SEE ALSO: Newsletter of January 24, 2023

[doc. web no. 9845312]

Corrective and sanctioning measure against the Giuliano Isontina University Company - 15 December 2022*

* The provision was challenged before the Court of Trieste; the Court ordered the suspension of the executive effectiveness of the provision as a precautionary measure.

Register of measures

no. 417 of 15 December 2022

THE GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, which was attended by prof. Pasquale Stanzione, president, prof.ssa Ginevra Cerrina Feroni, vice president, dr. Agostino Ghiglia and the lawyer Guido Scorza, components and the cons. Fabio Mattei, general secretary;

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 circulation of such data and repealing Directive 95/46 /CE, "General Data Protection Regulation" (hereinafter "Regulation");

HAVING REGARD TO Legislative Decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national legal system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of individuals with regard to the processing of personal data, as well as to the free circulation of such data and which repeals Directive 95/46/EC" (hereinafter the "Code");

CONSIDERING the decree law of 19 May 2020, n. 34 law, converted with amendments into law 17 July 2020, n. 77, and, in particular, the art. 7 relating to predictive methodologies of the evolution of the population's health needs;

CONSIDERING the Regulation n. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor for the protection of personal data, approved with resolution no. 98 of 4/4/2019, published in the Official Gazette no. 106 of 8/5/2019 and in www.gpdp.it, doc. web no. 9107633 (hereinafter "Regulation of the Guarantor n. 1/2019");

HAVING REGARD to the documentation in the deeds;

HAVING REGARD TO the observations made by the general secretary pursuant to art. 15 of the Regulation of the Guarantor n. 1/2000;

Speaker Prof. Pasquale Stanzione;

WHEREAS

1. Premise

It has been reported to this Authority that the resolution of the Friuli Venezia Giulia Region Council, no. XX of the XX, instructed General Practitioners (hereinafter also GPs) to validate, for the purpose of the pro rata payment of part of the variable fee, "through the regional IT portal, a list of users/assisted persons previously identified by the Healthcare company, according to its own (unknown) criterion, such as in conditions of complexity and comorbidity for the (apparent) purpose of statistical stratification by filling in computer files in which to report personal bio-humoral data, therapies, pathological status, family addresses, conditions/habits of life, etc.". Together with the report, a copy of the attachment to the aforementioned resolution was provided containing the "memorandum of understanding between the FVG Region and the trade union organizations of GPs for the regulation of relations for the two-year period 2020 -2021 and of the activities connected to the epidemiological emergency from Covid-19 ". The first of the objectives indicated in the aforementioned report concerns the "stratification, complexity and comorbidities at high risk of major complications from Covid-19 infections", with respect to which in the "notes" section of the report synthetic indications are provided on the preparation of the lists of patients to be submitted to the initiative medicine plans and on the ways in which they are downloaded, through the company Insiel, "from the portal of continuity of care" and then made available to the health authorities.

It was also reported that the aforementioned resolution would require GPs to communicate data on the health of their patients without the possibility for them to verify "whether the Healthcare Company has [preventively] given consent" to the processing of their personal data for purposes of "statistical stratification", also highlighting how this specific discipline provides for "the anonymous transmission of data for statistical or administrative purposes".

2. The preliminary investigation

In relation to the above, the Office has launched a preliminary investigation (note of the XX, prot. n. XX) requesting the Friuli Venezia Giulia Region and another regional health agency for specific information elements in order in particular to:

the initiatives taken in order to ensure that the treatments necessary to carry out the aforesaid initiative medicine activities were implemented in compliance with the regulations on the protection of personal data, with particular reference to what is indicated in the provisions of the Guarantor adopted on the subject (Opinion to the Council of State on the new ways of

allocating the health fund among the regions proposed by the Ministry of Health and based on population stratification, of 5 March 2020, web doc. n. 9304455, opinion on the draft law of the Autonomous Province of Trento containing specific provisions on proactive medicine, of 8 May 2020, web doc. No. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for proactive medicine in the provincial health service, of 1 October 2020, web doc. 9469372, provision dated 17 December 2020, web doc. n. 9529527; provisions dated 24 February 2022 n. 63, 64, 65, 66, 67, 65, 68, 69 and 70, doc. web no. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524);

the purposes pursued with the data processing envisaged by the report attached to the aforementioned resolution, and for each of them the relative legal basis of the processing, as well as the relative owners and managers, pursuant to articles 9, 24 and 28 of the Regulation;

if the treatment, although aimed at the pursuit of treatment purposes, is not strictly necessary for this purpose, the methods of prior acquisition of the informed and explicit consent of the interested parties, pursuant to art. 9, par. 2, lit. a) of the Regulation;

the description of the personal data flows indicated in the report attached to the aforementioned resolution, specifying whether the processing concerned health data or anonymous and aggregated data;

the impact assessment carried out, pursuant to art. 35 of the Regulation, considering that we are dealing with large-scale processing of particular categories of personal data and therefore at high risk.

The Region, with note of the XX prot. no. XX stated that: “as regards, in particular, objective n. 1 [of the recalled understanding] relating to the validation [of the] list of clients in conditions of complexity and comorbidity (target population) for the purpose of making the Lists available on the Continuity of Care Portal, the General Managers of the Company pertaining to the individual are invited GP to provide INSIEL as soon as possible, as for previous years, the operational indication to make the relative functions visible only for those patients who have given their specific consent to the communication of their data to their GP”. It was also specified that, for this purpose, "ARCS has provided the methodological support for the preparation of the algorithm for defining the lists of fragile subjects belonging to the RUB 4 and 5 categories. The tool used by ARCS for the preparation of the algorithm does not contains patient name information but an anonymous numeric identifier, subject to change every 6 months. Within the syntactic rules used, an extraction filter was inserted for subjects belonging to the RUB 4 and 5 categories who had already given their consent to visibility by the GP. (...). The lists, already purged, are published by

INSIEL, on behalf of the Healthcare Companies, for each GP who, being able to identify their patients, proceed with the validation of the same".

With reference to the aforementioned personal data processing operations, the Region declared that "the identification of assisted persons and their inclusion in the lists finds the legal basis in the generic consent provided by the interested party and relating to the visibility by the GP".

