

Ministry of Health approves Directive that establishes the treatment of personal data related to health or personal data in health

On September 2, 2020, Ministerial Resolution No. 688-2020/MINSA was published in the Extraordinary Edition of the Official Gazette El Peruano, which approves Administrative Directive No. 294-MINSA/2020/OGTI, which establishes the treatment of personal data related to health or personal data in health, with the aim of contributing with full respect for the person and the Fundamental Right of Protection of Personal Data related to health, as well as the Fundamental Right to personal privacy and family, and the secrecy or inviolability of private documents, recognized by national regulations, so that they are safeguarded in the health sector.

Next, we comment on the most relevant aspects:

ÿ General Provisions:

- ÿ Regarding the scope of application: The Directive is mandatory for all bodies and organic units of the Ministry of Health, its decentralized bodies, attached public bodies, and national programs; in the Regional Health Directorates, Regional Health Management Offices or those that take their place in the regions and their networks, micro-networks and health establishments. Likewise, it applies to EsSalud, the Health Directorate of the National Police and the Peruvian Armed Forces, as well as their corresponding health establishments, and other public or private entities that carry out activities in the National Health System.
- ÿ On the classification of data in the health sector: The Ministry of Health classifies the information related to the problems, situation or health condition of the population in the health sector, in:
 - ÿ Personal Data in Health (DPS) or Personal Data Related to health.
 - ÿ Health Information or Health Information (IS).

ÿ About Personal Health Data (DPS):

- ÿ They are all those referred to the health situation or illness of a person, and that identifies it and makes it individually identifiable, said information corresponds to the health or illness past, present or predicted, physical or mental, of a person, including the degree of disability and their genetic information. The DPS are generated in any medical act or health act, or any health care received in health establishments or outside of it.
- ÿ Limitations can only be established by law.
- ÿ The DPS are considered as sensitive data, which means that for their treatment, the written consent of the owner of said DPS must be obtained. Even when there is no consent of the owner, the processing of sensitive data can be carried out when authorized by law, provided that it meets important reasons of public interest.
- ÿ All DPS have a holder to whom they belong and can exercise their rights of access, rectification, cancellation, opposition, right to guardianship, objective treatment, among others indicated in Law No. 29733, Law on Protection of Personal Data and its Regulations.



- The Ministry of Health regulates, supervises and sanctions as appropriate, guarantees compliance with the right to protection of the DPS of users of public, private and mixed health services
- ÿ As long as there is the prior and explicit written consent of the owner of their DPS, the Health Establishment (hereinafter, EESS) public, private and mixed, may share them with another EESS that provides direct health care to the aforementioned owner.
- ÿ The construction of nominal lists containing DPS is not allowed, whether of patients, of sick people, who receive treatment or not from the State, or as a beneficiary of social programs.

ÿ Of Health Information - IS:

- ÿ It is the one that arises from care in health establishments and services, and that is made up of the set of statistical data, dissociated or anonymized data related to health, that do not allow the individual identification of one or more people or users, therefore, does not include DPS. It also includes the administrative and financial data of the management of the organization or entity in the health sector.
- ÿ The SI is of public interest, every person is obliged to provide the National Health Authority with the information that is required according to Law.
- ÿ The SI, for its presentation or publication, must not consign items that allow the identification of the person from whom it was obtained, that is, the individual identification of one or more persons or users. ÿ SI refers to epidemiological, statistical, and population information, which is anonymised.

ÿ Specific Provisions:

ÿ On the generation of the DPS:

- ÿ All records of care provided in health facilities or in home and pre-hospital care, or support medical services generate information that corresponds to DPS.
- The healthcare staff of the health facility that participates in the various services is responsible for the proper use of the DPS.
- Administrative staff act responsibly to ensure the protection of DPS.
- ÿ The directors, managers, chiefs, chief physicians or those who take their place in the health establishments or medical support services, must have the corresponding measures to guarantee the protection of the DPS.

ÿ On the protection of DPS:

- ÿ The EESS or Medical Support Service (hereinafter, SMA) public, private and mixed must take the necessary technical, organizational and legal information security measures to ensure the protection of the DPS.
- ÿ The DPS registered in storage media, based on the care provided, are subject to the provisions of the current Technical Health Standard for Clinical History Management, and to the standards on documentary files in force in the State.



