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Compliance Today - December 2019
Vive la différence? American and French healthcare fraud, waste, and abuse laws

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America and France share many common ideals. The American Constitution is founded on the principle of government "of the people, by the people, and for the people." The French Constitution embodies this same principle in the ideals of "*liberté, égalité, fraternité.*" Based upon these shared values, our two countries have forged an indelible alliance through which we have triumphed together side-by-side in the American War of Independence, two World Wars, and even the Cold War. Now, our two nations work together as allies to lead the world in responding to a wide variety of economic, political, medical, technological, and scientific challenges that confront a rapidly changing world.

The US and France participate in a truly global network of healthcare providers, with significant economic and scientific dependence between these two countries. Hundreds of biotech companies are based in France, many of which also do business with American-based companies.[1] For example, in the medical device sector alone, in France this year, revenues from medical device sales are expected to reach €31.2 billion (more than $35.2 billion).[2] Sales from device exports from France are expected to account for €8.9 billion (almost $9.8 billion), which is 26% of the total market.[3] Of the 1,300 medical device firms operating in France, one-third of these are based outside of France.[4] Foreign medical device companies generate two-thirds of the device sales revenues in France, with American companies accounting for the largest share, 22% of the total revenues.[5]

One major challenge confronting both America and France is developing and implementing a healthcare system that can provide life-extending care in a way that is effective, innovative, and cost efficient. Although the healthcare systems in America and France differ in many respects, there is one challenge that confronts both countries: the problem of fraud, waste, and abuse. Both countries take this problem seriously. For example, in America the federal government recovered more than $2.5 billion in 2018 alone from healthcare fraudsters,[6] while in France estimates indicate that at least one in five emergency room visits in 2017 was deemed "inappropriate."[7]

This article will focus on myriad statutes and regulations enacted in America and France to combat fraud, waste, and abuse. It will highlight some of the important similarities as well as differences between these laws. Given the close historical and commercial ties between America and France, particularly healthcare companies that operate regularly in both countries, it is essential that all players involved in healthcare (e.g., businesses, manufacturers, providers, and attorneys) have a working understanding of the fraud, waste, and abuse laws of both countries.

The American and French healthcare systems

There is no dispute that the United States and France both invest tremendous public resources in their healthcare systems. In America, which has a population of over 326 million, estimates indicate that more than $3.5 trillion was spent on healthcare in 2017.[8] This represents an expenditure of $10,739 per citizen in the United States. By comparison, in France, which has a population of over 67 million, estimates indicate that more than $328 billion dollars was spent on healthcare in 2017. This represents about $4,902 per person in France. There are many complicated reasons for the differences in healthcare spending. However, there is little doubt that both America and France commit an extraordinary amount of their public wealth to delivering healthcare to their citizens. One obvious and primary difference between the healthcare in America and France is that the American system is made up of a hybrid of public and private payers, but France has a publicly run "universal" health insurer. These differences are examined further below.

The American healthcare system

It is a misnomer to label healthcare in America as one "system." Rather than a singular system, healthcare in America is delivered through a hybrid of two different, but interrelated healthcare systems: (1) the government-funded or "public" health system, and (2) the numerous for-profit and nonprofit private health insurers. This hybrid system provided some measure of healthcare to 91.2% of Americans in 2017.[9]

The first part of the American hybrid health system is government-funded public insurance. The main pillars of government-funded insurance are the giant Medicare and Medicaid systems. The Medicare system was created in 1965 to provide government-funded healthcare to millions of Americans older than age 65. Over time, Medicare has been expanded to now include: Part A (hospital insurance); Part B (medical insurance); Part C (Medicare Advantage Plans, which are "managed care" alternatives to Parts A and B); and most recently, the massive Part D prescription drug coverage program. Additionally, Medicare has been expanded to now cover individuals older than 65, disabled individuals, and individuals with end-stage renal disease or those requiring a kidney transplant. By 2017, 58.5 million people were enrolled in Medicare, and Medicare spending reached $705 billion (20% of the total spending on healthcare in America). This behemoth government-funded healthcare program is run by the Centers for Medicare & Medicaid Services (CMS), a division of the United States Department of Health and Human Services (HHS).

The other main pillar of American government-funded insurance is the Medicaid system. Medicaid, also created in 1965, was set up to provide government-funded healthcare for poor and low-income families. Like Medicare, the Medicaid program has been expanded over time, and now covers low-income families, pregnant women, people of all ages who have long-term disabilities, and people who need long-term care. Also, like Medicare, the Medicaid program provides hospital insurance, medical insurance, "managed care," and prescription drug coverage. However, unlike Medicare, the Medicaid program is not funded solely by the federal government. Rather, the Medicaid program is *jointly* funded by the federal government and each of the 50 states (plus territories including Puerto Rico, Guam, and the District of Columbia). Moreover, unlike Medicare, the Medicaid program is run by each individual state, and thus the program can vary significantly from state to state. In terms of size, the Medicaid program covers more than 73 million Americans. Medicaid spending nationwide grew to $581 billion in 2017.[10]

Medicare and Medicaid are the two main pillars of the American public health system, but there are other significant, publicly funded health insurance programs, including, but not limited to: the Children's Health Insurance Program (CHIP), TRICARE (the health system for the US military), the Department of Veterans Affairs (the health system for US military veterans), and the Federal Employees Health Benefit (FEHBP) program.

