

LAW 31 May 2022, n. 62

Provisions regarding transparency of relationships between companies
producers, entities operating in the health sector and
healthcare organizations. (22G00076)
(GU n.135 of 11-6-2022)
Effective as of: 6-26-2022

The Chamber of Deputies and the Senate of the Republic have
approved;

THE PRESIDENT OF THE REPUBLIC

Promulgate

the following law:

Article 1

General principles

1. The provisions of this law, in the context of protection of health, implementing the principles contained in articles 32, 41 and 97 of the Constitution, determine, pursuant to article 117, second paragraph, letter m), of the Constitution, the essential level of the services concerning the right to know the relationships between companies and entities operating in the health sector.
2. The provisions of this law, for the purposes of transparency as well as prevention and combating corruption and degradation of administrative action, guarantee the right to knowledge of relationships having economic or advantageous relevance, between companies producing drugs, instruments, equipment, goods and services, including non-healthcare ones, and the subjects who work in the health sector or health organisations.
3. However, the application of the provisions of

regulation referred to in the decree of the President of the Republic 16 April 2013, n. 62, containing the employee code of conduct public, as well as the provisions of Title VIII of the decree legislative 24 April 2006, n. 219.

Article 2

Definitions

1. For the purposes of this law it means:

a) for "producing company": any entity, including belonging to the Third Sector, who, directly or in the role of intermediary or associated company, carries out a direct activity to the production or marketing of medicines, instruments, equipment, goods or services, including non-healthcare, including i

nutritional products, marketable in the health sector

human and veterinary, or the organization of conferences and conferences regarding the same subjects;

b) for "subjects operating in the health sector": i subjects belonging to the healthcare or administrative area and others subjects who operate, in any capacity, within the scope of a healthcare organisation, public or private, and which, regardless of the position held, they exercise responsibilities in the management and allocation of resources or intervene in decision-making processes regarding drugs, devices, technologies and other goods, including non-healthcare goods, as well as research, experimentation and sponsorship. They are equivalent to subjects operating in the sector health professionals registered in the national register mandatory for the members of the judging commissions in the procedures for awarding public contracts, referred to in the article 78 of the code referred to in the legislative decree of 18 April 2016, n. 50, managed by the National Anti-Corruption Authority, and selectable by

the publicly available procedures for the purchase and production of goods and services in the healthcare sector;

c) for "health organisation": local health authorities, the hospital companies, the university hospital companies, the scientific and other hospitalization and treatment institutions public or private legal person that provides healthcare services, university departments, graduate schools, public and private research institutes and associations and companies scientific bodies in the health sector, the professional associations of health professions and associations between health workers, too not having legal personality, public and private entities that they organize continuing education activities in medicine as well as companies, patient associations, foundations and other bodies established or controlled by the subjects referred to in this letter or who control them or hold ownership of them or perform them the intermediation role for the aforementioned healthcare organizations.

Article 3

Advertising of grants and agreements and agreements

1. They are subject to advertising in accordance with the provisions hereof article the agreements and payments in money, goods, services or other utilities carried out by a manufacturing company in favor of:
 - a) of a person operating in the health sector, when have a unit value greater than 100 euros or a value annual total greater than 1,000 euros;
 - b) of a healthcare organisation, when they have value unit greater than 1,000 euros or a total annual value greater than 2,500 euros.
2. Agreements between companies are also subject to publicity

producers and entities operating in the health or safety sector
healthcare organizations, which produce direct or indirect benefits,
consisting of participation in conferences, training events,
committees, commissions, advisory bodies or scientific committees
or in the establishment of consultancy, teaching or consultancy relationships
research.

3. The publicity of the disbursements, the agreements and the
agreements referred to in paragraphs 1 and 2 of this article is carried out a
care of the manufacturing company through data communication
relating to the provision, convention or agreement, to be inserted
in the electronic public register established pursuant to article 5.

The communication referred to in this paragraph is transmitted in format
electronically according to the methods established by the Minister's decree
of health referred to in article 5, paragraph 7. If the company
manufacturer is based abroad, the fulfillment can be carried out
by its representative in Italy.

4. The communication referred to in paragraph 3 indicates, for each
provision, convention or agreement:

a) the following identification data of the beneficiary
of the provision or counterparty of the convention or agreement:

1) surname and name, professional domicile and
qualification, if the beneficiary or the counterparty is a person
physics;

2) the company name, headquarters and nature of the activity,
where the beneficiary or the counterparty is a legal person;

b) the tax code or value tax number

added (VAT) of the beneficiary or the counterparty;

c) the date of disbursement or the reference period of
convention or agreement;

- d) the nature of the provision or the convention or the agreement;
- e) the amount or value of the disbursement or the remuneration of the convention or agreement; in the case of goods, services or others utility, the market value is indicated;
- f) the cause of the provision, convention or agreement;
- g) the subject, identified through the data referred to in the letters a) and b), who, in his capacity as intermediary, has defined the conditions of the provision or the terms of the agreement or of the agreement or, in any case, has maintained relations with the beneficiary or the counterparty on behalf of the producing company, even if he is an employee of the company itself;
- h) the registration number of the beneficiary or the counterparty to your professional body.