ÿ On the treatment of DPS and IS:

- ÿ Public, private and mixed EESS or SMA send statistical and anonymized information, according to what has been established by the National Health Authority, through normative documents.
- ÿ Health information must not transmit data that identifies the person, and will be disaggregated into the attributes of age, sex, residence, diagnoses, treatment, and others, as appropriate and as established by the National Health Authority.

ÿ About the SI flow:

- ÿ Each EESS or public, private and mixed SMA sends through electronic transmission or any other means, the health information required with the characteristics and within the terms established in the normative documents for the information platform that the National Health Authority make available.
- ÿ In the event that the EESS or SMA do not have internet services, they will physically send the health information to the micronetwork or EESS defined as a data entry point so that it can be entered into the corresponding computer platform.
- ÿ On information assets: The information together with the processes, systems, network equipment, technical personnel and services related to the treatment of the same, make up the information assets of the organization or entity, which are of vital importance for the fulfillment of its mission, vision, objectives, functions and plans of the Ministry of Health.

ÿ On sending the DPS to other entities of the public administration or private:

- ÿ The bodies, organic units, public agencies and programs of the Ministry of Health are not authorized, under administrative, civil or criminal responsibility, to send the DPS to any public or private institution or entity that requests it.
- ÿ The EESS, SMA, DIRIS, DIRESA or GERESA are not authorized to send the DPS to any institution or public or private entity that requests it with the exceptions described in the Directive and in current legal regulations.

ÿ About the rights of the holders of the DPS:

- ÿ The directors or heads of the EESS, SMA, DIRIS, DIRESA or GERESA must designate an area to respond to the requests of the holders of the DPS.
- ÿ The holders of the DPS must have the appropriate conditions to grant their consent to the treatment of DPS, by means of a handwritten or digital signature, or another authentication mechanism that guarantees the unequivocal will of the holder.
- The holder of the DPS may at any time revoke the consent to the treatment of his DPS.
- ÿ On information security measures: The following information security measures must be applied or implemented, as appropriate, in addition to the security measures established in the

Regulation of Law No. 29733:



- The user registration and cancellation process must be implemented to allow the assignment of access rights to the DPS.
- ÿ The assignment and use of privileged access rights must be restricted and controlled, according to the assigned responsibilities and for a period of three months, requesting renewal if warranted.
- ÿ The Information Technology Offices, or those acting on their behalf, designate a responsible and competent staff in their jurisdiction, with the purpose of reviewing the access rights of users at regular intervals at the national level.
- Access to the DPS in the information systems must be restricted and controlled by a secure entry procedure, in charge of the personnel that implement the security measures of the DPS.

ÿ On the treatment of the DPS in the State of Sanitary Emergency or Pandemic Situations: ÿ

- Information should receive the same treatment that DPS receives in normal conditions.
- ÿ Files of a transitory nature, and that contain DPS, must be subject to the corresponding security measures, which guarantee the privacy, security, and inviolability of the information contained therein.
- ÿ In no case can patient care documentation containing DPS be eliminated during the health emergency period.

ÿ Final Provisions:

- ÿ In case the transmission is detected without the authorization of its holders, as well as the falsification, manipulation or modification of the DPS, the directors or heads of the EESS, SMA, Directorate of Integrated Health Networks (DIRIS), Regional Directorate of Health (DIRESA) or Regional Health Management (GERESA), are obliged to report this fact to the Anti-Corruption Transparency Office of the Ministry of Health, the National Police or the Public Ministry, under administrative, civil or criminal responsibility that may apply.
- ÿ It is the responsibility of the General Directors, or Heads of the EESS, SMA, DIRIS, DIRESA or GERESA, officials and public servants and managers of private entities that the DPS are stored and safeguarded for the established time and until it has been fulfilled with the purpose for which they were collected. Its treatment and final disposal must be carried out with the same criteria established in NTS No. 139-MINSA/2018/DGAIN, Technical Health Standard for the Management of Clinical History, and the legal regulations that apply to it.

This rule takes effect from the day after its publication and its full text can be found at the following link:

https://www.gob.pe/institucion/minsa/normas-legales/1133776-688-2020-minsa



JOHN-ANDRÉ
FLORES URIBE
Associate Lawyer of the Area of Competition and Intellectual Property.
i oresu@bvu.pe



CARLO FABRICIO SANCHEZ CONCHA Head of the Property area Intellectual and Competition



lexandra spinoza ssistant of the competition & Intellectual roperty Area