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Compliance Today - November 2021
The differences and similarities between American and Italian healthcare fraud, waste, and abuse laws: Part 1

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This is Part 1 of a three-part series discussing the similarities and differences between the US and Italian healthcare fraud, waste, and abuse laws. Part 2 of this series will be published in the December issue of Compliance Today, *and Part 3 will be published in January 2022 issue of the magazine.*

The United States of America and the Italian Republic share many common ideals. America was named after Amerigo Vespucci, an Italian explorer.[1] The American Constitution is based on the principle of government "of the people, by the people, for the people." The Italian Constitution embodies this same principle in the ideals of sovereignty to the people: "La sovranità appartiene al popolo." As of 2003, almost 16 million Americans claimed to have had Italian heritage.[2] With shared values, our two countries have forged an indelible alliance. These allied nations work together as world leaders in responding to a wide variety of economic, political, medical, technological, and scientific challenges that confront a rapidly changing world.

A major challenge confronting both America and Italy is providing a healthcare system that extends medical treatment that is effective, innovative, devoid of fraud, and cost efficient. While the healthcare systems in America and Italy differ in many respects, they suffer from the same obstacles: fraud, waste, and abuse. Both countries take these problems seriously. For example, in America, the federal government recovered more than $2.2 billion in 2020 alone from healthcare fraud and false claims,[3] while in Italy the National Anti-Corruption Authority (Autorità Nazionale Anticorruzione) is actively monitoring, preventing, and responding to corruption, as well as issuing anti-corruption plans.

This article highlights laws enacted in America and Italy to combat fraud, waste, and abuse, showing important similarities as well as differences between these enforcement efforts. Given the close historical and commercial ties between America and Italy, including healthcare companies that regularly operate in both countries, all stakeholders involved in healthcare (i.e., financial stakeholders, manufacturers, marketers, distributors, providers, and attorneys) should have a working understanding of the systems to deter and respond to fraud, waste, and abuse.

Additionally, due to the worldwide COVID-19 pandemic, two simultaneous phenomena have emerged: (1) an unprecedented increase of healthcare spending by governments and (2) a focus on fast performance of urgent public healthcare services, sometimes at the expense of values such as transparency, controls, and application of corruption prevention measures. This article aims to also understand how anti-fraud policies in America and

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Italy will be affected by the unprecedented spending in response to the pandemic that crippled both countries for over a year.

The American and Italian healthcare systems

Despite many complicated differences in healthcare spending, both America and Italy commit extraordinary public resources to healthcare delivery. One primary distinction between the two is that the American healthcare delivery system is a hybrid of public and private payers, while Italy relies predominantly on a universal public healthcare system augmented by a growing private system.

The American healthcare system: A public-private hybrid

To label healthcare in America as one "system" is a misnomer. Americans receive medical care through a hybrid of two different but interrelated healthcare delivery systems: (1) the government-funded or "public" health system, which has federal and state components, and (2) the numerous for-profit and nonprofit private health insurers. This hybrid system provided some measure of healthcare coverage to 92% of Americans in 2019.[4]

The first prong 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 (although there are other significant publicly funded health insurance programs such as the Children's Health Insurance Program; TRICARE, which is the health system for the US military; the Veterans Health Administration, which is the health system for US military veterans; and the Federal Employees Health Benefits Program and similar programs throughout the country that cover state employees). Created in 1965, Medicare provides government-funded healthcare to millions of Americans aged 65 and over. Over time, Medicare has expanded to include Part A (hospital insurance); Part B (medical insurance); Part C (Medicare Advantage plans, which are "managed care" plans funded on a per member, per month basis rather than the fee-for-service coverage under Parts A and B); and most recently—as of 2006—the massive and costly Part D (drug coverage).