5. The communication provided for in paragraph 3 is carried out, for disbursements made and the agreements and conventions established in each semester of the year, by the end of the semester following. In case of exceeding the annual value limits indicated in paragraph 1 during the year, the communication is carried out within the semester following the one in which the overcoming.

Article 4

Communication of shareholdings and securities bonds and proceeds deriving from property rights industrial or intellectual.

1. Production companies established in corporate form, by January 31st of each year, they communicate the data to the Ministry of Health identifiers referred to in article 3, paragraph 4, letters a) and b), of individuals who operate in the health sector and organizations healthcare for which one of the following conditions applies:

a) are holders of shares or shares of the capital of company or bonds issued by it, registered for the previous year, respectively, in the members' register or in the book of bonds;

b) have received from the company, in the previous year, fees for the granting of licenses for use economic rights of industrial or intellectual property.

2. The communication referred to in paragraph 1 indicates, for each owner:

a) for shares or capital units and for bonds listed on regulated markets, the value determined pursuant to of article 9, paragraph 4, letter a) or b), of the consolidated text referred to in decree of the President of the Republic 22 December 1986, n. 917;

b) for bonds not listed on regulated markets, the total nominal value of the securities held, broken down by each issue, with an indication of the annual yield;

c) income from shares, capital shares and bonds received by the owner during the year;

d) proceeds from industrial property rights or intellectual income received by the owner during the year.

3. In the communication referred to in paragraph 1 of this article it is also indicated is the total value of the shares or quotas constitutes a qualified holding defined pursuant to of article 67, paragraph 1, letter c), of the consolidated text referred to in decree of the President of the Republic 22 December 1986, n. 917.

4. The communication referred to in paragraph 1 is transmitted in format electronically according to the methods established by the Minister's decree of health referred to in article 5, paragraph 7.

5. In the case provided for in paragraph 3 of this article, the communication referred to in paragraph 1 is published by the Ministry

of health in a specific section of the electronic public register established pursuant to Article 5.

6. If the shares, units or bonds referred to herein article are attributed to the person who operates in the sector health or to the healthcare organization from the manufacturing company a free of charge or as compensation, even partial, for services made by them, the required communication obligation remains from article 3. For this purpose, the value of the participation or of the obligation is determined pursuant to paragraph 2 hereof item.

Article 5

Electronic public register

1. Within six months of the date of entry into force of this law is established on the institutional website of the Ministry of health, the public electronic register called «Health transparent". The start date of the register operation is communicated by notice published in the Official Journal.
2. The information is published in the electronic public register communications referred to in article 3 and, in separate sections, the data resulting from the communications referred to in Article 4 and the documents of imposition of the sanctions referred to in article 6, paragraph 7.
3. The electronic public register is freely accessible for consultation and is equipped with functions that allow the search and extraction of communications, data and documents referred to in paragraph 2 according to open data standards.
4. The communications published pursuant to this article are available for consultation for five years from the date of publication. Course this deadline they are canceled from the electronic public register.
5. The data published in the electronic public register can

be reused only under the conditions established by the legislation on reuse of documents in the public sector, referred to in the decree legislative 24 January 2006, n. 36. It remains understood that, where it concerns information relating to natural persons, the reuse of data published must be in terms compatible with the purposes originating for which the same information was collected by Ministry of Health.

6. With the stipulation of the conventions or agreements, of which respectively in paragraphs 1 and 2 of article 3, or with the acceptance of the disbursements, referred to in the same paragraph 1 of article 3, by subjects operating in the sector health and healthcare organizations, as well as with acquisition of shareholdings, bonds and proceeds deriving from industrial property rights or intellectual, referred to in article 4, paragraph 1, is considered to be provided on consent to advertising and processing of data by aforementioned subjects and organizations, for the purposes referred to in this article. However, manufacturing companies are required to provide information to entities operating in the sector health and health organizations, specifying that the communications referred to in the previous paragraphs are the subject of publication on the institutional website of the Ministry of Health. The rights of the interested parties referred to in the paragraphs are reserved articles 15, 16, 17, 18, 19 and 21 of Regulation (EU) 2016/679 of European Parliament and of the Council, of 27 April 2016, as well as the forms of protection of a jurisdictional and administrative nature therein expected.

7. Within three months of the date of entry into force of this law, with decree of the Minister of Health, after consulting the Agency for

digital Italy, the national anti-corruption authority and the Guarantor for the protection of personal data, the structure and are determined the technical characteristics of the electronic public register as well as the requirements and methods for the transmission of communications e data entry, according to the following criteria:

- a) ease of access;
- b) simplicity of consultation;
- c) comprehensibility of the data and homogeneity of their data presentation;
- d) provision of functions for simple and advanced search e for data extraction.

