PD 16/2019

Report in relation to the Proposal presented by the Department of Health, to be included in the Draft Law on fiscal and financial measures for 2020 (M-354-1)

The Proposal submitted by the Department of Health is submitted to the Catalan Data Protection Authority, to be included in the Draft Law on fiscal and financial measures for 2020 (M-354-1), for study and issuance of the corresponding report.

The text of the Proposal is accompanied by a copy of the General Report and the Impact Assessment Report.

Having examined the Proposal, and having seen the report of the Legal Counsel, the following is reported.

Legal foundations

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Decree Law 4/2010, of August 3, on measures to rationalize and simplify the structure of the public sector of the Generalitat of Catalonia, in its article 2.1, creates the Agency for Quality and Professional Development in Health, which is renamed "Agency for Health Quality and Evaluation of Catalonia" (hereinafter, AQUAS), by application of article 134 of Law 11/2011, of December 29, on the restructuring of the public sector to streamline administrative activity.

AQUAS was created with the aim of generating relevant knowledge to contribute to the improvement of the quality, safety and sustainability of the health system in Catalonia, which facilitates decision-making by citizens, professionals and managers. managers in the field of health, and to the bodies responsible for health planning, as well as facilitating the integration of health professionals in the system and their co-responsibility in the achievement of common goals and the quality of the attention (article 2.1 DL 4/2010).

Article 3 of DL 4/2010, in the wording given by Law 3/2015, of March 11, on fiscal, financial and administrative measures, provides for the functions of AQUAS in the following terms:

"a) Define, in accordance with the guidelines of the competent department in health matters, promote and deploy the strategy of the information system for the health system that provides the Health Administration with the information necessary for the evaluation of the quality of health care and manage it by generating knowledge of the system. b) Carry out the management and maintenance of the common and/or unified elements of the information system of the Integral Health System of Public Use of Catalonia (SISCAT). c) Carry out evaluation tasks of new treatments, organizational and care procedures, medicines, technologies, health research and innovation.

d) Measure, evaluate and disseminate in a public and transparent manner the global results achieved in health and in the field of health care by the different agents that make up the health system, based on the management of the Integrated Information System of Health in Catalonia, configured by the information of an administrative and statistical nature contained in the records and information systems of the department and the competent bodies in the field of health, those of health centers, services and establishments and those of health professionals, in order to facilitate co-responsible decision-making in the service of the quality of health care provided to citizens. To this end, said agents must communicate the relevant data to the System through their responsible bodies and in accordance with current regulations in the field of statistics and protection of personal data. However, the communication of data from clinical histories requires, unless the patient has previously given consent, the prior dissociation of the identification data of the holder in accordance with the regulations governing the patient autonomy and rights and obligations regarding clinical information and documentation. e) [Not valid] f) [Not valid] g) [Not valid] h) [Not valid] i) Establish and manage an integrated information system on professionals who carry out their activity in Catalonia, on their own account or for others, in public and private centers, that respond to the needs of the Health Administration for the exercise of its powers, especially in matters of planning and organization of health resources and professional development, and from which they are communicated to the Registry of health professionals the data necessary for the maintenance and development of the health information system of the National Health System, in the terms of article 53 of State Law 16/2003, of May 28, on cohesion and quality of the National Health System. For these purposes, the Agency can access the necessary personal data contained in the human resources records of the public administrations and the entities linked to them, the professional corporations, the centers, services and health establishments and the entities of insurances that act in the field of illness. Communications of this data must be subject to data protection legislation. and bis) Design, approve, put into practice and supervise the actions relating to the security of the information of the department competent in health matters and of the attached entities and bodies. j) Cooperate with homonymous bodies from other autonomous communities, at national, European and international level, in order to achieve synergies and disseminate the respective knowledge. k) Carry out all the activities that are necessary for the fulfillment of its objectives, in accordance with the statutes that are issued in development of this Decree Law, as well as the actions in relation to the aforementioned functions that are entrusted to it."