In relation to the need to draw up an impact assessment, it was also represented that "no initiative medicine activity can, therefore, be recognized in the activity described above and, consequently, no specific risk assessment activity is necessary primarily on the part of the Region, which in any case never has access to personal data, nor by the regional health authorities".

The Office, in acknowledging what was indicated by the Region and the results of a similar investigation initiated against another Regional Health Authority, i.e. that the treatment in question had involved all the regional health authorities, carried out an additional investigation in the against the latter, including the Giuliano Isontina University Health Authority (hereinafter also ASUGI or Company) and the Friuli Venezia Giulia Region (note of the XX, prot. n. XX).

In particular, the Office asked the Region and Insiel S.p.a. to indicate the specific databases from which the information used to carry out the aforementioned activity of stratification of the assisted was extracted and the related data controllers and processors; the type of information and clinical documents that have been processed for the stratification activity, highlighting any techniques used to ensure the non-identifiability, even indirectly, of the interested parties; the legal basis of the aforementioned treatments; the number of clients involved in the aforementioned stratification activity.

In response to the aforementioned request for information, the Friuli Venezia Giulia Region, with a note of the XX (prot. n. XX), declared, in particular, that:

− "the undersigned, as a superordinate body, manages the governance of the health infrastructure within the scope of its tasks of health planning, verification of the quality of care and evaluation of health care. Healthcare companies, for the area of their competence, are the owners of the data contained in the databases of the infrastructure pursuant to Article 24 of the GDPR. ARCS is the Regional Health Coordination Company and carries out support and liaison activities between the Region and the Companies. Insiel S.p.A. is the in-house company appointed by the companies responsible pursuant to art. 28 of the GDPR";

− "to deal with the spread of infections and above all to prevent improper access to hospital facilities, in compliance with DL

23/2020 and DL 34/2020, it promoted vaccination by activating GPs on the basis of the agreement referred to in resolution no. 1737/2020";

− "In this process, the Region, signatory of the AIR agreement with the GPs, had the role of organization and government by delegating to the Healthcare Trusts and to the GPs, holders for their respective areas of competence of the health data of their patients, as well as to the appointed, the implementation of the program envisaged by the AIR";

− "The cohort of subjects thus identified by each doctor therefore becomes the basis for the evaluation of subsequent activities: (...) if it has not already been compiled, as required by current legislation (The DPCM n. 178/2015 introduces the concept of a synthetic health profile or "patient summary", which is the electronic health and social document drawn up and updated by the general practitioner or pediatrician of free choice, which summarizes the patient's clinical history and his known current situation. is to favor the continuity of care, allowing a rapid classification of the patient at the time of contact with the NHS)";

- "the lists made available to GPs, as expressly indicated in the AIR agreement, are defined using the tool called ACG through the selection of patients to whom the system has assigned RUB 4 and 5 classes". In particular, it was shown that the "RUBs (Resource Utilization Bands) are synthetic measures of the degree of care complexity of a population understood in terms of expected consumption of resources" and that they "classify the level expected absorption of healthcare resources, (...) and do not provide an economic quantification or a description of the type of expected resources". The algorithm of the "Johns Hopkins ACG System is implemented (...) by Insiel which obtains the results", i.e. the list of patients that has been provided to each general practitioner (GP) who, in relation to their patients, could have modify or validate it on the basis of the information at its disposal.

In response to the aforementioned request for information, Insiel S.p.a., with a note of the XX (prot. n. XX), as manager of the regional health authorities, declared, in particular, that:

− “The information used to perform the requested processing activity was extracted from the regional data warehouse. Each Healthcare Company (ASU GI, ASU FC, AS FO) is the Data Controller of the personal data of its clients contained in the aforementioned regional data warehouse".

On this point, ARCS has represented that Insiel would have fed the "Johns Hopkins ACG System" with input datasets, containing information on codified diagnoses, drugs taken, costs incurred by the SSR, age and gender (cf. ARCS note of the

XX protocol XX).

According to what was declared in the deeds, the processed data were pseudonymized through the application of random numerical codes elaborated by ARCS for the attribution "of the filters on the Rub 4 and 5 classes and on the presence of consent to view the health record" and made available to the Insiel company. This company, "In order to communicate the data to each GP in relation to its patients, added the tax code, surname and name to the extraction and made the list of patients available on the regional application Portal of Continuity of Care according to the following path: − GP tax code − GP regional code − assisted tax code − assisted surname − assisted name − age class − integrated care plan − pneumococcal vaccines − ACG-RUB".

Finally, in relation to the number of patients involved in the aforementioned treatment operations, it was represented that the list consists of over 40,000 (of which 13,537 at ASUGI).

In relation to what was declared in the documents, the Office, with a note of the XX (prot. n. XX), requested information from the health authorities of the Friuli Venezia Giulia Region, including ASUGI, so that the databases from which the extracted the information used to carry out the aforementioned activity of stratification of the assisted; the legal premise on the basis of which ARCS is allowed to access, in the forms mentioned above, the data of the clients of these companies, and Insiel is allowed to process the data through the use of the "Johns Hopkins ACG System".

In response to the aforementioned request for information, this Company, with a note dated XX, represented, in particular, that:

"With note prot. no. XX of the XX (Annex 1), the Central Health Directorate (DCS) of the Friuli Venezia Giulia Region sent the Regional Council Resolution (DGR) no. 1737 of 20 November 2020 approving the 2020-2021 Agreement between the Friuli Venezia Giulia Region and the trade union organizations of General Practitioners (GPs)"

"In this note, highlighting what was established in the resolution, in point 3 of the device, the DCS prescribed that the regional health authorities were "obligated to follow up on the implementation obligations of the 2020-2021 Agreement in compliance with the provisions contained therein and consistently with the national and regional provisions on the matter", literally referring to the aforementioned Regional Government Decree no. 1737/2020";

"With the aforementioned note DCS prot. no. XX of the XX, the General Managers of the SSR Companies have, for this purpose, been called upon "to provide INSIEL as soon as possible [...] the operational indication of making the related functions visible only for those assisted who have given specific consent to the communication of their data to their GP".

