



Ministry of Health

ESTABLISHMENT OF THE ELECTRONIC PUBLIC REGISTER

GIVEN the law of 31 May 2022, n. 62, containing “Provisions regarding the transparency of relationships between manufacturing companies, entities operating in the health sector and healthcare organisations”;

GIVEN, in particular, article 5, paragraph 7, of law 31 May 2022, n. 62, which provides that "within three months from the date of entry into force of this law, by decree of the Minister of Health, after consulting the Agency for Digital Italy, the National Anti-Corruption Authority and the Data Protection Guarantor personal, the structure and technical characteristics of the electronic public register are determined, as well as the requirements and methods for transmitting communications and entering data, according to the following criteria: a) ease of access; b) simplicity of consultation; c) comprehensibility of the data and homogeneity of their presentation d) provision of functions for simple and advanced search and data extraction.”;

HAVING REGARD to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, as well as on the free movement of such data, which repeals Directive 95/46/EC (General Data Protection Regulation);

HAVING REGARD to the legislative decree of 30 June 2003, n. 196, containing “Code regarding the protection of personal data”;

HAVING REGARD to article 5 of the legislative decree of 14 March 2013, n. 33, containing "Reorganization of the regulations concerning the right of civic access and the obligations of publicity, transparency and dissemination of information by public administrations";

HAVING REGARD to the legislative decree of 24 January 2006, n. 36, containing "Implementation of Directive (EU) 2019/1024 relating to the opening of data and the reuse of public sector information which repealed Directive 2003/98/EC";

GIVEN the "Guidelines on the accessibility of IT tools", pursuant to Law 9 January 2004, n. 4 and subsequent amendments;

HAVING REGARD to the legislative decree of 7 March 2005, n. 82, containing "Digital Administration Code (CAD)";

GIVEN the "Design Guidelines for Public Administration websites and digital services", pursuant to art. 71 of the CAD;

HAVING REGARD to the legislative decree of 10 March 2023, n. 24, containing "Implementation of Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 concerning the protection of persons reporting breaches of Union law and containing provisions concerning the protection of persons reporting breaches of national regulatory provisions" and, in particular, art. 4 which regulates the "Internal reporting channels

CONSIDERING that the data subject to publication in the electronic public register referred to in art. 5 of law 31 May 2022, n. 62 must be available for consultation for five years;

CONSIDERING that the data necessary for the provision of the electronic public register, including data not subject to publication, are kept for the same period of time;

HAVING CONSIDERED the Agency for Digital Italy;

HAVING CONSULTED with the National Anti-Corruption Authority;

HAVING CONSIDERED the Guarantor for the protection of personal data.

Article 1

(Definitions)

1. For the purposes of this decree:

a) Law, law 31 May 2022, n. 62;

b) manufacturing company, as defined by paragraph 1, letter a) of article 2 of the Law;

c) entity operating in the health sector, as defined by paragraph 1, letter b) of article 2 of the Law;

d) healthcare organization, as defined by paragraph 1, letter c) of article 2 of the Law;

e) beneficiary, the person who works in the health sector or the health organization that benefits from payments of money, goods, services or other benefits made by the producing company;

f) counterparty, the person who operates in the health sector or the health organization with which the manufacturing company stipulates a convention or agreement;

g) intermediary, the person who, on behalf of the production company (even if it is an employee of the company itself), has defined the conditions of supply or the terms of the convention or agreement, or in any case, has entertained the relationships with the beneficiary or the counterparty;

h) owner of participations, bonds or proceeds, the person who operates in the health sector or the healthcare organization that: a) is the owner of participations (shares or shares) of the producing company, registered in the shareholders' register; b) is the owner of bonds issued by the producing company, registered in the bond register; c) has received from the manufacturing company, in the previous year, income deriving from shares, quotas, bonds or industrial or intellectual property rights;

i) data controller, as defined by art. 4, par. 1, no. 7, of Regulation (EU) 2016/679;

j) Registry, the information system established at the Ministry of Health which allows the management of data useful for the purposes of the Law;

k) Electronic public register or «Transparent healthcare», the part of the register that can be consulted by the public on the website of the Ministry of Health;

l) Internal reporting channels, the reporting channels regulated by the art. 4 of the legislative decree 10 March 2023, n. 24.

Article 2

(Scope of)

1. This decree establishes, pursuant to Article 5 of the Law, the requirements and methods for the transmission of communications and the insertion of data by the subjects required to provide the Register.

