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The differences and similarities between American and Italian healthcare fraud, waste, and abuse laws: Part 3

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Part 1 of this article series, published in the November 2021 issue of Compliance Today, outlined in general the American and Italian healthcare systems. Part 2, published in the December 2021 issue, outlined America's primary healthcare fraud laws. Part 3 of this series outlines the Italian healthcare enforcement regime, criminal law, and the Anti-Corruption Act.

Italian enforcement against fraud and corruption, including in the healthcare field, has traditionally been reserved to criminal courts, with no specific effort to coordinate or combine these actions through civil remedies. In light of the largely state-funded healthcare system in Italy, government corruption is in the foreground of efforts to detect and prevent fraud, waste, and abuse in healthcare. Egregious scandals erupted in Italian healthcare sectors, especially in the 1990s. Perhaps the most notorious case involved Dr. Duilio Poggiolini, the Ministry of Health's general manager of the pharmaceutical department whose fortune included gold, jewels, and paintings of enormous value.[1] Poggiolini was charged and arrested for using his position for personal benefit, and his sentence of seven and a half years in prison was reduced on appeal.[2] The scandal surfaced during an investigation, called "mani pulite," by a pool of public prosecutors operating out of the Milan criminal court. They were able to pierce the veil of silence that long protected government corruption. While its success resulted from significant cooperation and solidarity among the prosecutors, their coordination was not officially structured as an institutional team.

Italy's criminal law

Italian criminal law always has included crimes of government corruption. The Italian Criminal Code has been amended periodically, not only to increase the sanctions (as, for example, in the latest "Spazza-Corrotti" amendments in 2019), but also with the aim of criminalizing more subtle corruption than an outright offer of cash in exchange for favorable treatment by a public official.

The single most important criminal statute in Italian anti-corruption law is no. 190/2012 of November 28, 2012, titled "Provisions for prevention and repression of corruption and illegality in the public administration" (the

Anti-Corruption Act).[3] First, the Anti-Corruption Act identified evolving and more nuanced conduct in order to combat ever more sophisticated corruption phenomena, such as the following:

- **Corruption forced by a public official** ("concussione"): Section 317 of the Italian Criminal Code has been amended so that this type of corruption now applies to public officials and is no longer limited to persons in charge of a public service.[4] The revised Section 317 of the Criminal Code now sanctions both giving or promising money or other benefits and is no longer limited to the receipt of the inducement. The minimum period of imprisonment has been increased to six years from four years.

- **Corruption related to the exercise of official functions** ("corruzione per l'eserciziodellafunzione"), pursuant to Section 318 of the Italian Criminal Code, sanctions the acceptance by a public official, in connection with the exercise of their functions or powers, of an undue sum of money or benefit. This provision is typically interpreted as applicable regardless of whether the official actually performs or refrains from a public duty and has been extended by the Anti-Corruption Act to the public official's "functions" (whereas before it was strictly linked to the public official's "office"). The period of imprisonment following conviction has been increased to the current range of one to five years.

- **Inducement to give or promise undue benefits** ("induzione indebita a dare o promettere utilità"). The offence of corruption through inducement, which previously appeared under Section 317 of the Italian Criminal Code, has been completely recodified under the new Section 319-quarter. It sanctions public officials or persons in charge of a public service who induce a person to pay an undue sum of money or other benefit, as well as persons actually giving or promising such benefits to public officials or persons in charge of a public service.

- **Trade of undue influence** ("traffico di influenze illecite"). A new criminal offence has been introduced under Section 346-bis of the Italian Criminal Code. It sanctions persons who take advantage of their existing or alleged relationship with a public official or a person in charge of a public service in order to receive an undue sum of money or other monetary benefits. The statute applies when such mediation is exercised to obtain a performance contrary to public duties, or an omission or postponement of any public duties. The sanction for violations is imprisonment of one to three years.

Additionally, the Anti-Corruption Act also has introduced criminal law sanctions for corruption among private parties ("corruzione tra privati"). Before the enactment of the Anti-Corruption Act, only conduct involving public officers was criminally relevant. The Anti-Corruption Act introduces an entirely new crime of corruption where both parties are private parties. Paragraph 1 of new Section 2635 of the Italian Civil Code applies to companies' directors, general managers, or executives having the task to draw up financial documents, including auditors and liquidators. If upon receipt or promise of money or other benefits they breach the duties assigned to them and damage the company, they are subject to criminal sanctions (namely imprisonment of one to three years). In addition, as per Paragraph 2, companies' employees who, under the direction of the above subjects, engage in the same conduct (upon receipt or promise of money or other benefits that breach their assigned duties and damage the company) also risk imprisonment of up to one year and six months. Persons who give or promise any such benefits to any of the above-mentioned actors can also be sanctioned, according to Paragraph 3.