"From the aforementioned documents it appears that the treatments object of the current request for information and, in particular, the stratification of assisted through the application of the ACG algorithm and the consequent elaboration of lists of assisted falling within the so-called categories RUB 4 and RUB 5, are carried out by ARCS and Insiel S.p.A., an in-house company of the Friuli Venezia Giulia Region, on a regional mandate";

“The role of the Healthcare Companies, including the writer, was exclusively to provide Insiel S.p.A. "the operational indication to make the functions visible [...] only for assisted persons who have given specific consent to the communication of their data to their GP", and verification of the achievement of the objectives by the GPs and consequent payment of the same, on the basis of their percentage of achievement”;

“The purposes (planning and evaluation of health care) and the means of treatment (application of the ACG algorithm to the databases present in the regional data warehouse) are entirely established at the regional level, through Council Resolution no. 1737/2020 approving the Agreement 2021-2022 between the Region itself and the trade union organizations of GPs, since the Regional Health Trusts must limit themselves to implementing it (see DGR Friuli Venezia Giulia n. 1737/2020 cit.)";

"As regards the specific databases/registers/lists present in the regional data warehouse - from which the information used to carry out the aforementioned activity of patient stratification was extracted - and the type of information and clinical documents treated in the same context, please refer as represented by ARCS and Insiel S.p.A. (…):

"As regards the legal basis of the activities subject to the request, ASUGI has complied with the provisions - with the primary purpose of governance - contained in the aforementioned Council Resolution, which, in turn, refers to the regulatory provisions referred to in articles 3, paragraph 2, and 4, paragraph 5, of the FVG regional law n. 22/2019, according to which "[...] the Regional Health Service activates innovative organizational methods of taking charge, based on proactivity and initiative medicine [...]" and "the activities for social and health assistance are defined [...]] as part of the annual lines for the management of the regional health service”;

“(…) the management lines of the SSR for the year 2020 (Annex 6) – approved with Regional Council Resolution no. 2195/2020 (Annex 7) - on p. 23, provide for “1. By 31.03.2020, the stratification of the reference population and by complexity must be available in each district, based on the ACG tool. The stratification must also be structured for each individual AFT and for each GP. 2. By 31.12.2020 the districts, on the basis of population stratification and on the additional information available, define, within the PAT, the 2021 commission for the reference population. If the district does not have a sufficiently

consistent size, the commissioning can also be defined at a supra-district level for clustering of districts";

"The government purpose underlying the activities being investigated by this Authority can then be deduced from the clarification contained in the management lines of the SSR 2021 mentioned above (...)".

In the light of these findings, the Office requested further information from the Region, Insiel S.p.a. and to the regional healthcare companies, including ASUGI, regarding the specific databases through which Insiel fed the John Hopkins ACGsystem from which the information used to carry out the stratification activity of the patients in question was extracted, as well as to indicate whether the aforesaid databases owned by the individual healthcare companies correspond to those used by them to feed the ESF or, if not, from which databases (note of the XX, prot. n. XX).

In response to the aforementioned note from the Office, the Friuli Venezia Giulia Region, with a note of the XX (prot. n. XX), specified that "GPs could have independently drawn up the aforementioned lists where the completion of the patient summary had been concluded , which hasn't happened yet. Therefore, given the particular moment of emergency, the writer has provided indications to the authorized and enabled subjects to give GPs the necessary technical support for the definition of the lists".

The Region also provided a note from Insiel S.p.a., of the XX (prot. n. XX), with which the Company indicated the databases used for the aforementioned activities, which also include those of the electronic health record.

In response to the aforementioned request for information, ASUGI represented that "its role in the matter was exclusively limited to following up on the implementation obligations envisaged in the 2020-2021 Agreement between the Friuli Venezia Giulia Region and the Trade Union Organizations of General Practitioners , in compliance with the Regional Council Resolution n. 1737 of 20 November 2020" (note of the XX).

In the aforementioned note, ASUGI also reiterated that:

"(…) its role in the matter was exclusively limited to following up on the implementation obligations set out in the 2020-2021 Agreement between the Friuli Venezia Giulia Region and the Trade Union Organizations of General Practitioners, in compliance with Regional Council Resolution no. 1737 of 20 November 2020";

to have been "invited by the Central Health Department, with note DCS prot. no. XX of XX (…) to supply Insiel S.p.A. "the operational indication of making the functions visible [...] only for assisted persons who have given specific consent to the communication of their data to their GP" [and to the EHR] and that his role was then limited to verifying the achievement of the

objective by GPs and the liquidation of the related incentives"

"The purposes of the processing, relating to the planning and evaluation of health care, were therefore entirely defined by the Region with the aforementioned Council Resolution";

"As regards the specific request of this Authority to be made aware of the "specific databases through which Insiel fed the John Hopkins ACG system from which the information used to carry out the stratification of assisted persons in examination" and their correlation with the functional architecture of the ESF, it should be noted that this specific activity was also defined by the Central Directorate of Health, Social Policies and Disability of the Friuli Venezia Giulia Region and by ARCS and implemented by the in-house IT company Insiel S.p.A., as already specified in the aforementioned note prot. no. XX".

3. The legislation on the protection of personal data and the specific regulation of the relevant sectors

According to the Regulation, "personal data" means "any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, with particular reference to an identifier such as a name, an identification number, location data, an online identifier or one or more characteristic elements of his physical identity, physiological, genetic, psychic, economic, cultural or social" (art. 4, point 1, of the Regulation).

Pseudonymisation means “the processing of personal data in such a way that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that this additional information is kept separately and subject to technical and organizational measures intended to ensure that such personal data are not attributed to an identified or identifiable natural person" (Cons. 26 and art. 4 (5) of the Regulation).

The legislation on the protection of personal data does not apply to "anonymous information, i.e. information that does not relate to an identified or identifiable natural person or to personal data made anonymous enough to prevent or no longer allow identification of the interested party” (see Cons. 26 of the Regulation and WP29 Opinion 05/2014 on Anonymisation techniques, adopted on 10 April 2014).

Anonymised data is such only if it does not in any way allow the direct or indirect identification of a person, taking into account all the means (economic, information, technological resources, skills, time) available to whom (owner or other subject) try to use these tools to identify a data subject. Anonymisation cannot be considered achieved through the mere removal of the personal details of the interested party or their replacement with a pseudonymous code. An anonymisation process cannot effectively be defined as such if it is not suitable for preventing anyone using such data, in combination with "reasonably

available" means, from:

1. isolate a person in a group (single-out);

2. link anonymised data to data referable to a person present in a separate set of data (linkability);

3. deduce new information referable to a person from anonymised data (inference) (cf. Opinion 05/2014 - WP 216 on anonymisation techniques, adopted on 10 April 2014).

