not days or weeks. You must signal to FDA the company’s understanding that FDA inspectional correspondence and warning letters are not “the cost of doing business,” and that the company’s response will not be “business as usual.”

*Insurance***Health Care Providers Should Consider Whether Insurance Covers the Defense or Settlement of Investigations of Allegedly Improper Billing Practices**

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Health care providers routinely find themselves the target of regulatory scrutiny. Now, however, health care providers must also consider the increasing risk of meeting the more difficult, unfamiliar challenge of being subjects of government civil and criminal fraud investigations. An increasing number of federal and state law enforcement agencies are being tasked to investigate claims of fraud of government funds. Prominent among the targeted areas for investigation are allegations of health care fraud, such as, the improper billing of Medicaid, Medicare or private insurance companies for services that were not performed, overcharging for certain services, charging for unnecessary and expensive procedures, and billing for costly new equipment that is not actually purchased.

Thus, for every health care provider, the time to develop a plan for responding to such an investigation is now, before becoming embroiled in a fraud investigation. One important area to prepare for is determining how to meet the substantial defense costs, in the event of an investigation, even if the underlying allegations are unfounded and ultimately disproved. In addition, careful consideration should be given to the possibility that an investigation may result in a multimillion dollar settlement or judgment. When faced with such a high-risk claim, a health care provider must review its insurance coverage program to determine if it has coverage available to respond to the claim. Indeed, in advance of an investigation, a health care provider may wish to consult an experienced insurance coverage practitioner, who can review the existing coverage to identify potential gaps in coverage and to obtain possible enhancements to coverage.

In many cases, health care providers should be entitled to coverage under their directors' and officers' liability policies ("D&O policies"). D&O policies afford coverage for certain losses resulting

from claims made against an insured for a wrongful act, including any actual or alleged error, misstatement, misleading statement, act, omission, neglect or breach of duty. They cover directors and officers for claims for which they are not indemnified and also afford "reimbursement" coverage to the entity that is indemnifying the directors and officers with respect to the underlying liability. In some cases, D&O policies also provide coverage to the entity for certain losses.

Although specific terms and breadth of coverage vary widely, most D&O policies are "claims made" policies meaning that they cover claims that are made against an insured (and in some cases, reported by an insured) during the policy period. This article addresses certain provisions that are likely to bear on whether a fraud investigation is covered and some of the potential defenses to coverage.

**Are Investigations "Claims" as Defined by the Policy?**

A threshold issue with respect to coverage for an investigation is whether such an investigation constitutes a covered "Claim" under the pertinent policy language. Some D&O policies define Claim broadly to include "any civil, administrative or regulatory proceeding, or investigation against an Insured Person." Other D&O policies, however, have narrower definitions. For example, the following language, or a variation thereof, may be used:

**Claim means:**

1. a written demand for monetary damages;
2. a civil proceeding commenced by the service of a complaint or similar pleading;
3. a criminal proceeding commenced by the return of an indictment or information or similar document; or
4. a formal civil administrative or civil regulatory proceeding commenced by the filing of a notice of charges or similar document or by the entry of a formal order of investigation or similar document against an Insured for a Wrongful Act, including any appeal therefrom.

Such a definition may raise questions as to whether there is a Claim where a regulatory investigation is

begun, perhaps through the service of a subpoena, but no “formal” proceeding has yet been instituted.

### **Defense Cost Obligations**

Once a health care provider determines that the investigation constitutes a covered Claim, a D&O policy will likely cover the defense costs the provider incurs in responding to the Claim, which may add up to hundreds of thousands, if not millions, of dollars. It is important to note, however, that “Defense Costs” are typically defined to include “reasonable and necessary legal fees and expenses in the investigation, defense, settlement and appeal of a Claim.” An insurer must honor its obligation to pay defense costs, even if a regulator ultimately decides not to bring charges or to file suit against the health care provider.

D&O policies typically provide that the insurer does not have a duty to defend the insured. Instead, the insured retains its own counsel and the insurer reimburses the insured’s defense costs. It is important to note, however, that D&O policies require that the insured obtain the insurer’s consent before incurring defense costs. Thus, a health care provider that fails to obtain such consent runs the risk that its insurer will deny coverage for the defense costs, a most undesirable result.

Lastly, D&O policies generally provide that defense costs are paid within the policy limit. This means that any dollars paid for defense costs reduce the policy limits available for the reimbursement of judgments and settlements.