2. The Ministry of Health is the data controller of the personal data contained in the Register.

3. This decree also establishes, pursuant to the same article 5, the structure and technical characteristics of the electronic public register.

4. The Ministry of Health makes available, on its website, the electronic public register, called "Transparent Healthcare" and organized into distinct sections containing the data relating to:

a) publicity of the disbursements, conventions and agreements, referred to in article 3 of the Law (Section A);

b) data relating to shareholdings, bonds and proceeds deriving from industrial or intellectual property rights, referred to in Article 4 of the Law (Section B);

c) acts of imposition of sanctions, referred to in article 6 of the Law (Section C).

Article 3

(Type of data collected)

1. For the pursuit of the purposes referred to in paragraph 2 of article 1 of the Law, the producing company, as owner of the processing of personal data, collects the relevant data provided for by

this article, in compliance with the specific indications contained in the technical specifications referred to in Annex A.

2. In compliance with the obligations referred to in articles 13 and 14 of EU Regulation 2016/679, the manufacturing company provides suitable information to interested parties, also specifying the elements required by the art. 5, paragraph 6 of the Law.

3. The manufacturing company guarantees the collection of data relating to agreements and disbursements of money, goods or other benefits made in favor of:

a) of a person who operates in the health sector, when they have a unit value greater than 100 euros or a total annual value greater than 1,000 euros;

b) of a healthcare organisation, when they have a unit value greater than 1,000 euros or a total annual value greater than 2,500 euros.

4. The manufacturing company also guarantees the collection of data relating to agreements stipulated with entities operating in the health sector or healthcare organisations, which produce direct or indirect advantages, even without economic relevance, consisting in participation in conferences, training events, committees, commissions, advisory bodies or scientific committees or in the establishment of consultancy, teaching or research relationships.

5. The producing company established as a company also guarantees the collection of data relating to subjects operating in the health sector and health organizations for which one of the following conditions applies:

a) are holders of shares or shares of the company's capital or of bonds issued by the same, registered for the previous year, respectively, in the shareholders' register or in the bond register;

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

Article 4

(Data transmission)

1. In order to ensure the supply of the Register, the production company designates, in the manner indicated in the technical specifications referred to in Annex A, one or more people who take care of the correct transmission of the data.

2. The manufacturing company ensures the correct transmission of the data referred to in paragraphs 3 and 4 of article 3 within the semester following the reference one.

3. The manufacturing company ensures the correct transmission of the data referred to in paragraph 5 of article 3 by 31 January of the year following the reference year.

4. The data being transmitted are described in the technical specifications referred to in Annex A.

Article 5

(Data publication)

1. The data subject to publication are described in the technical specifications referred to in Annex A.

2. The Ministry of Health publishes the data relating to Section A, within the first week following the deadline set for the transmission of the relevant data.

3. The Ministry of Health publishes the data relating to Section B, within the first week of March following the deadline set for the transmission of the relevant data.

4. The Ministry of Health publishes the data relating to the sanctions imposed on manufacturing companies, in Section C, by the 10th of the month following the date of imposition of the sanction itself.

Article 6

(Reports)

1. Where the conditions for the application of the regulations on the protection of persons who report violations of Union law and national regulatory provisions are met, the reports are processed pursuant to Legislative Decree no. 10 March 2023. 24. The Ministry of Health, with its own act, defines the methods of presentation and management of reports through a specific "internal reporting channel" pursuant to the aforementioned decree.

2. The Ministry of Health in exercising its supervisory functions, following the collection of appropriate supporting elements, reports to the manufacturing company the failure, incomplete or incorrect transmission of data to the Registry and adopts the necessary measures to ensure the correctness of the Registry data.

Article 7

(Requests for rectification)

1. The right of the interested party to obtain the rectification of inaccurate personal data concerning him published in the electronic public register, pursuant to Article 16 of the GDPR, remains unaffected.

Article 8

(Publication and data retention times)

1. The Ministry of Public Health makes the data relating to Sections A and B available to the public for five years from the date of their first publication, giving evidence of the date of any subsequent corrections.
2. The Ministry of Health publishes and makes the data relating to Section C available for consultation on a monthly basis and for at least 90 days from the date of their first publication.
3. The Ministry of Health retains the data transmitted pursuant to paragraphs 1 and 2 of this article for five years, proceeding with the relative cancellation on an annual basis.

Article 9

(Entry into force)

1. This decree comes into force on the day following its publication in the Official Journal.

This decree will be sent to the competent control bodies and published in the Official Journal of the Italian Republic.