That said, the processing of personal data must take place in compliance with the established principles and additional rules of the Regulation and the relevant provisions of the Code.

In relation to the case in question, we refer in particular to the principles of lawfulness, correctness and transparency and purpose limitation according to which personal data must be processed in a lawful, correct and transparent manner and collected for specific, explicit and legitimate purposes and subsequently processed in a way that is not incompatible with these purposes (Article 5, paragraph 1, letter a) and b), of the Regulation; see also Article 29 Data Protection Working Party, Opinion 03/2013 on purpose limitation of 2 April 2013).).

More specifically, the Regulation provides for a general prohibition on the processing of particular categories of data, including those relating to the health of the data subjects, unless one of the particular exemptions from this prohibition pursuant to art. 9, par. 2 of the same Regulation.

In this regard, the cases in which:

- the interested party has given his explicit consent, except in cases where the law of the Union or of the Member States provides otherwise (Article 9, paragraph 2, letter a) of the Regulation);

- the processing is necessary for reasons of substantial public interest on the basis of Union or Member State law, which must be proportionate to the aim pursued, respect the essence of the right to data protection and provide for appropriate and specific measures to protect the fundamental rights and interests of the data subject (Article 9, paragraph 2, letter g) of the Regulation). In this case, the art. 2-sexies of the Code according to which "the processing of particular categories of personal data pursuant to article 9, paragraph 1, of the Regulation, necessary for reasons of significant public interest pursuant to paragraph 2, letter g), of the same article, are allowed if they are provided for by European Union law or, in the internal legal system, by provisions of law or regulation or by general administrative acts that specify the types of data that can be processed, the operations that can be performed and the reason for relevant public interest, as well as appropriate and specific

measures to protect the fundamental rights and interests of the data subject";

- the processing is necessary for the purposes of preventive medicine or occupational medicine, assessment of the employee's ability to work, diagnosis, assistance or health or social therapy or management of health or social systems and services on the basis of Union or State law states or in accordance with the contract with a health professional (Article 9, paragraph 2, letter h) and par. 3 of the Regulation and 75 of the Code; provision of the Guarantor containing Clarifications on the application of the regulations for the processing of data relating to health in the health sector of 7 March 2019 doc. website 9091942).

With reference to the principle of transparency, we also note the related information charges pursuant to articles 13 and 14 of the Regulation, according to which each treatment must be preceded by a suitable information also in order to allow the interested parties to exercise the rights due to them (art. 15-22 of the Regulation). This principle also requires that information and communications relating to the processing of personal data be made in a concise, transparent, intelligible and easily accessible form, with simple and clear language (cons. 39 and 58 and art. 12 of the Regulation).

The Regulation also provides that "when a type of treatment, when it involves in particular the use of new technologies, given the nature, object, context and purposes of the treatment, may present a high risk for the rights and the freedoms of natural persons, the data controller carries out, before proceeding with the treatment, an assessment of the impact of the foreseen treatments on the protection of personal data. A single evaluation can examine a set of similar treatments that present similar high risks" (art. 35; Group art. 29 Guidelines n. 248 concerning "The assessment of the impact on data protection as well as the criteria for establishing whether a treatment" adopted in amended form on 4.10.2017).

In this regard, it should be noted, from the outset, that this requirement has not been waived by the emergency regulations adopted with reference to the pandemic context, as can be seen, for example, from the authorization provided by the Authority on the impact assessment carried out by the Ministry of Health with reference to the treatments carried out within the national contact tracing system - App Immuni (see provisions of 1 June 2020, 25 February 2021 and 24 November 2022), as well as the provisions adopted on the matter in the emergency context (see provisions of 13 May 2021, web doc. No. 9685332, of 13 January 2022, web doc. No. 9744496).

Noting that the initiative examined envisaged the extraction of data on the health of the patients from the Datawarehouse of the Company through the company Insiel SPA, an in-house ICT company of the Region, appointed as Data Processor, through the use of an algorithm provided by the regional agency for the coordination of health, the following is also highlighted.

This activity determines the collection and processing of health data in order to create, with reference to specific pathologies (which, in the case in question, are those that can expose the most fragile assistants to contracting more serious infections from SARS Cov-2) , a health risk profile of the person concerned, useful for implementing preventive interventions to take charge of the patient.

The activity of stratification of the health risk of the population is configured as an administrative activity prodromal to the care activity, consisting in taking charge of the patient, as it allows to classify the assisted persons considered to be at greater risk, in order to prepare in their compare an early and specific taking charge activity.

3.1 Stratification activities of the assisted population

With specific reference to the treatments carried out by healthcare bodies for purposes of public interest, also in the light of what is indicated by the Ministry of Health on the matter and supported by the Guarantor in the numerous provisions on the subject referred to above), these treatment operations fall within the scope of the so-called "initiative medicine", even if addressed, in the present case, only to the emergency context.

This is because, through these treatments, a stratification of the patients of the Regional Health Service is carried out on the basis of information relating to the individual state of health, for the relative placement in health risk classes, in order to identify assistance models aimed at the active promotion of health interventions aimed at an early taking charge of them (see also the aforementioned opinion on the draft law of the Autonomous Province of Trento which contains specific provisions on self-initiated medicine, of 8 May 2020, web doc. n. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for initiative medicine in the provincial health service, of 1 October 2020, web doc. n. 9469372, provision against the USL Toscana Sud Est of 17 December 2020, web document No. 9529527, provisions no. 63, 64, 65, 66, 67, 65, 68, 69 and 70 of 24 February 2022 web document No. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524).

3.2. Patient care activities

With specific reference to the purposes of treatment and prevention, it should be noted that the Guarantor has already highlighted that such treatments must be considered additional and independent of those strictly necessary for ordinary treatment and prevention activities (Article 9, paragraph 2, letter h) of the Regulation), and therefore can only be carried out on the basis of the specific informed consent of the interested party (Article 9, paragraph 2, letter a) of the Regulation) (see ex

multis, opinion on the draft law of the Autonomous Province of Trento which contains specific provisions on initiative medicine, of 8 May 2020, web doc. n. 9344635).