### **The Definition of Loss**

D&O policies cover “Loss” resulting from certain claims against insureds. Although the definition of Loss varies from policy to policy, it may be defined as the amount that an insured becomes legally obligated to pay on account of a covered Claim, including, but not limited to, damages, judgments, settlements, pre-judgment, and post-judgment interest. Some policies include punitive or exemplary damages, if they are insurable under the law of the jurisdiction most favorable to the insurability of such damages.

Many definitions of Loss exclude coverage for fines or penalties. But a D&O policy issued to a health care provider may cover fines and penalties for violations of the Internal Revenue Code, EMTALA,

HIPAA and for Regulatory Wrongful Acts, which are defined to include violations of the False Claims Act or similar laws, anti-kickback, illegal remuneration, self-referral or health care fraud and abuse laws. There may, however, be sub-limits of liability for coverage and a health care provider will want to review such sub-limits to ensure their adequacy. Also, some D&O policies expressly exclude coverage for Regulatory Wrongful Acts.

### **Fraud and Improper Personal Profit Exclusions**

There are several exclusions found in D&O policies that may be implicated by a health care fraud investigation. For example, virtually all D&O policies contain some type of exclusion for improper profit and fraudulent or dishonest conduct. Some D&O policies will not cover a Loss “where it is established in fact that the Insured gained any profit, remuneration or pecuniary advantage to which they were not legally entitled or committed any fraudulent or criminal Wrongful Act with actual knowledge of its wrongful nature or with intent to cause damage.”

In contrast, some D&O policies state that the personal profit and fraud exclusions apply only where the improper profit or deliberate fraud has been established by a final adjudication. Thus, where a health care provider settles an investigation without admitting guilt, such exclusions should not bar coverage.

### **Severability**

A health care provider will want to determine if the D&O policy contains a “severability” provision with respect to the policy exclusions. Such a provision protects innocent insureds, and establishes that, for purposes of determining whether an exclusion applies, the Wrongful Act of one insured is not imputed to other insureds. In some policies, the knowledge of certain insureds, such as the health care provider’s senior officers, may be imputed to the provider for purposes of applying the exclusions.

### **Insurer Consent**

Many D&O policies state that the insured shall not admit liability, consent to any judgment, agree to any settlement or make any settlement offer without

the insurer's prior written consent. If an insured fails to obtain the requisite consent, the insurer may not be liable for any Loss arising therefrom.

### Conclusion

This article touches upon just a few of the insurance coverage issues health care providers may face if they become a target of an investigation of allegedly improper billing practices. Because D&O policies vary greatly, each provider will want to consult with experienced insurance counsel to determine whether their policies afford coverage for the defense of such investigations or, if necessary, any settlement or judgment.

### Audits

## Responding to Medicare and Medicaid Recoupment Demands Based Upon Statistical Projections

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### Introduction

For many years, auditors of Medicare and Medicaid claims have engaged in statistical sampling and projection methods to recoup alleged overpayments. Based upon statistical extrapolations of findings of allegedly excessive or improper claims ranging in value from several hundred to several thousand dollars, demands for recoveries are made ranging from tens of thousands to hundreds of thousands of dollars and more.

Providers can expect to see a continuation of these sampling and statistical extrapolation methods with the Recovery Audit Contractors ("RAC") audits. In addition, audits by Medicare payment contractors and Medicaid civil and criminal investigation units are expected to increase now that the government's focus on driving down the cost of public health care programs is more intense than ever.

In the event that a health care provider has been audited and refuses to agree to a "reasonable settlement," threats are often made to terminate the provider's Medicare or Medicaid participation, impose civil money penalties, or conduct a more extensive medical record review involving

significant provider time and potentially greater exposure to more substantial liabilities. Faced with difficult to understand statistical procedures, which appear scientifically sophisticated and precise, health care providers are often reluctant to contest these claims, weighing the cost and expense of retaining expert consultants and legal advisors against the chance of prevailing in a technical dispute. A provider's tactical decision to settle without challenge, however, may invite repeated and periodic demands for additional recoveries and permit continuation of improper recovery techniques. Therefore, before buckling under to such pressure, providers should consider the bases for challenging such auditing methods and conclusions.