8. The decree referred to in paragraph 7 also establishes: models for the communications referred to in articles 3 and 4 and any further elements to be indicated in the same communications.

9. To the costs deriving from the implementation of the provisions of this article, equal to 300,000 euros for the year 2022 and 50,413 euros per year starting from the year 2023, 300,000 euro for the year 2022, through a corresponding reduction of the spending authorization contained in article 34-ter, paragraph 5, of law 31 December 2009, n. 196, registered in the state of forecast of the Ministry of Health for the year 2022, and, as to 50,413 euros per year starting from the year 2023, through a correspondent reduction in the projections of the allocation of the special fund current portion recorded, for the purposes of the 2022-2024 three-year budget, within the «Reserve and special funds» program of the «Funds to be distributed» mission of the Ministry's estimate of the economy and finances for the year 2022, for the purpose partially using the provision relating to the Ministry of Health.

10. The Minister of Economy and Finance is authorized to make, with its own decrees, the necessary budget changes.

Article 6

Supervision and sanctions

1. The manufacturing companies are responsible for the truthfulness of the data contained in the communications referred to in articles 3 and 4.
2. To the manufacturing company that fails to carry out the communication telematics referred to in article 3, within the deadline set therein, yes applies the sanction for each omitted communication administrative pecuniary payment of a sum of 1,000 euros increased by twenty times the amount of the disbursement to which it is applied reports the omission.
3. To the manufacturing company that fails to transmit the communication referred to in article 4, paragraph 1, within the deadline therein indicated, or omits, if the conditions are met, the indication of referred to in paragraph 3 of the same article, the sanction is applied administrative pecuniary payment of a sum of 5,000 to 50,000 euros.
4. In the event that the manufacturing company provides information incomplete in the communications referred to in articles 3 and 4, the same must be integrated within ninety days. In case in which the integration is not carried out within the established deadline, yes apply the sanctions provided for, respectively, in paragraphs 2 and 3 of this article.
5. Unless the fact constitutes a crime, to the manufacturing company who provides false information in the communications referred to in articles 3 and 4 the pecuniary administrative sanction of payment of is applied a sum of 5,000 to 100,000 euros.
6. To the manufacturing company with an annual turnover of less than one million euros, the sanctions referred to in paragraphs 2, 3 and 5 apply in

amount equal to half of the amounts defined by the aforementioned paragraphs, provided that such undertaking is not controlled, connected or bound by supply or subcontracting relationships with other manufacturing companies.

7. The acts of imposition of the sanctions provided for herein article are published in a specific section of the public register telematic system referred to in article 5. The Ministry of Public Health, in open format, these documents on the first page of your site institutional internet, for a period of no less than ninety days, with the indication of the names of the manufacturing companies that do not have sent the required communications or have provided fake news in communications.

8. The Ministry of Health exercises supervisory functions on the implementation of this law, making use of the Command police for health protection, and applies sanctions administrative provisions provided for by this article.

9. In accordance with the provisions of the law of 30 November 2017, no. 179, reporting to the Ministry of Health is permitted of conduct carried out in violation of this law.

With the decree referred to in article 5, paragraph 7, the methods for the implementation of this paragraph.

10. The financial administration and the Guard of finance, as part of the control activities carried out in with regards to the manufacturing companies, verify the execution of the obligations under this law. If they ascertain irregularities or omissions, unless the fact constitutes a crime, n inform the Ministry of Health for the purposes referred to in paragraph 8.

11. For the assessment, dispute and imposition of administrative sanctions referred to in this article apply, in as compatible, the provisions contained in chapter I, sections I e

II, of law 24 November 1981, n. 689.

12. The proceeds deriving from the collection of the sanctions referred to in this article flow into the revenue of the State budget to be reassigned, in an amount equal to 50 percent, to a specific person chapter of the forecast of the Ministry of Health ed be intended, in the reference year, for improvement the efficiency and effectiveness of the supervisory activities carried out pursuant to paragraph 8.

Article 7

Report to the Chambers

1. The Minister of Health transmits to the Chambers by the 31st December of each year, a report on the implementation status of the provisions of this law.

Article 8

Financial provisions

1. To the exclusion of the activities referred to in article 5, the interested administrations ensure the implementation of this document law in the field of human, financial and instrumental resources available under current legislation and, in any case, without new or greater burdens on public finances.

Article 9

Final provisions

1. The communication obligations provided for in Article 3 yes apply starting from the second semester following the one in course on the date of publication of the notice provided for by the article 5, paragraph 1.

2. The communication obligations provided for in Article 4 yes apply starting from the second year following the current one on the date of publication of the notice provided for in Article 5,

paragraph 1.

This law, bearing the seal of the State, will be incorporated
in the Official Collection of Regulatory Acts of the Republic
Italian. Whoever is responsible for observing it and doing it is obliged to do it
observe as state law.

Date in Rome, 31 May 2022

MATTARELLA

Draghi, President of the Council of
ministers

Seen, the Keeper of the Seals: Cartabia