3.3. The treatments carried out through the electronic health record

It should also be noted that through the Electronic Health Record (FSE) the aims set by the specific sector regulations can be pursued and in particular of: a) diagnosis, treatment and rehabilitation; a-bis) prevention; a-ter) international prophylaxis; b) study and scientific research in the medical, biomedical and epidemiological fields; c) health planning, verification of the quality of care and assessment of health care (art. 12, 18 October 2012, n. 179, converted with amendments into law 17 December 2012, n. 221, and dpcm 29 September 2015, n. 178).

Among the aims that can be pursued through the ESF, therefore, the one relating to predictive or initiative medicine does not appear. In fact, even in the recent interventions carried out on the subject, the legislator has not extended this purpose to those that can be pursued through the ESF. The data accessible through the ESF, deprived of direct identification elements, may instead be processed by the Ministry of Health, also through interconnection with other data sources, for the purposes and with the methods that will be established by decree of the Minister of Health, which must be adopted with the opinion of the Guarantor, in compliance with the provisions of the Regulation, the Code, the Digital Administration Code and the guidelines of the Agency for Digital Italy on interoperability (Article 2-sexies, paragraph 1-bis) (see also opinions issued on 22 August 2022, n. 294 and 295 web doc. n. 9802752 and 9802729).

The fact that the interested party's consent has been given to the processing of data present in the EHR for treatment purposes does not therefore legitimize the subjects who access this information tool to process the information contained therein to outline specific health risk profiles of the interested party.

3.4. Statistical activity

Bearing in mind that during the preliminary investigation, reference was made to a "statistical stratification" activity, it should finally be noted that the processing of personal data, carried out for these purposes by subjects participating in the national statistical system (SISTAN), must in any case take place in compliance, not only with the pertinent provisions of the Regulation (articles 5, paragraph 1, letter c) and e) and 89) and of the Code (articles 2-sexies, paragraph 2, letter cc) and 104 et seq.), but also of the Deontological Rules for treatments for statistical or scientific research purposes carried out within the National Statistical System, Annex A4 to the Code, as well as the specific sector discipline referred to in Legislative Decree no.

322/1989, containing "Regulations on the National Statistical System and on the reorganization of the National Statistical Institute".

4. The disciplinary procedure

Following the aforementioned findings, the Office, with deed no. XX of the XX, notified the Giuliano Isontina University Health Authority, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in article 58, paragraph 2, of the Regulation, inviting the aforesaid holder to produce defense writings or documents to the Guarantor or to ask to be heard by the Authority (art. 166, paragraphs 6 and 7, of the Code; as well as art. 18, paragraph 1, of law n. 689 of 11/24/1981).

In particular, the Office has detected the existence of elements suitable for configuring, by the Giuliano Isontina University Company, the violation of the legislation on the protection of personal data in relation to the processing of personal data relating to health, even if treated in pseudonymized form, in the absence of a suitable legal prerequisite and, therefore, in violation of the principles applicable to the treatment referred to in articles 5, par. 1 lit. a) and 9, of the Regulation, as well as of the art. 2-sexies of the Code; in violation of the principle of transparency, not having provided the interested parties with specific information regarding such processing of personal data as provided for by art. 14 of the Regulation; in violation of the owner's obligations regarding the impact assessment on the protection of personal data pursuant to art. 35 of the Regulation.

With the note dated XX (prot. XX), ASUGI sent a "partial acknowledgment" to the notification of violation by the Office pursuant to art. 166 of the Code and asked to "clarify its position in a hearing", as well as reserved the right to "produce further documentation useful to better clarify its position on the point".

On the 20th date, the requested hearing was held in which, in addition to what has already been represented above, the Company stated in particular that:

- "is an instrumental body of the Region and operates within the indications and guidelines formulated by the same in health matters"
- "[...] in the context of the ongoing procedure, the same has no decision-making and implementation autonomy as all the information systems are managed by Insiel, an in-house company of the Region, and which in the present case has operated in implementation of deliberative acts of the regional council. These elements lead us to believe that the de facto owner of the treatments in question is the Region and not the Company, as the Region is attributable to determining both the purpose, on

the basis of a supplementary agreement approved by resolution of the Regional Council, and the means of treatment (software and algorithm have been chosen by the Region). For these reasons, the filing of the administrative procedure in progress is requested";

- "[...] some companies including ASUGI have added additional clauses to the standard ones provided by the Region in the appointment as manager of Insiel regarding the precautions and responsibilities on the processing of personal data carried out by the Company";

- "With specific reference to the dispute relating to the legal basis of the treatment carried out to carry out the stratification of the population by morbidity classes, it is believed that it is to be identified in the resolution of the regional council. It should also be noted that the aforementioned stratification was the means imposed by the Region to allow the Company to pursue the aim of assessing the achievement of the objectives of the approved medicine. It should be noted that the Company has not carried out any stratification activity, which was carried out by Insiel on the indication of the Region, having only used the results for the purpose of achieving the aforementioned purpose as indicated by the regional resolution. It should be noted that this activity is therefore not attributable to initiative medicine, since it is a method identified by the Region to allow the Company to proceed more easily with the assessment of the objectives of the agreed medicine";

- "was not consulted during the adoption of the resolution and the trade union agreement and never asked for the algorithm identified by the Region to be applied to proceed with the aforementioned stratification, therefore the obligations regarding impact assessment do not fall on it . Therefore, it is important to highlight that the Company acted in good faith, implementing what was already provided for by the Region and in the union agreement. For these reasons, it did not consider the burden of the impact assessment to be attributable to it";

- "With reference to the failure to fulfill the transparency obligations (articles 13 and 14 of the Regulation), [...] in all the information on the processing of health data carried out by the Company there is an express reference to the purpose of assessing health care also affiliated";

- "With reference to the warning measures adopted by the Guarantor on 24.2.2022 against 8 Regions, [...] the case in question appears substantially different in that the Company was bound to comply with what was indicated in a resolution of the Council unlike of the case already examined by the Guarantor in which the regions responded to a mere invitation from the Ministry of Health ".

5. Outcome of the preliminary investigation

Having taken note of what was represented by the Company in the documentation in the documents and in the aforementioned hearing in the light of the aforementioned regulatory framework and of what emerged in the context of the information acquired from the Friuli Venezia Giulia Region, from Insiel s.p.a. and by ARCS the preliminary assessments of the Office are confirmed, within the limits set out in the following reasons.

