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Medical data

Enhanced rights for patients, more obligations for healthcare providers



Many healthcare providers receive access requests from patients. As of 1 July 2020 healthcare providers need to comply with additional obligations relating to the access of patient personal data. This is laid down in the Dutch Data in Healthcare (Supplementary Provisions) Act (Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg, hereinafter: Wabvpz), more specifically in Article 15d and 15e. These provisions add rules to the existing obligations on electronic access to the medical file and logging data as well as the receipt of an electronic copy of the medical file. The rights of the patients are extended by these new rules. Healthcare providers must ensure that the patient can indeed exercise these rights. In this article, we will outline the new obligations and explain the additional value compared to the already existing legal framework. Also, we will shed a light on the implementation of the new obligations in the health care practice.

Existing legal framework

The right to access personal data dates back from the Data Protection Directive (95/46/EC) and has been extended in the General Data Protection Regulation (GDPR). Furthermore, specific inspection rights are laid down in the Dutch Medical Treatment Act (Wet op de Geneeskundige Behandelingsovereenkomst, hereinafter: Wgbo). These more general frameworks will continue to apply after 1 July 2020.

GDPR

Under the GDPR, the patient has the right of access to its personal data and the right to data portability. These are general data subject rights, not specifically designed for the patient – healthcare provider relationship. Following the right of access as laid down in the GDPR, a data controller (i.e. the healthcare provider) must provide a copy of the personal data on the patient's request. When such request is filed electronically, this must be provided in a commonly used electronic form (Article 15 GDPR).

Furthermore, the patient also has the right to data portability (Article 20 GDPR). The patient can request to receive their electronic file in a commonly used format, after which the personal data can then be transferred to another data controller. This right only applies, however, to personal data that the patient actively and freely provided and does not entail diagnoses or treatment plans of the healthcare provider. Furthermore, the right to data portability can only be invoked if the processing

is based on the patient's consent or on the performance of a contract between the patient and the health care provider.

Strictly speaking, when processing personal data in relation to the Medical Treatment Contracts Act, this is not solely based on the legal ground of 'performance of a contract'. Data processing activities can also be based on the ground of a legal obligation. According to the EgiZ Code of Conduct (Gedragscode Elektronische Gegevensuitwisseling in de Zorg), both legal grounds can be present. The Dutch Data Protection Authority presumes that the legal ground of 'performance of a contract' applies, since it states on its website that the right to data portability applies to the medical file – albeit partially.

Wgbo

The Wgbo contains specifications to the general right of access under the GDPR. Based on the Wgbo, the patient has the right of access and the right of a copy of its medical records. (Article 456, Book 7 of the Dutch Civil Code).

“The right to access also entails the right of access to logging data.”

Wabvpz: right of access, copy and logging

The rules of the Wabvpz form an addition to the existing rules as laid down in the GDPR and the Wgbo. The obligations under the Wabvpz specifically apply to healthcare providers that process personal data of patients through an electronic exchange system (elektronisch uitwisselingssysteem) or a message system in which messages are sent to a specific recipient. An electronic exchange system is – in short – a system by which records or parts of records can be made electronically available for other healthcare providers. Examples are the National Exchange Point (Landelijk Schakelpunt), access portals and the Edifact-mailbox.

Access to or a copy of the medical record

Based on article 15d Wabvpz, the patient can request for the whole or a part of an electronic copy of the medical record, or access to the information that is made available through an electronic exchange system / the information that is sent to a specific healthcare provider with a designated (or intended) treatment relation. The right to access also entails the right of access to logging data, which will be outlined below.

The request must be processed according to the relevant rules of the GDPR and the Wgbo as outlined above. The Wabvpz adds that the patient records must be provided by electronic means and/or the patient must have the possibility to access the record by electronic means whenever the patient requests so. Healthcare providers are not required by Wabvpz to keep an electronic record of the patient, or to alter the contents or form of the record, which is already regulated by the Wgbo (Article 454, paragraph 1, Book 7 of the Dutch Civil Code). Healthcare providers do have the obligation to provide for an electronic version of a paper record if the patient requests this. When the medical record is (partially) on paper, this means that the paper record must be scanned in order to provide this in electronic form (e.g. on USB drive). If the patient does not wish for electronic access or a copy, the healthcare provider is then free to physically provide for the record.