The Proposal presented by the Department of Health to be included, as an additional provision, in the Draft Bill of Fiscal and Financial Measures for 2020 (hereinafter, the Proposal), aims to assign to the competent bodies of the Department of Health the functions of the AQUAS that are affected by the modification of article 3 of DL 4/2010 provided for in Fiscal and financial measures law:

"Additional provision. Health provisions

1. The Catalan Health Service is responsible for the management and maintenance of the common and/or unified elements of the Integral Health System information sy

of Public Use of Catalonia (SISCAT) that letter b) of article 3 of Decree-law 4/2010, of August 3, on measures to rationalize and simplify the structure of the public sector of the Generalitat of Catalonia, repealed by article xxx of this Law, attributed to the Health Quality and Assessment Agency of Catalonia.

- 2. Corresponding to the competent department in health matters are the functions that letters i) ii bis) of the article of Decree Law 4/2010, of August 3, on measures to rationalize and simplify the structure of the public sector of the Generalitat de Catalunya, repealed by article xxx of this Law, attributed to the Health Quality and Assessment Agency of Catalonia.
- 3. With regulatory rank, the functions provided for in section 2 of this provision are attributed to the following units and bodies:
- a) The function of establishing and managing an integrated information system on the professionals who develop their activity in Catalonia, on their own account or for others, in public and private centers, which responds to the needs of the Health Administration for to the exercise of their powers, especially in matters of planning and organization of health resources and professional development, and from which the data necessary for the maintenance and development of the health information system are communicated to the State Register of health professionals of the National Health System, under the terms of article 53 of State Law 16/2003, of May 28, on cohesion and quality of the National Health System, to the competent management unit in the matter of health professionals the health of the competent department in health matters. For these purposes. the aforementioned organic unit can access the necessary personal data contained in the human resources records of the public administrations and the entities linked to them, the professional corporations, the centers, services and health establishments and the entities of insurances that act in the branch of the disease. Communications of this data must be subject to data protection legislation. b) The function of design, approval, implementation and supervision of the actions relating to the security of the information of the department competent in matters of health and of the entities and bodies attached, to the competent unit of the General Secretariat of the department competent in health matter
- 4. The Government must adapt the statutes of the Health Quality and Assessment Agency of Catalonia to what is established in this Law.
- 5. The competent department in health matters and the Catalan Health Service are subrogated in the legal relations in which the Quality and Evaluation Agency Sanitàries de Catalunya is an active or passive subject and that are related to the functions assumed in accordance with sections 1 and 2 of this provision."

The Proposal is motivated, as can be seen from the accompanying General Report, by the changes that have occurred in the organization and operation of the health services of the Generalitat de Catalunya since the promulgation of DL 4/2010, which have meant that the regulatory regulations of AQUAS do not reflect the reality of the functions it currently carries out.

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From the point of view of data protection, the Proposal that is submitted to report entails a modification in the responsibility for the processing of personal data linked to

the exercise of the function referred to in article 3.i) of DL 4/2010, that is the establishment and management of an integrated information system on health professionals.

The Regulation (EU) 2016/679, of the Parliament and of the European Council, of April 27, 2016, General Data Protection (hereinafter, RGPD), defines "responsible for the treatment" as "the natural or legal person, public authority, service or other body that, alone or together with others, determines the ends and means of the treatment" (article 4.7).

With the approval of this Fiscal and Financial Measures Law, this responsibility will fall to the competent managerial unit in the matter of health professionals of the Department of Health (section 3.a) Proposal), which is substituted in the position of the AQUAS (section 5 Proposal).

From the data protection aspect, the main consequence of this modification of the person in charge of the treatment will be the transfer or communication of personal information from AQUAS to the new person in charge, for the purposes of guaranteeing by this the correct development of the function it assumes.