5.1 Absence of a suitable legal basis for the treatment

The Company represented, in particular, that the treatments in question would have been carried out on the basis of the Resolution of the Council of the Friuli Venezia Giulia Region, n. 1737 of 20 November 2020 which in point 3 of the provision, required the regional health authorities to "follow up the implementation obligations of the 2020-2021 Agreement in compliance with the provisions contained therein and consistently with the national and regional provisions on the matter" and therefore on regional mandate. Therefore, the Company would have complied with the provisions - with primary governance purposes - contained in the aforementioned Council Resolution, which, in turn, refers to the regulatory provisions pursuant to Articles 3, paragraph 2, and 4, paragraph 5, of the FVG regional law n. 22/2019, according to which "[...] the Regional Health Service activates innovative organizational methods of taking charge, based on proactivity and initiative medicine [...]" and "the activities for social and health assistance are defined [...]] as part of the annual guidelines for the management of the regional health service".

These annual lines for the year 2020 were approved with Resolution of the Friuli Venezia Giulia Region Council, no. 2195/2019 providing that "By 31.03.2020 in each district the stratification of the reference population and by complexity must be available, on the basis of the ACG tool. The stratification must also be structured for each individual AFT and for each GP. 2. By 31.12.2020 the districts, on the basis of population stratification and on the additional information available, define, within the PAT, the 2021 commission for the reference population. (…)";

In this regard, it should be noted that the assumption of lawfulness of such processing cannot be found in the regulatory framework represented above and in particular in the aforementioned Regional Decree no. 1737 of 20 November 2020 and n. 2195/2019, this is because they do not comply with the requirements of art. 2-sexies of the Code, lacking the indication of the subjects who can carry out the processing, of the operations that can be carried out and of the relevant public interest (see in this sense the opinion on the bill of the Autonomous Province of Trento which contains specific provisions on initiative

medicine, of 8 May 2020, web doc. No. 9344635, opinion on the draft regulation relating to the implementing provisions of the Trentino provincial law for initiative medicine in the provincial health service, of 1 October 2020, web doc. 9469372).

As already reiterated by the Authority also in the opinion to the Council of State, the profiling of the user of the health service, be it regional or national, determining an automated processing of personal data aimed at analyzing and predicting the evolution of the health situation of the individual patient and any correlation with other elements of clinical risk (in this case, Sars Cov-2 infection), can only be carried out in compliance with specific requirements and adequate guarantees for the rights and freedoms of the interested parties (see art. 4, paragraph 1, no. 4 articles 13, paragraph 1, letter f); 14, par. 2, lit. g), 15, para. 1, lit. h) art. 21, par. 1 and 35, paragraph 3, lett. a) of the Regulation), or on the basis of a provision that has the requisites established by the regulations on the protection of personal data, referred to in the aforementioned article 2-sexies, paragraph 1, of the Code.

In this regard, it should be noted that the use of predictive medicine systems by the Ministry of Health has in fact been provided for by a specific regulatory provision, or by the referred to in art. 7 of the so-called "Relaunch" decree (d.l. n. 34 of 2020), which expressly provides that the aforementioned Dicastery, within the scope of its institutional tasks and in particular, of the functions relating to general guidelines and coordination in the field of prevention, diagnosis, treatment and rehabilitation of diseases, as well as technical health planning and guidance, coordination, monitoring of the regional technical health activity, can process personal data, also relating to the health of the patients, collected in the information systems of the National Health Service, for the development of predictive methodologies of the evolution health needs (art. 7, paragraph 1, legislative decree n. 34/202). This article refers to a regulation, to be adopted with a decree of the Minister of Health, subject to the opinion of the Guarantor, in which personal data are identified, also relating to the particular categories of data that can be processed, the operations that can be performed, the methods for acquiring data from the information systems of the subjects who hold them and the appropriate and specific measures to protect the rights of the interested parties, as well as the retention times of the processed data (Article 7, paragraph 2).

Furthermore, with specific reference to the circumstance that only the data of those who have given their consent to consult the EHR would have been extracted from the Insiel company, taking into account the specific purposes pursued through the Dossier which do not include those of self-initiated medicine, it is represented that the consent expressed for the treatments carried out through the FSE cannot be considered a suitable prerequisite of lawfulness for the treatments in question carried

out by the Company.

Nor does the fact that Insiel has extracted the data on the health of the patients from the Company's databases without an express authorization from the owner "in implementation of the aforementioned regional resolution, and that therefore the Company "does not consider itself the owner of this treatment. In this regard, the following is specified.

As highlighted by the Company itself, Insiel accesses the aforementioned database as data processor, from which it can be seen that the ownership of the treatment falls on ASUGI, ownership deriving from the provisions of the sector, as the health company is the only subject legitimated to process information on the health of patients on the basis of the current regulatory framework.

Moreover, this ownership is also recognized in the declarations in the documents of the Region (note of the XX, prot. n. XX) and of Insiel (note of the XX, prot. n. XX) to which ASUGI expressly refers in relation to the claims by the aforementioned entities in relation to the databases from which the data were processed by Insiel (note delXX).

It is also represented that, as highlighted in the 07/2020 Guidelines on the concepts of data controller and data processor of the EDPB of 7 July 2021, it is the task of the data controller, in this case the Company, to decide what the data controller must do in relation to personal data, who has the duty to comply with the instructions of the data controller, but also has the general obligation to comply with the sector legislation (paragraphs 139, 147). It is also up to the data controller to adopt the final decision approving the methods of carrying out the processing as well as requesting any changes (point 30 of the aforementioned Guidelines).

Although the Company has not authorized the treatment linked to the stratification of the assisted population through the processing of data present in the databases it owns, at the state of the records it does not appear that it has intervened against the manager to prevent such treatment or to ask for it termination if deemed unlawful.

