

**L.N. 263 of 2019****HEALTH ACT  
(CAP. 528)****Processing of Personal Data (Secondary Processing)  
(Health Sector) Regulations, 2019**

IN EXERCISE of the powers conferred by articles 27 and 30 of the Health Act, the Minister for Health, after consultation with the Data Protection Commissioner, has made the following regulations:-

Citation and  
scope.

**1.** (1) The title of these regulations is the Processing of Personal Data (Secondary Processing) (Health Sector) Regulations, 2019.

(2) The objective of these regulations is to regulate the further processing of personal data in the health sector, hereinafter referred as "secondary processing" which is not linked to the primary purpose for which the data was originally collected.

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(3) The provisions of these regulations shall be read in conformity with the provisions of the Data Protection Act and the provisions of 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 and on the free movement of such data, and repealing Directive 95/46/EC, hereinafter referred to as the "General Data Protection Regulation".

Interpretation.

**2.** In these regulations, unless the context otherwise requires:

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"health care professional" means any health care professional regulated by the Health Care Professions Act;

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"non-governmental organisation" means a voluntary organisation, as recognised by the Ministry for Health, and which has been enrolled with the Commissioner for Voluntary Organisations under the Voluntary Organisations Act.

For the purposes of these regulations, the "data controller", referred to under the General Data Protection Regulation, shall also include the Chief Executive Officer of entities providing a healthcare service to patients, including but not limited to residential services to such patients within the Ministry for Health but not solely, or such other officer appointed by the respective Ministry to be responsible for such entity under such Ministry;

"pseudonymisation" means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

**3. Secondary processing of personal data in the health sector** shall be permitted where such secondary processing is related to - Secondary processing of personal data.

(a) the processing and analysis of records kept by all entities falling within the ambit of the health sector, and the administration of the systems and services by entities, which entities are licensed to deliver any kind of service to patients or individuals, for the purpose of managing and enhancing the health service;

(b) the analysis of health records supplied to the Ministry for Health in accordance with licensing legislation, contractual obligations, compliance with EU regulations on public health statistics and to safeguard other public health interests, to produce the indicators required for monitoring, to ensure the quality and cost effectiveness of the health services at national level;

(c) the monitoring of contractual obligations, including the purposes of quality control, management information and monitoring of such services and systems, arising from the public-private partnerships and partnerships with non- governmental organisations which the Ministry for health has entered into with third parties, to ensure that the afore-mentioned partners are adhering to their contractual obligations to deliver a safe and accessible service;

(d) the fulfilment of the obligations related to the provision of statistical information, whether to international organisations or local clients; this may involve the linkage of existing administrative databases and disease registers;

(e) the compilation of evidence in medico-legal cases and in cases referred by public bodies, in the course of exercising their duties as provided by law;

(f) the investigation and monitoring of health threats, which typically requires the processing of health record data for the protection of public health; and

(g) access to health records, for the purpose of research activities.

Access to health records.

4. In pursuance of regulations 3(c) and 3(g), personal data may be processed where the research activities are in the public interest. Where such processing cannot be conducted using anonymised data, it is only permissible subject to the following conditions:

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(a) following approval by the Health Ethics Committee within the Ministry of Health, where the research activity is conducted within the Ministry for Health or its partners, and after obtaining prior authorisation from the Commissioner for Data Protection in terms of article 7 of the Data Protection Act;

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(b) following approval by any other Ethics Committee recognized by the Information and Data Protection Commissioner where the research activity is conducted by academics or students, or any other NGO or public body having the remit to assist patients in need for health services, and after obtaining prior authorisation from the Commissioner for Data Protection in terms of article 7 of the Data Protection Act:

Provided that processing of such data is conducted using pseudonymised data, and where this is not possible appropriate measures are taken to safeguard the rights and fundamental freedoms of the data subject by providing that data should be anonymised as soon as the research or the statistical study no longer requires identifiable data.

Consent.

5. In all other cases, processing health records for any purpose other than that pursuant to regulation 3, shall require the consent of the data subject concerned as provided for in the General Data Protection Regulation.