The second part of the American hybrid health "system" is the private health insurance market. In 2017, an estimated 67.2% of Americans had private health insurance. Private insurance spending has grown to more than $1.1 trillion per year. The most common form of private insurance is employer-based insurance in which nongovernment employers offer their employees group insurance plans, typically administered by private, for-profit insurance companies. Additionally, about 16% of Americans received private insurance by purchasing coverage directly from insurance companies, rather than through their employers. Private insurance companies are, as the name suggests, privately run. However, they are regulated at the state level by individual state insurance departments that guard against fraud, waste, and abuse through their own sophisticated internal fraud monitoring and special investigations units, often directed by former law enforcement personnel.

Perhaps the most significant recent trend in the American private insurance market is the rapid consolidation of mega insurance companies, driven (among other reasons) by increased competition and an aging American population.

The French healthcare system

The French healthcare system is primarily a government-funded, single-payer system known as *l'assurance maladie*, or the *sécurité-sociale (Sécu)*.[11] The Sécu system picks up most healthcare costs, but French citizens can also voluntarily purchase private insurance (*assurance complèmentaire* or the *mutuelle santé*) to cover those medical costs that are not covered by the state Sécu. This voluntary health insurance is provided through mutual organizations and private insurers, and it is not always compulsory.

Historically, *l'assurance maladie* comprised a number of private or mutual insurance carriers that collected insurance premiums from their clients, which were then used to pay for the costs of healthcare. Today, health insurance is a public organization and operates under the supervision of the government, which has ultimate financial responsibility. The funds are committed through legislation enacted each year by the French Parliament, which covers the financing of the Sécu.

The main health insurance fund is a general fund called the *Régime Général.* This fund covers about 85% of the population working in industry and commerce, as well as the unemployed and those retired or not covered by another fund. Within the *Régime Général,* the Protection Universelle Maladie (PUMA) guarantees permanent health coverage for all persons who are legal residents in France, whether they are employed or not. This universal system of healthcare has been in place in France since January 2016.

At the national level, healthcare strategy in France is the responsibility of the Ministry of Social Affairs, Health, and Women's Rights. At a local level, the General Fund is administered by a health authority, called the *Caisse Primaire d'Assurance Maladie (CPAM).* For self-employed workers in France, there is a separate state-controlled insurance scheme called *Régime Social des Indépendants* (*RSI*). However, since 2018, the *RSI* has been in the process of being dismantled, and all those affiliated with it will be transferred to their local *CPAM* in the future.

American healthcare enforcement

In America, the task of preventing and combating fraud, waste, and abuse in the hybrid healthcare system is spread among a complex patchwork of actions: federal and state law enforcement agencies and investigators, private insurance company fraud investigations/monitoring departments, and private-citizen whistleblowers. Adding to this complexity are the numerous federal and state criminal and civil laws and regulations that apply to combat fraud, waste, and abuse in the healthcare system. Untangling this web is essential to understanding the American healthcare system, and to avoid the worst effects of being caught up in a potentially devastating healthcare fraud investigation and/or civil or criminal prosecution.

America's healthcare fraud enforcement team

Although the various groups responsible for healthcare enforcement in the US often work together, or at least cooperatively, it would be an overstatement to call them a unified team. However, each of the government agencies, private organizations, and individuals plays a key role in reducing fraud in the multitrillion-dollar American healthcare system. Any practitioner involved in this area should understand the various duties and responsibilities of the members of America's highly diversified healthcare fraud prevention team.

The first part of the American healthcare enforcement team is the government (federal and state) law enforcement agencies and investigators who are primarily responsible for policing the American system. At the federal level, these duties are shared by several agencies, including: (a) the Office of Inspector General for the United States Department of Health and Human Services (HHS-OIG), which, among other things, investigates allegations of fraud against the Medicare and Medicaid programs; (b) the United States Food and Drug Administration's Office of Criminal Investigations (FDA-OCI), which investigates alleged illegal practices by pharmaceutical and medical device manufacturers; and (c) the United States Department of Justice (DOJ), and its 93 separate United States attorneys, who initiate and prosecute criminal and civil healthcare fraud cases on behalf of the federal government. The 93 United States attorneys are appointed by the president of the United States and are subject to confirmation by the Senate. Each US attorney serves as the chief federal prosecutor for a specific geographic area of the United States (referred to as federal districts). Although the US attorneys often change with the election of a new president, the individual prosecutors who work for the US attorney (known as assistant United States attorneys, or AUSAs) typically remain on the job through multiple administrations as career prosecutors.