Measures aimed at preventing corruption under the Italian Anti-Corruption Act

The same Anti-Corruption Act also sets forth a number of additional measures to combat corruption:

- **ANAC**: The Italian Anti-Corruption Authority (Autorità Nazionale Anticorruzione, or ANAC) has been established, replacing the prior agency on public contracts. ANAC focuses on prevention of corruption by

creating a cooperative network among public administrations to maximize the impact of anti-corruption measures on public resources. ANAC must approve a national anti-corruption program, as well as provide nonbinding opinions about public administrations' specific behaviors or policies.

- **Anti-corruption program**: Public administrations are required to draft a three-year anti-corruption program to combat corruption risks likely facing their officers, and to implement preventive measures. Further, each public administration must appoint an individual responsible for preventing corruption ("responsabile della prevenzione della corruzione"), adopting the specified anti-corruption program, and monitoring its functioning and implementation.

- **Transparency obligations**: The Anti-Corruption Act also imposes increased transparency obligations on public officials. They must publish on their websites any information concerning administrative authorizations, concessions, calls for tenders, criteria of selection of contractors, and the issuance of allowances and aid in favor of private and public entities. With regard to public tenders, administrations may require adherence to legal protocols or integrity agreements and may exclude any candidate who fails to comply with them.

- **Conflicts of interest**: The Anti-Corruption Act also deals with conflicts of interest. Any person in charge of an administrative proceeding ("responsabile del procedimento") and any officer in charge of opinions, technical evaluations, decisions, and final resolutions within such proceeding must abstain from performing any such actions in case of a conflict of interest, which must be duly disclosed.

- **Code of conduct of public employees**: The law also mandates a code of conduct for public employees to ensure quality of services, prevention of corruption, and compliance with the constitutional principles of diligence, loyalty, and impartiality. It prohibits public employees from requesting and accepting gifts or other benefits in connection with the performance of their functions, except for customary gifts of low value and within the limits of normal courtesy relationships.

- **Restrictions on the activities of former public employees**: Former employees who were vested with negotiating or decisional powers on behalf of public administrations in the previous three years are prohibited from performing any work or professional activity for any private entities to which their former public activities were addressed. Any agreement in breach of this provision is void, and any private entities found to have breached this provision are barred from negotiating with public administrations for three years. This rule prevents the phenomenon of "pantouflage" or "revolving doors," whereby public officials with powers over a private entity are corrupted through the promise of post-employment professional engagement, which is a problem that also plagues agencies involved in healthcare administration in the US.

Protection of whistleblowers

The same Anti-Corruption Act introduced specific measures to protect public sector whistleblowers. These measures on whistleblowers in the private sector were only introduced recently by Law No. 179/2017. Public employees who become aware of suspected illegal behavior within their professional duties and then inform judicial authorities or their supervisor cannot be subject to sanctions, termination, or discrimination due to such a complaint. The same prohibition protects private-sector employees, who are encouraged (but not mandated) to set up whistleblowing channels, including anonymous complaints. Whistleblower reports in Italy, however, continue to be the exception, rather than the norm, in both sectors. This dynamic starkly contrasts with the American fraud-prevention statutes, particularly the false claims statutes, whose whistleblower provisions fuel both compliance efforts and government enforcement activities.

Corporate criminal liability: Decree 231 and the rise of corporate compliance programs

Legislative Decree 231/2001 introduced into the Italian legal system the criminal accountability of legal entities and companies, a concept previously excluded on the basis of the principle "societas delinquere non potest" (i.e., only individuals, and not corporations, may be subject to criminal sanctions). In fact, in 2001, the Italian legislature, to implement certain international conventions ratified by Italy, established specific sanctions affecting the assets of companies—and, therefore, the economic interests of the shareholders—if crimes are committed in the interest of or for the benefit of the organization. The list of such crimes has been expanded through subsequent legislation.

The liability of an entity pursuant to Decree 231 arises if:

- One of the crimes listed in Decree 231 has been committed (such crimes include, but are not limited to, corruption crimes);
- A crime has been committed in the interest or for the benefit of the entity; and
- The perpetrator is an individual who has the capacity to represent, administer, or manage the entity (or an organizational unit thereof with financial and functional autonomy), or a person that exercises, even de facto, the management and control of the entity (i.e., one of the so-called "apical subjects," hereinafter referred to as "Apical") and/or an individual subject to the direction or the supervision of one of the Apicals.

On the other hand, the entity is not responsible when the aforementioned persons have acted in the exclusive interest of themselves or of third parties.