Additionally, Medicare has expanded to cover individuals over 65, disabled individuals, and those with end-stage renal disease or those requiring a kidney transplant. By 2018, 60 million people had been enrolled in Medicare, and Medicare spending reached more than $704 billion[5] (almost 20% of the total spending on healthcare in America).[6] The Centers for Medicare & Medicaid Services, a division of the United States Department of Health & Human Services, administers this behemoth government-funded healthcare program.

The second major pillar of American government-funded insurance is the Medicaid system. Medicaid, also established in 1965, provides government-funded healthcare for poor and low-income families. Like Medicare, the Medicaid program has been expanded over time, and now covers pregnant people, people with 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. Unlike Medicare, however, 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 50 states, five territories of the United States, and District of Columbia. Unlike Medicare, the dual-funded Medicaid program is administered by the states, and programs can vary significantly from state to state. As of April of this year, the Medicaid program covered more than 75 million Americans.[7] Medicaid spending nationwide grew to $613.5 billion in 2019, a 2.9% increase from the previous year.[8]

The third pillar of the American hybrid health system is the private health insurance market. In 2019, according to the U.S. Census Bureau, an estimated 68% of Americans had private health insurance.[9] Also in 2019, private

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insurance spending was $1.195 billion per year.[10] The most common form of private insurance is employer-based insurance in which nongovernmental employers offer their employees group insurance plans, typically administered by private, for-profit insurance companies. Additionally, in 2019, about 10% of Americans received private insurance not through their employers, but rather by purchasing coverage directly from insurance companies.[11] Private insurance companies are, as the name suggests, run privately and are regulated at the state level by each state's insurance department. These insurance departments guard against fraud, waste, and abuse through their own sophisticated internal fraud monitoring and special investigations units often directed by former law enforcement personnel.

The Italian healthcare system: Primarily a single, government-funded payer

The Italian healthcare system relies fundamentally, but not solely, on public universal healthcare services. The national health service (Servizio Sanitario Nazionale, or SSN) was established more than 40 years ago[12] to ensure health to Italian citizens while respecting human dignity. The basic principles of the SSN are universality, equity, and solidarity. SSN's goals include (i) collective preventive public healthcare, (ii) healthcare assistance in public hospitals, and (iii) healthcare assistance through territorial providers other than hospitals. Responsibility for administering the SSN has gradually shifted from the national level to each of the 20 regions of Italy, which are financially responsible for managing public healthcare delivery and costs. This additional responsibility of expense management has rendered the system even more difficult to administer and has exposed regional inequalities in healthcare services, as well as the health migration as patients seek regions with better healthcare services.

The SSN is tasked with developing the standards for healthcare to be provided to all citizens (Livelli Essenziali di Assistenza, or LEA), as determined by national decree,[13] most recently amended in 2017. LEA healthcare services under the SSN are entirely free for citizens with income below established thresholds as well as for those who are affected by certain conditions. All other citizens are required to contribute to the cost of their healthcare services.

In order to obtain healthcare services beyond LEA coverage guaranteed by the SSN, many Italians contribute to private collective funds or have entered into private insurance policies. Therefore, the Italian healthcare system is built on the following three pillars:

1. The SSN, covering the basic universal services (LEA);
2. A system of collective private insurance to fund services beyond LEA; and
3. Private insurance policies covering individuals or families.

Over time, the resources available to cover the first pillar, the SSN, have decreased, particularly as investments have been insufficient to keep up with rising costs. On the other hand, the second and third pillars have become more popular,[14] and therefore, services under LEA have failed to meet citizens' needs.

Currently, the cost of providing healthcare in Italy is still borne predominantly by the national health system as follows:

- 74,2% of healthcare is provided through a single public or regional payer;
- 25,8% of healthcare is funded privately: of that portion, and the great majority of such private funding is made directly out of pocket by the patient.[15]

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In addition to the public hospitals, there also are many private hospitals as well as hospital chains. Such private hospitals have entered into national or regional agreements to provide healthcare under SSN and obtain reimbursements from the government.

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