At the state level, the duties of combating healthcare fraud are shared among 50 individual state attorneys general, 50 individual state Medicaid Fraud Control Units (MFCUs),[12] and hundreds of local prosecutors within each state (often referred to as district attorneys). The individual state MFCUs work together through the National Association of Medicaid Fraud Control Units (NAMFCU), which promote efficiency in healthcare fraud prosecutions by sharing information and dividing responsibility for investigating and prosecuting fraud cases on behalf of all member states. The task of coordination among these many government efforts is neither simple nor straightforward.

Although these federal and state law enforcement agencies often focus on individual cases, they have become increasingly more aggressive and coordinated. For example, in July 2017, the DOJ announced a national healthcare fraud takedown, which was the largest ever healthcare fraud enforcement action. It involved 412 charged defendants across 41 federal districts, including 115 doctors, nurses, and other licensed professionals. The alleged healthcare fraud schemes totaled approximately $1.3 billion in false billings to federal and state agencies.[13] Thirty state MFCUs also participated in these arrests, and HHS-OIG initiated suspension actions against 295 providers, including doctors, nurses, and pharmacists. These coordinated government takedowns dramatically demonstrate the escalating sophistication and coordination among the federal and state law enforcement agencies charged with combating healthcare fraud, waste, and abuse in the US.

Private healthcare insurance enforcement

The second part of the American healthcare enforcement team comprises the fraud investigations/monitoring departments of large private insurance companies. These departments often employ sophisticated claims monitoring programs and medical chart review teams to identify any outliers or anomalies in healthcare claims data. Former law enforcement agents are often hired to fill these roles. Although these private insurance company investigation departments cannot institute criminal fraud prosecutions, they frequently refer cases of

suspected fraud to United States attorneys and state attorneys general for investigation and prosecution. Additionally, these private investigation departments frequently make repayment demands from healthcare providers and file civil lawsuits against providers who submit improper healthcare claims. Providers and manufacturers that operate in America would be wise to deal carefully with private insurance company auditors and investigators, because a small case regarding private insurance claims can easily become a full-blown federal or state criminal and/or civil fraud investigation.

Whistleblowers and their private lawyers

The third part of the American enforcement team are the private-citizen whistleblowers (also known as relators) whose role in combating healthcare fraud in America is truly unprecedented and extraordinary. Although members of the public are frequently told, "If you see something, say something," the reality is that private citizens are loath to blow the whistle on suspected fraud. It is simply easier to turn a blind eye, rather than get personally involved. That certainly was the case in America when it came to healthcare fraud, at least until Congress amended the federal False Claims Act (FCA) in 1986. Through those amendments, Congress deputized citizens, with the help of their private counsel, to file lawsuits on behalf of the government against anyone who presented, or caused to be presented, a false or fraudulent claim for payment to the United States, including through any federally funded healthcare program like Medicare and Medicaid.

These private-citizen whistleblower lawsuits are called "qui tam" actions, after the Latin phrase "qui tam *pro domino rege quam pro se ipso in hac parte sequitur*," meaning "he who sues in this matter for the king as well as for himself." The FCA enables any "person" to file a qui tam lawsuit. The person can be an individual or a corporation (e.g., a competitor).

Whistleblowers do not need to be US citizens or even live in the United States. They can live anywhere in the world, including France. The primary requirement is that the whistleblower have specific, credible information that the defendant presented false or fraudulent claims for payment of US government funds. Given that the US government spends money throughout the world, and that businesses across the globe receive US government funds, the number of qui tam lawsuits filed under the FCA by whistleblowers located outside of America has increased in recent years. In fiscal year 2018 alone, the US government awarded more than 110,000 prime contracts that were either performed outside the US or were awarded to businesses located outside the US—including 1,179 prime contracts in France.[14]

Since 1986, private whistleblowers have filed more than 7,600 qui tam lawsuits involving alleged healthcare fraud, and those lawsuits have recovered more than $32 billion for federal taxpayers. Through the qui tam provisions in the FCA, the government can now reach every healthcare provider, hospital, and manufacturer whose products or services are funded by the Medicare and Medicaid programs.

Private-citizen whistleblowers expose fraud schemes that otherwise would have gone unpunished. Qui tam whistleblowers have exposed a wide array of illegal practices, such as bribes and kickbacks paid to physicians, illegal marketing of pharmaceuticals and medical devices, medically unnecessary services, and dangerous treatment within nursing homes. Moreover, qui tam whistleblowers have come from every level of healthcare entities, including the boardroom, the C-suite, the emergency room, and the sales/marketing team. As a result, the FCA has been widely recognized as the US government's most effective tool in combating fraud, waste, and abuse in the American healthcare system.