Sanctions against companies that are found responsible under Decree 231 can be both monetary (up to EUR1.5 million, in addition to the confiscation of resulting profits) or, worse, blacklisting. The latter include the following bans for a period of three months to two years:

- Ban from carrying out the company's business;
- Suspension or revocation of permits, licenses, or concessions;
- Ban from contracting with the public administration;
- Exclusion from benefits, loans, contributions, or subsidies;
- Ban from advertising goods or services; and
- Appointment of a judicial commissioner.

Article 6 of Paragraph 1 of Decree 231, however, exempts an entity from responsibility under the following circumstances:

> a. the management body has adopted and effectively implemented, before the commission of the fact, organizational and management models suitable for preventing crimes of the same type of the one that occurred;
>
> b. the task of supervising the functioning and the observance of the models

and of taking care of their updating has been given to a body of the entity with autonomous powers of initiative and control;

c. people committed the crime by fraudulently evading the organization and management models;

d. there has been no omission or insufficient supervision by the body referred to in letter b).

Exemption from liability requires not only a compliance program, but also a committee (organismo di vigilanza) actively supervising such program. The committee must be independent from the management of the company and may be composed of one to three members. The exclusion of corporate liability under Decree 231 is therefore conditioned on an active, effective, preventive, and continuous adoption of an organizational and management model charged with preventing the offense at issue. For the exemption to apply, the crime must have been committed by the fraudulent avoidance of the compliance structure put in place by the organization, without any failure or lack of supervision by the organismo di vigilanza. Incidentally, these are similar to principles that have been adopted in America. The organization's compliance model must also include systems to provide information flows to and from the organismo di vigilanza, as well as a specific channel to report suspected violations directly to the organismo di vigilanza.

Such organizational, management, and control model must:

a. Identify the activities in which crimes may be committed;

b. Provide specific protocols aimed at planning the decision-making and implementation of the entity's decisions in connection with the crimes to be prevented;

c. Identify methods of management of financial resources suitable for the prevention of crimes;

d. Set forth obligations to provide information to the body responsible for overseeing the functioning and compliance with the models;

e. Introduce a suitable disciplinary system for sanctioning the failure to comply with the measures indicated in the model.[5]

Healthcare industry 231 programs

Following the introduction of the Decree 231, many companies, especially in the healthcare industry, have adopted an organizational compliance program, and have appointed a "231" compliance committee. These steps have increased focus on the prevention of corruption, among other crimes, and have prompted companies operating in Italy to adopt increasingly sophisticated anti-corruption measures.

Italian 'soft' laws: Codes of conduct

Soft laws are an essential component of anti-corruption laws. Under Italian law, apart from the actual laws and orders, there are guidelines and regulatory memoranda drafted by important stakeholders, which are integrated into the compliance framework and recognized by the Italian courts as guidelines in enforcement actions.

Several organizations have provided guidelines on the circumstances where Decree 231 will impose criminal liability. Confindustria (the general employers' association) and Assobiomedica (the med tech manufacturers'

association) both have issued such guidelines. Additionally, codes of conduct for companies interacting with healthcare professionals have been issued by Farmindustria (the Italian pharma association) and Assobiomedica. Importantly, in the healthcare space, physicians also have their own professional code of conduct, which requires they act with professional integrity.

Such soft codes identify a number of best practices that are recognized by the industry as business and ethical standards for interactions with public officials, especially for healthcare professionals and healthcare organizations.

Lastly, a bill purporting to introduce an equivalent of the American Sunshine Act in Italy has twice been presented in Parliament. To date, the statute has yet to see the light of day, metaphorically.

Italy: Anti-corruption policies during the pandemic

During the COVID-19 pandemic, which flared up in Northern Italy as early as March 2020, the public healthcare system has been under tremendous pressure to perform. With hundreds of people dying each day, it was of paramount importance to urgently provide healthcare services to COVID-19 patients. All expectations were aimed at ensuring that the healthcare system efficiently worked without delays and obstacles to detect and prevent fraud, waste, and abuse under normal conditions.

The goals of efficiency and celerity have inspired Italian authorities throughout the crisis. This approach has been clearly exemplified by the ANAC guidelines issued during such months, primarily aimed at facilitating and accelerating procedures for the execution of public contracts. In its guidelines (e.g., "Vademecum per velocizzare e semplificare gli appalti pubblici," published in a communication from the ANAC president on April 22, 2020),[6] ANAC provided guidance to public hospitals on the fastest procedures available to purchase goods, thus addressing the urgent need to speed up public procurement processes. On July 2, 2020, the president of ANAC submitted to the Italian Parliament its annual report, focused on the Italian situation during the first half of 2020, in which he highlighted how authorities operated with the intent to simplify public procurement.

