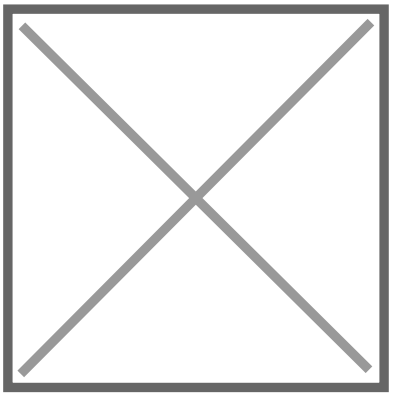

Healthcare Transparency Under the Spotlight: Navigating the Sunshine Act

Descrizione

Healthcare Transparency Under the Spotlight: Navigating the Sunshine Act
The Italian Sunshine Act, introduced by Law 62/2022, is a major step forward in promoting transparency in the healthcare sector. It is designed to regulate and make public the economic relationships between companies operating in the health industry and healthcare professionals or organizations. Inspired by similar legislation in the United States and Europe, the law aims to:

Prevent corruption and conflicts of interest

Reinforce public trust in the healthcare system

Guarantee the right to access information on financial ties that may influence clinical or administrative decisions

At the heart of the law is the “Sanità Trasparente” (Transparent Healthcare) registry, an open-access platform managed by the Ministry of Health, where companies must publish detailed reports on all transfers of value (ToV) made to healthcare professionals or organizations.

? Legal Background: How the Law Evolved
The law came into force in June 2022, with a phased implementation plan. Within a few months, the Ministry was tasked with setting up the registry and defining its technical specifications. Public consultations followed in 2023, and by 2025 the first pilot tests of the online platform were initiated.

The official activation of the registry is expected by the end of 2025, triggering the obligation for companies to begin reporting data on a semiannual or annual basis, depending on the type of relationship.

???? Who Is Involved?
The legislation affects three main categories of stakeholders:

Producing Companies: Businesses that manufacture, distribute, or organize events in the human or veterinary health sector—including suppliers of goods and services, even if not strictly medical.

Healthcare Professionals: Not only doctors and nurses, but also administrative personnel and decision-makers who influence procurement or use of medical technologies and resources.

Healthcare Organizations: Hospitals, universities, research institutes, ECM providers, professional bodies, patient associations, and scientific societies.

? What Must Be Reported?
Companies must report electronically the following:

Transfers of value (money, goods, services, or other benefits) if they exceed certain thresholds:

Over €100 (single) or €1,000 annually for individuals

Over €1,000 (single) or €2,500 annually for organizations

Agreements that provide economic benefit (direct or indirect): participation in events, consultancy, training, research, etc.

Financial relationships: shareholdings, bonds, royalties related to intellectual property

Each report must include key data: beneficiary identity, value, reason, nature of the transfer, and intermediaries if applicable.

? Deadlines and Reporting Cycles
The law establishes two types of reporting cycles:

Semiannual reporting for agreements, transfers, and sponsorships

Annual reporting for shareholdings and royalties

Reports must be submitted in the period following the one in which the transaction took place. For example, a sponsorship in the first half of 2026 must be reported by December 2026.

? The “Sanità Trasparente” Portal
The portal has two distinct user views:

A public area, accessible to anyone, where it is possible to search by beneficiary, agreement, or sanction

A company dashboard, for uploading XML files, validating data, checking for errors, and managing submissions

It is a comprehensive monitoring and transparency tool managed by the Ministry of Health.

? Enforcement and Penalties
The Ministry of Health is responsible for enforcement, supported by the Carabinieri NAS (Health Protection Unit) and the Guardia di Finanza.

Companies are fully accountable for the accuracy and completeness of the information submitted.

Penalties include:

€1,000 + 20x the unreported value for missing ToV disclosures

€5,000 to €100,000 for false or incomplete information

50% reduction in fines for companies with annual revenue under €1 million

Names of fined companies will be published in the registry for at least 90 days

?? Becoming Compliant: An Operational Approach
Complying with the Sunshine Act is not just about sending XML files. It requires an organizational shift:

Mapping all types of value transfers

Updating SOPs, contracts, and compliance models (e.g., 231 Model)

Involving key departments (legal, marketing, CRM, finance, compliance)

Digitalizing approval workflows and data collection

As one speaker emphasized: “Start from the organization, not the tool.”

? Digital Tools and Real-World Examples
The presentation showcased companies already investing in dedicated platforms to manage:

ToV tracking

Workflow approvals

XML reporting

Budget control and event oversight

A case study of Theras Group was highlighted. Starting in 2019, they built a full internal platform for managing transparency-related processes. By 2025, all ToV and event-related workflows were fully digital, compliant, and efficiently controlled.

? Conclusion
The Sunshine Act presents a significant challenge—but also a unique opportunity. It invites companies to strengthen their internal governance, align with evolving ethical standards, and demonstrate a clear commitment to transparency and integrity.

Those who act early will not only comply with the law, but also enhance their reputation, competitiveness, and trustworthiness in the healthcare ecosystem.

Tag

1. Foreign companies

Data
09/10/2026

Data di creazione
18/04/2025