The RGPD establishes that all processing of personal data must be lawful (Article 5.1.a)). In order for this treatment to be lawful, one of the legal bases of article 6.1 of the RGPD must be met, either the consent of the affected person (letter a)) or one of the other legal bases provided for in the same article, such as, for the purposes that concern, that "the treatment is necessary for the fulfillment of a mission carried out in the public interest or in the exercise of public powers conferred on the person responsible for the treatment" (letter e)).

As can be seen from article 6.3 of the RGPD and expressly included in article 8 of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (hereinafter, LOPDGDD), the processing of data can only be considered based on this legal basis of article 6.1.e) of the RGPD when this is established by a rule with the rank of law.

As we have seen, the Proposal attributes to the competent Department of Health (specifically, to the managerial unit competent in the matter of health professionals) the function of establishing and managing an integrated information system on the professionals who develop their activity in Catalonia. At the same time, the same Proposal envisages that this Department will occupy the position of AQUAS, with respect to all the legal relationships that are related to the exercise of said function.

In view of these forecasts, it can be said that the transfer or communication of the personal data for which, until the approval of this Proposal, AQUAS is responsible linked to the exercise of the aforementioned function towards the Department as as its subsequent treatment by it, in the exercise of this function attributed to it by the Fiscal and Financial Measures Law, would be legitimated by the legal basis of article 6.1.e) of the RGPD.

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In relation to the processing of data linked to the exercise of the functions referred to in article 3.b) ii bis) of DL 4/2010, it should be noted that, unlike the previous case, in this case the DL 4/2010 assigns functions to AQUAS that this entity must carry out at the service of various third parties: the participating entities of SISCAT, the Department of Health and affiliated entities and bodies.

Remember, AQUAS is responsible for managing and maintaining the common and/or unified elements of the SISCAT information system (article 3.b)), as well as designing, approving, implementation of the system (article 3.b).

practice and supervise the actions relating to the security of the information of the department competent in matters of health and of the attached entities and bodies (article 3.i bis)).

With the approval of this Law on fiscal and financial measures, these functions are attributed, on the one hand, to the Catalan Health Service (section 1) and, on the other, to the competent unit of the General Secretariat of the department competent in health matters (section 3.b)), which they are substituted in the position of the AQUAS (section 5).

The main consequence of this modification will be the access of the Catalan Health Service and the Department of Health to the personal information necessary for the exercise or development of said functions held by the aforementioned third parties.

Considering that the Proposal expressly attributes to these entities the exercise of the aforementioned functions and also foresees their subrogation in the position of AQUAS, the access by these entities to the personal information mentioned, as well as their subsequent treatment by them, would also be legitimized by the legal basis of article 6.1.e) of the RGPD.

Having said that, just to point out that, despite not being considered responsible for the treatment, it will be up to the Catalan Health Service and the Department of Health to establish the necessary technical and organizational measures to guarantee adequate security of the personal information processed for the exercise of the functions they assume, without prejudice to compliance with the other instructions or requirements that, in this regard, may be required of them by the various persons responsible for the treatment.

In view of the wording used in section 3.b) of the Proposal, it can be said that the Proposal reflects this circumstance quite clearly with regard to the actions of the Department of Health. On the other hand, it could be convenient to modify section 1, in order to offer greater transparency on this action by the Catalan Health Service.

In this sense, the following wording is proposed:

"1. The Catalan Health Service is responsible for the management, maintenance and determination of security measures for the common and/or unified elements of the information system of the Integral Health System for Public Use of Catalonia (SISCAT) that letter b) of article 3 of Decree-law 4/2010, of August 3, on measures to rationalize and simplify the structure of the public sector of the Generalitat of Catalonia, repealed by article xxx of this Law, attributed to the Health Quality and Evaluation Agency of Catalonia."

For all this the following are done,

Conclusions

The Proposal presented by the Department of Health, to be included in the Draft Law on fiscal and financial measures for 2020 (M-354-1), is considered adequate to the forecasts established in the corresponding regulations on the protection of personal data .

Barcelona, November 28, 2019