It has been argued that during the pandemic, and in crisis periods in general, the purposes of celerity and efficiency could lead to a lessening of preventive controls, which inevitably slows down processes.[7] This may lead to a decreased expectation of impartiality, as goods and services that are deemed necessary (such as, for example, vaccines, sanitation supplies, personal protective equipment) must be guaranteed "no matter what." Can this trend, coupled with increased spending in healthcare by the government, also lead to an increase in corruption?

The answer appears to be positive. The Organisation for Economic Co-operation and Development (OECD), which issued *Policy Measures to Avoid Corruption and Bribery in the COVID-19 Response and Recovery*,[8] certainly agrees. COVID-19 "has brought about unprecedented challenges of human suffering, uncertainty and major economic disruption on a global scale" that can create a breeding ground for corruption and bribery. For this reason, in order to prevent corruption risks, the OECD recommends that "corruption prevention measures," as well as "anti-corruption, integrity, procurement and competition standards," continue to apply; that the use of intermediaries is avoided; and that whistleblowers' protection mechanisms are strengthened.

Lastly, in Italy and in Europe the risks of corruption are bound to increase, in light of the envisaged injection of capital due to the national and European recovery funds, through the so-called Recovery Plan (which is also expected to benefit the healthcare system). As underlined by the OECD, identifying and addressing corruption risks will be crucial to protect trust in public institutions and business, and to galvanize public confidence in the

government's ability to mobilize an effective crisis response. "It is imperative that fundamental safeguards of the rule of law and public integrity are not weakened or disregarded in both the immediate response as well as the longer-term recovery from COVID-19."

Conclusion

The American and Italian systems for preventing healthcare fraud, waste, and abuse encompass a broad scope of laws and regulations affecting global healthcare providers. The reality is that competent counsel familiar with both countries' compliance frameworks are best equipped to advise their multinational clients through the complex and ever-evolving patchwork of statutory and regulatory requirements. While the delivery of quality healthcare remains a shared goal, eliminating waste through fraud and abuse in the delivery of such critical services remains an equally daunting but achievable task, all the more so in light of the historic financial commitments governments have recently made to fighting the COVID-19 pandemic.

Takeaways

- The Italian Anti-Corruption Act introduced criminal law sanctions for corruption among private parties. Prior to this enactment, only conduct involving public officers was criminally relevant.
- Measures to prevent fraud under the Italian Anti-Corruption Act include: the Italian Anti-Corruption Authority, anti-corruption program, transparency obligations, code of conduct, and activity restrictions on former public employees.
- In stark contrast to the US, Italian whistleblower reports, both public and private, continue to be the exception rather than the norm, in both sectors.
- "Soft" laws (e.g., codes of conduct) are guidelines and regulatory memoranda, integrated into the compliance framework, and recognized by the Italian courts as guidelines in enforcement actions.
- Like the US, the risks of corruption will increase in Italy due to the injection of capital and loosening of enforcement as a result of the COVID-19 pandemic.

1 Flavia Amabile, "Perché la Sanità è nel mirino?" *La Stampa*, last edited July 11, 2019, https://www.lastampa.it/cultura/2011/06/16/news/perche-la-sanita-e-nel-mirino-1.36956487.
2 la Repubblica, "Sanitopoli, la sentenza condannati i Poggiolini," archive, July 21, 2000, https://www.repubblica.it/online/cronaca/poggiolini/poggiolini/poggiolini.html.
3 Legge 6 novembre 2012, n.190, G.U. Nov. 13, 2012, n.265 (It.).
4 Whoever performs a public service for whatever reason, where public service means an activity that is governed in the same way as a public function, except that the power vested in the latter is absent.
5 Decreto legislativo 8 giugno 2001, n.231, G.U. Jun. 19, 2001, n.140 (It.).
6 "Comunicato del Presidente del 22 aprile 2020," Consulta i documenti, Autorità Nazionale Anticorruzione, April 22, 2020, https://www.anticorruzione.it/-/comunicato-del-presidente-del-22-aprile-2020?p_p_id=com_liferay_journal_web_portlet_JournalPortlet.
7 Autorità Nazionale Anticorruzione, Relazione Annuale 2019, Intervento del Presidente Francesco Merloni, July 2, 2020, http://www.astrid-online.it/static/upload/anac/anac.presentazione.02.07.2020_2.pdf.
8 Organisation for Economic Co-operation and Development, *Policy measures to avoid corruption and bribery in the COVID-19 response and recovery*, May 26, 2020, https://www.oecd.org/coronavirus/policy-responses/policy-measures-to-avoid-corruption-and-bribery-in-the-covid-19-response-and-recovery-225abff3/.

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