In an effort to help providers make that decision, this article examines some of the basic strategies available for challenging statistical projections. These options range from common-sense responses that can be conducted with minimal expert assistance to more extensive strategies appropriate for larger and more complex claims. What is critical to understanding all of these defenses, however, is that the very power of statistical projection techniques commonly utilized by Medicare and Medicaid auditors also makes the use of the projection techniques themselves vulnerable to attack. Any errors that are shown in the process of conducting an audit or applying projection methods to the sample may reduce and perhaps eliminate the overpayment resulting from extrapolation of conclusions reached about the sample.

### The First Line of Defense: Are the Audit Findings Accurate?

Often, the small dollar values associated with individual transactions appear not to warrant a careful scrutiny of the documentation, facts and circumstances surrounding the transactions. Since auditors draw inferences regarding a large universe of transactions based upon a review of a small sampling, flyspecking the results of the audit of individual claims disallowed in whole or in part becomes critical. Any finding that can be proven inaccurate reduces the multiplication of that finding across the universe of claims. As a result, the first and often best line of defense is to go back to the basics: 1) review thoroughly the rules and

requirements pertaining to the claims in question; and 2) check and double-check the accuracy of the audit results. A painstaking review of this type is essential not only because reversing findings regarding individual claims will reduce the total dollar value of a projection, but also because reversing or modifying findings with respect to a small number of transactions may decrease the level of statistical reliability associated with a particular sample below the level needed to make statistical projections. In addition, although this task can be time-consuming, it can often be done internally and verified later through hired consultants, which means it can be a cost-effective review.

### **Turning the Tables: Did the Audit Adequately Consider Errors Made in Favor of the Auditing Entity?**

Auditors often have incentives to discover errors and omissions made by contractors, providers or other audit subjects. For example, RAC auditors are retained on a contingency fee basis and a recent administration project revealed that 96% of the improper payments found by those auditors were for overpayments. In any event, auditors far too many times fail to consider adequately, or at all, whether appropriate payments have been made for individual claims; whether claims have been paid on a timely basis; or whether claims that have been disallowed were properly handled. To illustrate, if a sample is pulled only from a universe of paid claims, and not from all claims submitted, it will be impossible to determine whether improper disallowances or claims reversals occurred. To correct such an omission, one technique is to conduct an independent audit of disallowed claims and offset the findings against the audited claims. Alternatively, the very use of such a biased sample in itself may provide a basis for disqualifying any statistical projections.

### **Demanding That Auditors Play by the Rules: Were Official Policies and Procedures Followed?**

Audits relying on statistical projections, especially when conducted on a contingent fee basis, are often subject to their own set of complex procedural requirements, which are ideally intended to ensure the reliability of findings. When dealing with audits utilizing statistical projection techniques, one must keep in mind that everyone involved in the process,

from the auditor to the courts that may be reviewing the audit on appeal, have varying levels of understanding about the sampling and extrapolation methods. The combination of uncertainty about how to evaluate statistical projections and the possibility that violations of complex procedural requirements often occur may tip the playing field in favor of the subject of audits and away from the auditor or agency engaging the auditor. In some cases, a statistical expert can easily explain errors that would otherwise be unknown to the parties involved. To take advantage of this situation, parties that are subject to audits using statistical projections should carefully review the rules, regulations, or guidance documents which govern the activity of auditors. If any errors are discovered, especially any pattern of repeated or multiple errors, an explicit or implicit presumption may arise that the audit findings are unreliable. This presumption may prove to be difficult to rebut.

### **Insisting on Fundamental Fairness: Do the Findings Justify the Remedy Requested?**

Not all errors and omissions nor patterns of such discovered by audits are of equal severity. In circumstances where a provider is found to have knowingly and intentionally made errors and omissions to obtain payments or allowances to which the provider was clearly not entitled, the use of powerful statistical projection techniques to punish these practices may be justified. By the same token, however, when innocent errors or omissions occur (such as, for example, errors and omissions that have not been previously encountered or been the subject of prior audits; or that result from good faith misunderstandings of complex technical requirements; or for which the application of regulations and policies is subject to legitimate dispute), the application of projection techniques is typically not appropriate. In those instances, agencies should be more inclined to disallow or reduce payments only for the particular claims discovered and insist upon the implementation of a prospective corrective action plan. Between these two extremes lies a vast middle ground upon which the appropriate approach to recovery will require a scrutiny of the subject transactions.