In this regard, it should be reiterated that the fact that a third party, in the case in question represented by the Region, asks a data controller (Health Agency), also through the manager, to carry out processing operations on personal data with respect to which this the latter is the owner, also indicating the methods, does not exclude that it is up to the latter, also on the basis of the principle of accountability (articles 5, paragraph 2 and 24 of the Regulation), to evaluate the legitimacy of the request and, in particular, the existence of an appropriate legal basis for carrying out the requested processing operations, especially since, in the present case, the aforementioned operations concerned data on the health of a large number of patients at a regional

level through the use of algorithms (cf. in particular provision of the Guarantor n. 63, 64, 65, 66, 67, 68, 69 and 70 of 24 February 2022, web doc. n. 9752177, 9752221, 9752260, 9752299, 9752410, 9752433, 9752490 and 9752524).

Having said all of the above, it has been ascertained that the Company has processed personal data, including those relating to the health of the patients of the regional health service, in the absence of a suitable legal prerequisite and therefore in violation of the principles applicable to the processing and of the provisions pursuant to articles 5, par. 1, lit. a), 9, of the Regulation, as well as of the art. 2-sexies of the Code.

5.2. Information for interested parties

On this point, the Company represented that "[...] in all the information on the processing of health data carried out by the Company there is an express reference to the purpose of evaluating health care, including those with agreements".

It clearly emerges that the data controller has not complied with his information obligations by failing to provide the interested parties with the specific information regarding such processing of personal data envisaged by art. 14 of the Regulation, as the data of the interested parties have been collected from third parties,

Given this, given that for the treatments carried out, none of the exemptions from carrying out this information obligation, pursuant to art. 14, par. 5 of the Regulation and that the data were obtained by the Company by accessing its Datawarehouses, the violation of the principle of transparency pursuant to articles 5, par. 1, lit. a) and 14 of the Regulation.

5.3 Impact assessment

The treatments carried out by the Company concerned data relating to the health of a large number of vulnerable subjects, therefore the position of the data controller cannot be shared on the basis of which a prior impact assessment, pursuant to art. 35 of the Regulation, it would not have been necessary, this having regard to the provisions of the aforementioned provision which establishes the circumstance in which the obligation to carry out this fulfillment exists, the criteria identified by the Group art. 29 in the Guidelines concerning "Guidelines on data protection impact assessment and determination of the possibility that the processing "may present a high risk" for the purposes of Regulation (EU) 2016/679, adopted on 4 April 2017 as amended and most recently adopted on 4 October 2017, as well as the numerous previous pronouncements of the Guarantor.

On this point, although the Company declared that it had acted "in good faith, implementing what was already foreseen by the Region and in the union agreement" believing "For these reasons [that] it was not [...] attributable to the same of the impact assessment", the treatments carried out are attributable to the Company, having extracted the information from its database as

data controller, the latter was required to carry out an impact assessment pursuant to art. 35 of the Regulation as the case in question is one of those for which the data controller is required to carry out, "before proceeding with the processing, an assessment of the impact of the processing envisaged on the protection of personal data" (Article 35 of the Regulation) . This is because, for the treatment in question, there are certainly two of the criteria indicated by the European Data Protection Committee to identify the cases in which a treatment must be the subject of an impact assessment. In particular, reference is made to the following criteria: processing of "sensitive data or data of a highly personal nature" and of "data relating to vulnerable data subjects" including patients (see Guidelines on impact assessment on data protection and determining whether the processing "may present a high risk" for the purposes of Regulation (EU) 2016/679 adopted on 4 April 2017, as amended and last adopted on 4 October 2017, and endorsed by the European Committee for data protection on 25 May 2018 - WP 248 rev.01, III, letter B, points 4 and 7). Furthermore, it is believed that, with reference to the present case, the criteria relating to the "processing of data on a large scale" can also be satisfied considering that, according to what the Company declared, the processing concerned over 13,500 and the innovative use o the application of new technological or organizational solutions (see the aforementioned Guidelines, III, letter B, points 5 and 8).

It should also be noted that the emergency provisions adopted over the last few months provide for emergency interventions which involve the processing of data and which are the result of a delicate balance between public health needs and those relating to the protection of personal data, in accordance to what is dictated by the Regulation for the pursuit of reasons of public interest in the sectors of public health (cf. art. 9, par. 1, letter i)). Of course, it remains understood that the processing of personal data connected to the management of the aforementioned health emergency must take place in compliance with the regulations in force on the protection of personal data and, in particular, with the principles applicable to the treatment, pursuant to articles 5 and 25, par. 2, of the Regulation, partially referred to above.

Given this, it should be noted that the aforementioned emergency legislation has not derogated from the provisions on the protection of personal data relating to the assessment of the impact on data protection (Article 35 of the Regulation), as demonstrated by the numerous interventions of the Authority on the subject . In fact, the Guarantor intervened with reference to the impact assessment with reference to the treatments carried out in an emergency context in relation to the national contact tracing system - Immuni App (see provisions of 1 June 2020, 25 February 2021 and 24 November 2022), to the Covid-19 green certifications (so-called green pass, see opinion of 9 June 2021, web doc. n. 96680064, opinion of 31 August

2021, web doc. n. 9694010, opinion of 11 October 2021, web doc. n 9707431, dated 27 January 2022, web doc. n. 9742129 and dated 18 February 2022, web doc. n. 9746905) and to specific treatments carried out by Healthcare Companies in relation to the emergency from Covid-19 (see provisions of 13 May 2021, web doc. No. 9685332, of 13 January 2022, web doc. No. 9744496).

Therefore, the violation of the obligation pursuant to art. 35 of the Regulation.

6. Conclusions

In the light of the assessments referred to above, taking into account the statements made by the Company during the investigation and considering that, unless the fact constitutes a more serious offence, anyone who, in a proceeding before the Guarantor, falsely declares or certifies news or circumstances o produces false deeds or documents and is liable pursuant to art. 168 of the Code "False statements to the Guarantor and interruption of the execution of the duties or the exercise of the powers of the Guarantor", the elements provided by the data controller in the defense briefs do not allow to overcome all the findings notified by the Office with the act of initiation of the procedure, since none of the cases provided for by art. 11 of the Regulation of the Guarantor n. 1/2019.

For these reasons, the preliminary assessments of the Office are confirmed and the illegality of the processing of personal data carried out by the Friuli Centrale University Company is noted in violation of the principles of processing pursuant to articles 5, par. 1 lit. a), 9, of the Regulation, as well as of the art. 2-sexies of the Code; in violation of the principle of transparency, not having provided the interested parties with specific information regarding such processing of personal data envisaged by art. 14 of the Regulation; in violation of the owner's obligations regarding the impact assessment on the protection of personal data pursuant to art. 35 of the Regulation.