Access to or a copy of data that is exchanged among healthcare providers

The right of access and of a copy of data exchanged among healthcare providers applies to both push and pull systems. “Pull systems” are used in the situation where a healthcare provider makes patient data available to a

group of healthcare providers that are not known in advance, and with whom a treatment relationship with the patient does not yet exist. “Push systems” are used when personal data is sent to a specific healthcare provider with an existing (or intended) treatment relationship.

If the patient requests access to the medical data that the healthcare provider makes available via an electronic exchange system, the health care provider only needs to provide the information that the healthcare provider has made available himself. The data that another healthcare provider has made available, cannot be provided to the patient on the basis of the Wabvpz.

The Wabvpz does not prescribe how a healthcare provider has to give (electronic) access to the medical record. A healthcare provider has to arrange for this at its own discretion. However, the access must be given in a secure and careful manner and that it is in line with the Resolution on Electronic Data Processing by Healthcare Providers (Besluit elektronische gegevensverwerking door zorgaanbieders). The resolution prescribes that the industry standards NEN 7510 and NEN 7512 must be met. In practice, the standard NEN 7516 also needs to be taken into account when the health care provider communicates via e-mail.

Right to receive logging information

Following article 15e Wabvpz, a patient must receive an overview of logging information at his request. The overview must – depending on the request – contain the following information:

- who made certain information available through the electronic exchange system and on which date (this rule only applies to pull systems); and
- who has accessed or requested certain information of the medical file and on which date.

The healthcare provider is also required to provide logging information about a third party healthcare provider, so that the patient can identify data exchanges. The logging data must be made available by the health care provider in an understandable and readable manner.

Logging access and activities in relation to the medical files has been a requirement apart from the Wabvpz. The Decree on electronic data exchange by healthcare providers determines that this logging must be in line with the standards of NEN 7513.



“They should be able to open the books for the patients.”

In practice

The obligations under the Wabvpz have serious implications on healthcare providers. Although already obliged to keep accurate medical files and to log them, they should be able to open the books for the patients. If a patient requests for electronic access, this must be provided in a secure environment, which means that the healthcare provider must take an extra step in data security.

Possibilities for the providing of a copy are, for example, sending an email with a hyperlink to a secured environment and the providing of data through a Personal Health Environment (“PHE”, *Persoonlijke Gezondheidsomgeving* or PGO). Electronic access can also be facilitated by enabling the patient to watch on the monitor of the healthcare provider.

Stichting MedMij (“MedMij”) is an initiative of the Patiëntenfederatie Nederland (Netherlands Patients Federation) an administrative collaboration between participants in the care sector and the Ministry of Health, Welfare and Sport. MedMij has defined a solid framework for the digital exchange of health data between residents of the Netherlands and the health care providers. PHE’s that comply with the framework will receive the MedMij label. This gives the patients the trust that the exchange of their data meets with stringent security standards and encourages the PHE providers to continuously review and improve their standards.

A few weeks ago, Sylvia Veereschild, project manager at MedMij and chronic patient herself, published an article in the Dutch magazine *ZorgVisie* on her experiences with exercising her access rights under the Wabvpz. Veereschild submitted access requests to 17 different health care providers. In her opinion, the responses to her access requests have been disappointing; only 3 of the healthcare providers were able to provide her personal data in a secure manner. Veereschild looks forward to a more common use of the Personal Health Environment: ‘Once millions of patients are able to review the results of care and can check correctness and amend their data, this can improve both the quality as the efficiency of care’.

Although this is not a broad research, it appeared that most healthcare providers (and their service providers) will need to take an extra step in enabling patients to exercise their rights. We expect more patients to invoke their rights under the Wabvpz, just as the general access rights under the GDPR are more and more invoked vis-à-vis data controllers in general.



About the author

Eva de Vries is a lawyer and partner data protection and privacy at SOLV. Eva handles cases in relation to new technologies, e-privacy, e-commerce and e-health. Eva advises on compliance and assists clients in contact with supervisory authorities, such as the Data Protection Authority.



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