In evaluating whether audit findings justify the use of extrapolation techniques, consideration should be given to whether failures to properly document claims, or errors made in the submission of claims, justify a conclusion that the services provided would not have been entitled to payment or recognition. When this occurs, it becomes critical to evaluate whether based on the circumstances that led to the claim being incorrectly submitted, it is appropriate to disallow such claims in their entirety, recalculate the payments or allowance, or disregard the errors or omissions as harmless. This is particularly relevant in the many instances where services were appropriately provided and payment should be made, but a technical error occurred in billing.

Similarly, the evaluation of the facts and circumstances surrounding errors or omissions should include a review of whether the customs and practices of the agency caused or contributed to any errors or omissions. For example, were the relevant claims submission requirements or policies clear, or were they poorly written and misleading? Did errors or omissions result from a reliance upon reasonable interpretations of laws and policies contrary to the position taken by the agency in an audit and about which the agency knew or reasonably should have known. In such instances, a course of conduct may bind the agency, or, at a minimum, bar the agency from making audit adjustments based upon such practices.

### **Refusing to Play the “Gotcha Game:” Can Omissions in Documentation be Corrected?**

A common practice in statistical audits is for an auditor or agency to assert that if a claim was improperly submitted, or contained errors and omissions, the mistakes cannot be corrected subsequently with the submission of additional data. Where such assertions occur, it is important to evaluate whether any such requirements are embodied in law or regulation, constitute legally non-binding policy statements, or are contrary to applicable laws and regulations. In this regard, it is critical to note that in the context of Medicaid programs, several states have adopted laws expressly authorizing the submission of supplemental data to correct initial errors or omissions in claims. Many other jurisdictions also hold to the view that if such policies are to be applied as “binding norms,” but

have not been validly enacted as agency rules pursuant to notice and comment procedures, the requirements are a nullity and may not be enforced.

### **Challenging the Fundamental Basis of Statistical Projections: Are Transactions Selected for Review Fairly Representative of the Universe to Which Projections Are Applied?**

Of fundamental importance to any justifiable reliance upon statistical projection techniques is whether a sample represents a fair and unbiased representation of the universe from which a sample is drawn. In addition to checking whether an auditor failed to use proper randomization techniques or engaged in any conduct that injected bias into the sample, at least three factors should always be considered in evaluating the fairness of statistical projections. First, does the sample include any “outliers,” which due to unique facts and circumstances or a significant deviation from other sample findings should be disregarded? Second, if errors or omissions are uncovered only or primarily with respect to certain types of claims, should projections be limited only to similar types of claims? Finally, did any significant differences exist regarding the handling of different types of claims, or the handling of claims at different times, which suggest the need to stratify the sample to obtain a higher degree of precision? Consideration should also be given to requesting the use of a larger sample size, or to conducting a more extensive test audit, to determine whether the sample is fairly representative.

### **What Standard of Proof Should Apply?**

All statistical projections have a margin of error that is stated as part of the result of the calculation. This margin of error is typically referred to as the “confidence interval.” The confidence interval is usually not explained as part of the overpayment findings by Medicare or Medicaid auditors. In the Medicare program, the standard approach to projecting overpayments is based on the lower limit of a one-sided 90 percent confidence interval. In other contexts, for example in environmental testing, a more conservative approach is used. As a result, projections based upon the sample mean, or based on a less precise confidence interval, are suspect and vulnerable to a challenge. Projection

techniques should also be challenged if, based on the size of the universe being sampled, the costs of reviewing transactions and amounts in controversy render reliance upon statistical projection techniques unjustified.

### **How Should an Expert Consultant Be Selected?**

Consultation with an expert trained in the use of sampling techniques can be valuable in developing a strategy to challenge audits using statistical projections, and essential to presenting evidence in any adjudicative hearing. At a minimum, an expert should have a master's degree in statistics or comparable experience. Of note, however, is that an expert's familiarity with the type of transactions under review is often of much greater relevance than an expert's academic and research credentials. Knowledge of the program under review, the relevant regulations and policies, and the manner in which a program is administered, including familiarity with local practices, can be particularly valuable in devising the most effective approaches to challenging audit results which rely upon statistical projections.

### **Conclusion**

The strategies listed above reflect only some of the mechanisms and arguments available to challenge any audit based upon statistical projections. Health care providers, contractors, and other persons subject to such audits should seek competent technical and legal advice in devising the most appropriate approach to evaluating and determining how best to respond to demands for repayment or recoupment which are based on extrapolation of the results of findings from a sample of transactions within a universe of claims or records.

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