The violation of the aforementioned provisions also renders the administrative sanction envisaged by art. 83, par. 4 and 5 of the Regulation, pursuant to articles 58, par. 2, lit. i), and 83, par. 3, of the same Regulation.

In this context, considering the absence of a suitable legal basis for the processing of the personal data in question and that ASUGI has not provided any indications regarding the cancellation of the same, it is deemed necessary to order the aforementioned Company, pursuant to the art. 58, par. 2, lit. d), of the Regulation, the deletion of data resulting from the aforementioned processing of information present in the company databases covered by this provision, to be completed within 90 days of the adoption of this provision.

7. Adoption of the injunction order for the application of the pecuniary administrative sanction and accessory sanctions (articles 58, paragraph 2, letter i and 83 of the Regulation; article 166, paragraph 7, of the Code)

The violation of the articles 5 par. 1, lit. a), 9, 14 and 35 of the Regulation as well as of the art. of the art. 2-sexies of the Code, caused by the conduct of the Friuli Centrale University Company is subject to the application of the administrative pecuniary sanction, pursuant to art. 83, par. 4, lit. a) and 5, lett. a) and b) of the Regulation.

The Guarantor, pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, has the power to "impose a pecuniary administrative sanction pursuant to article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, according to the circumstances of each single case" and, in this context, "the College [of the Guarantor] adopts the injunction order, with which it also orders the application of the ancillary administrative sanction of its publication, in whole or in part, on the website of the Guarantor pursuant to article 166, paragraph 7, of the Code" (art. 16, paragraph 1, of the Guarantor's Regulation no. 1/2019).

The aforementioned pecuniary administrative sanction imposed, depending on the circumstances of each individual case, must be determined in the amount taking into account the principles of effectiveness, proportionality and dissuasiveness, indicated in art. 83, par. 1, of the Regulation, in the light of the elements provided for in art. 83, par. 2 of the Regulation. In relation to the violation of personal data notified by the data controller, pursuant to art. 33 of the Regulation, it is noted that:

- the conduct involved data relating to the health of over 40,000 patients of the regional health service, of which over 13,500 from ASUGI;
- the treatment took place in the emergency context caused by the covid-19 pandemic;
- the Guarantor has not received any reports or complaints from specific interested parties in relation to the question examined;
- the Company collaborated with the Authority during the investigation and in this proceeding.

Based on the aforementioned elements, evaluated as a whole, it is decided to determine the amount of the pecuniary sanction provided for by art. 83, par. 4 letter. a) and 5, lett. a) and b) of the Regulation, in the amount of €55,000 (fifty-five thousand) for the violation of articles 5, par. 1 lit. a), 9, 14 and 35 of the Regulation and 2-sexies of the Code, as a pecuniary administrative sanction withheld, pursuant to art. 83, par. 1 and 3, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of publication on the Guarantor's website of this provision should be applied, provided for by art. 166, paragraph 7 of the Code and art. 16 of the Regulation of the Guarantor n. 1/2019, also in

consideration of the type of personal data subject to unlawful processing.

Finally, it should be noted that the conditions pursuant to art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

ALL THIS CONSIDERING THE GUARANTEE

declares the unlawfulness of the processing of personal data carried out by the Azienda Universitaria Giuliano Isontina, for the violation of the art. 5, par. 1, lit. a), 9, 14 and 35 of the Regulation and of the articles of the articles 2-sexies of the Code in the terms set out in the justification.

ORDER

pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, to the Giuliano Isontina University Company with registered office in Via Costantino Costantinides, 2, 34128 Trieste (TS), Tax Code and VAT number 01337320327, to pay the sum of €55,000 (fifty-five thousand) as an administrative fine for the violations indicated in this provision. It is represented that the offender, pursuant to art. 166, paragraph 8, of the Code, has the right to settle the dispute by paying, within 30 days, an amount equal to half of the fine imposed.

ENJOYS

to the aforementioned Company:

- in case of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of €55,000 (fifty-five thousand) in the manner indicated in the attachment, within 30 days of notification of this provision, under penalty of adopting the consequent executive acts pursuant to art. 27 of the law n. 689/1981;
- pursuant to art. 58, par. 2, lit. d), of the Regulation, to the Giuliano Isontina University Company within 90 days of notification of this provision, to proceed with the cancellation of the data resulting from the processing of the information present in the company databases covered by this provision.
- pursuant to art. 58, par. 1 lit. a) of the Regulation and 157 of the Code, to communicate which initiatives have been undertaken in order to implement the above enjoined with this provision and in any case to provide adequately documented feedback, within 20 days of the expiry of the aforementioned term; any failure to reply may result in the application of the pecuniary administrative sanction provided for by art. 83, paragraph 5, of the Regulation

HAS

pursuant to art. 166, paragraph 7, of the Code, the entire publication of this provision on the website of the Guarantor and believes that the conditions set forth in art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

Pursuant to art. 78 of the Regulation, of the articles 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision it is possible to lodge an appeal before the ordinary judicial authority, under penalty of inadmissibility, within thirty days from the date of communication of the provision itself or within sixty days if the appellant resides abroad.

Rome, 15 December 2022

PRESIDENT

station

THE SPEAKER

Station

THE SECRETARY GENERAL

Matthew

(1) By "initiative medicine" we mean a model of care oriented towards the "active promotion" of the health of the individual, especially if suffering from chronic diseases or disabilities, and towards empowering people in their own treatment path (source: Ministry of Health http://www.salute.gov.it/portale/temi/p2_6.jsp?id=496 &area=Cure%20primarie&menu=cure, see, among many references, Ministry of Health, General Assembly of the Superior Health Council , "Telemedicine - national guidelines", 10 July 2012, see par. 2.3.2, Decree 02 April 2015, n. 70 - Regulation establishing the definition of qualitative, structural, technological and quantitative standards relating to hospital assistance, Agreement between the Government, the Regions and the autonomous Provinces of Trento and Bolzano on the planning guidelines for the use by the Regions of the restricted resources pursuant to article 1, paragraphs 34 and 34 bis, of the law of 23 December 1996, n. 662 for the realization of the priority objectives of national importance for the year 2014.