

# Ireland's proposed Health Information and Safety bill

Part of a series of initiatives that aim to modernise the collection, use and management of information in the Irish health system, Ireland's proposed Health Information and Patient Safety Bill would have a significant impact on the privacy and data protection laws of Ireland as they apply to the health sector. Adam Finlay, Partner at McCann FitzGerald, reviews the proposed Bill and notes that it is of interest to anyone who handles health information that relates to individuals.

In November 2015, a general scheme of a Health Information and Patient Safety Bill was published as one of a number of proposed legislative measures announced by the Minister for Health as part of a 'Patient Safety Package.' The Bill is stated to be the latest step in a series of initiatives designed to modernise the collection, use and management of information in the Irish health system, which have included the launch of Ireland's eHealth Strategy in 2013 and the adoption of the Health Identifiers Act in 2014. If enacted, this Bill would, amongst other things, provide for significant changes to privacy and data protection law and practice as it applies to the health sector. Since the general scheme was published during the term of office of a coalition Government that will not return to power following the general election held on 26 February, it remains to be seen whether it will proceed to enactment and, if so, when. This article outlines some of the key changes regarding the use of personal information in the Irish health sector that will be brought about if this Bill is enacted in

substantially the same form as the draft published in November.

The draft Bill is broad in scope, as it will address not only health information, but also patient safety, the conduct of research and the extension of the remit of the Health Information and Quality Authority ('HIQA') to private hospitals and prescribed private health services. In relation to health information, the key provisions are as follows:

- The Bill will introduce and provide for obligations regarding a newly coined statutory term of 'personal health data,' which will be defined as 'personal data' (as defined in the Data Protection Acts 1988 & 2003 (the 'DPA')) that relates to an exhaustive list of health-related matters. This new defined term will be more detailed than the current concept of 'personal data relating to health,' which is a subset of the definition of 'sensitive personal data' set out in the DPA. There will be a statutory right for individuals to require that a copy of any 'personal health data' relating to them be transferred from one 'health services provider' to another who provides similar health services (e.g. from one GP to another). This will be in addition to existing access rights provided for under the DPA and the Freedom of Information Act 2014 ('FOIA') and is similar to the 'right of portability' provided for in the proposed General Data Protection Regulation (the 'GDPR').

- All data controllers will be obliged to maintain records of any disclosure of 'personal health data.' It is notable that this obligation will apply to all data controllers (i.e. it is not limited to 'health services providers' and would extend, for example, to any employer who discloses 'personal health data' relating to its employees to any third party).

- The Bill will create new criminal offences for buying or selling 'personal health information' obtained in a professional capacity or in the course of employment or business. The definition of 'personal health information' will be similar to 'personal health data,' except that it will extend to health information relating to any individual, living or deceased (whereas 'personal health data' will not cover information that is not 'personal data' and, as a result, will not extend to information relating to deceased individuals or to data which is not held in electronic form or in a relevant filing system). Under proposed amendments to the DPA, the Bill will also extend the security obligations which apply to 'personal data' under the DPA to such 'personal health information.'

- There will be a new right for a 'prescribed health regulatory body' to share personal data with another 'prescribed health regulatory body,' or a 'prescribed regulatory body,' where this is reasonably believed to be relevant to the performance by the latter of its functions.

- The Minister will be empowered to specify standards for the efficient and effective electronic exchange of health information. The explanatory note in relation to this provision elaborates that it is envisaged that such standards may be drafted for the Minister by HIQA and will be adopted on an incremental basis to improve interoperability. It is stated that they will indicate the direction that is being taken in Irish healthcare services to the adoption of internationally accepted standards, such as Health Level 7.

- HIQA may specify standards for the processing of personal data by health service providers, subject to approval by the Minister and by the Data Protection Commissioner

(‘DPC’).

- Health researchers may apply to the DPC for a specific exemption from certain data protection obligations to cover the processing of personal data for health research purposes.

- Parts 4 and 5 of the Bill provide for frameworks for the operation of a ‘prescribed data matching programme’ and a ‘prescribed health information resource,’ with specific derogations from data protection obligations that would otherwise apply under the DPA. The underlying rationale in each case is that, subject to appropriate controls and restrictions, derogations from ‘fair collection and processing obligations’ under the DPA, and particularly obligations to notify affected data subjects and to obtain their consent, are appropriate to facilitate the collection and use of personal data for these purposes for matters of public interest. In this context, ‘data matching’ is essentially defined as comparing and contrasting information held in separate data sets; ‘health information resources’ covers public health registers and indexes. It is notable that the explanatory notes regarding ‘health information resources’ cite the Health Information Bank regime that applies in British Columbia under the E-Health (Personal Health Information Access and Protection of Privacy) Act 2008 as an example of another regime providing for the collection and use of health information in this manner. In either case, a person may apply to the Minister for regulations prescribing conditions

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for the operation of a data matching programme or a health information resource. If such regulations are made (following consultation by the Minister with the DPC and HIQA) then an operator of a ‘prescribed data matching programme’ or ‘prescribed health information resource’ may require any data controller to provide it with a ‘data set’ containing health information within that data controller’s possession or control and the data controller will be required to make such a disclosure, irrespective of whether it has the relevant data subject’s consent to do so. Data obtained under these frameworks may be used only for the purposes specified in the relevant regulations and breach of this obligation will constitute a criminal offence. HIQA will have the power to set general standards for the processing of data in these circumstances, subject to the approval of the Minister (in consultation with the DPC).

- Part 7 of the Bill provides for a framework for mandatory notifications by ‘health services providers’ of serious ‘patient safety incidents’ to certain public bodies, such as the State Claims Agency and the relevant service provider’s main regulatory authority. From an information management perspective, it is notable that the Bill provides that such notifications will be exempt from the Freedom of Information regime (which applies generally to records held by public bodies, subject to certain exceptions and exemptions), except that an individual who is the subject to such a notification may

request a copy of it under the Freedom of Information Act. This exemption is stated to be intended to address some of the concerns that would arise from such a mandatory notification regime. For similar reasons, the Bill also provides that such notifications will not be admissible in evidence in any civil proceedings in connection with any personal injury or death alleged to have been caused by the relevant health services provider.

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While the GDPR and its likely impact on health services and other sectors continues to dominate privacy law-related headlines in Ireland and throughout the EU, the Health Information and Patient Safety Bill should also be taken into account in the plans of anyone operating in, or intending to enter, the Irish health sector. Since certain of its provisions will apply to any data controller of ‘personal health data’ or person handling ‘personal health information,’ it should also be considered by anyone who handles health information relating to individuals (living or deceased).

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