Factsheet

Explanation of the forms given to patients during consultations

A number of organisations and professional associations provide a consent form template for doctors and other therapists (physiotherapists, kinesiologists, osteopaths, etc.) to give to their patients. Alongside these consent form templates, therapists also use their own forms, some of which are based on the templates. All these forms raise a number of data protection issues. The FDPIC wishes to draw the attention of service providers and their professional associations to the requirements of the Data Protection Act (FADP, RS 235.1) and expects them to adapt their forms if necessary.

This document addresses three issues: the essential distinction in terms of data protection between requirements relating to the duty to provide information and those relating to consent (sections 1 and 2), secure data communication (section 3) and the principle of proportionality (section 4).

This document is written primarily with the doctor–patient relationship in mind. In essence, however, the principles set out here also apply to other private therapeutic professions. However, as this document addresses the issue from the perspective of the Data Protection Act, public institutions such as cantonal hospitals, which are subject to cantonal data protection laws, are not directly concerned.

1. Duty to provide information

The duty to provide information is nothing new; it already existed under the former FADP with regard to sensitive data such as health data, as a means of ensuring compliance with the principle of transparency and the fundamental right to self-determination in information matters. With the entry into force of the new FADP, the duty to provide information has been extended to all categories of data.

The information must include all the elements necessary to guarantee the transparency of the processing of the data and enable data subjects to assert their rights. It must be adapted to the situation and must cover at least the data referred to in Article 19 paragraph 2 FADP (the controller's identity and contact details, purpose of processing, recipients or categories of recipients, including processors). If personal data are transmitted abroad, the name of the country in which the recipient is located and, where applicable, details of the guarantees required by Article 16 paragraph 2 of the Data Protection Act must also be provided. Data subjects must be able to see why the data are being collected and understand what the data will be used for. If the information is provided in written form, it must be easy to read and drafted according to the needs of the recipients. On the basis of the information received, the data subject must be able to ascertain what processing is envisaged, in particular in order to be able to exercise their rights (e.g. the right to information (Art. 25 FADP) or the right to object to processing (Art. 30 para. 2 let. b FADP)). The level of detail depends on the type of data collected, the nature and extent of the processing, its foreseeability, the risk of a breach of privacy and the potential seriousness of that breach. Depending on the case, the data controller may have to provide more information, for example on the duration of processing, anonymisation of data, etc.

The duty to provide information is not subject to any formal requirements. Information must be transparent, concise, understandable and easily accessible. This concerns both form and content: Documents that are too long or explanations that are too technical should therefore be avoided.

Information must also be active; when data are collected, the data controller must ensure that the data subject does not have to search for the information but can access it immediately, without having to ask for it. In other words, the doctor must ensure that the patient has a reasonable opportunity to acquaint themselves with the information; however, the doctor does not have to ensure that this actually happens.

Even if the information can be given orally, in order to prove compliance with the duty it may be appropriate to record that the information has been given (in the consultation notes, for example) or to provide the information in writing anyway. In practice, writing the details on a form or providing a specific information sheet are sufficient. One question that comes up regularly is that of the patient's signature on a document of this type (which they sometimes refuse to give), in particular to certify that they have been informed. Here it should be emphasised that this is merely a matter of providing information – as distinct from consent (see section 2 below) – and that the doctor fulfils the duty to provide information even if the patient pays no attention to it. A doctor's compliance with the duty to inform does not therefore depend on the patient's signature, and patients themselves are not under any obligation to certify that they have been informed. To avoid creating unnecessary difficulties, it is preferable not to ask for a signature.

2. Consent

Under the FADP, consent is not a prerequisite for doctors to process their patients' personal data. Data processed when providing a medical service is covered by the healthcare contract. Health professionals are also required by law to process certain types of data, particularly under cantonal public health legislation (e.g. to meet the requirement to keep medical records). In practice, the question of consent arises primarily when it comes to disclosing data (Art. 30 para. 2 let. c FADP): This is particularly the case when data are passed on to a colleague, a billing company, etc. It should also be noted that some disclosures are based directly on the law, without consent being required (e.g. Art. 12 of the Federal Epidemics Act – RS 818.101).

Where consent is required, to be valid it must be given before or at the start of the treatment to which it relates, and must be:

- informed: the data subject must be provided with all the information required to enable them in the circumstances to make a decision in full knowledge of the facts. The data subject must therefore be able to clearly understand what type of data will be processed and for what purpose. This is the only way that they can assess the consequences and risks of the planned data processing in relation to their personal rights and express legally valid consent. They must therefore receive the information referred to in Article 19 of the FADP as a minimum. Depending on the context and the nature of the data processed, it is sometimes necessary to provide additional information so that the data subject is able to assess exactly what they are agreeing to. The information must be objective, comprehensible and as complete as possible. Insofar as is relevant, the information may relate in particular to the data controller; the purposes for which the data is processed; the type and extent of the data processed; the nature of the processing and any risks; the storage period; the categories of recipients; whether the data is disclosed abroad; the consequences of a refusal; and the procedure by which the data subject may withdraw consent or exercise their right of access. Generally speaking, the considerations set out in section 1 also apply here.

- specific: consent must be given for one or more specific processing operations and cover all the purposes of those operations. The patient must be able to understand clearly what the requested consent entails. A declaration of consent to processing in general or without specifying what is being consented to is not permitted. For example, clauses are not valid if they are so broadly worded that they allow the entire medical file or certain elements to be disclosed in advance to third parties (other doctors/therapists, pharmacies, laboratories, etc.) without explaining how this is linked

to specific data processing operations . Similarly, listing a whole series of abstract and hypothetical disclosures is not acceptable .

For example, general consent given in advance for the file to be disclosed to a specialist is not valid. Consent should be requested on a case-by-case basis, when the question arises in practice.

Nor does it seem acceptable to ask the patient to consent in advance to a debt collection procedure being entrusted to a third-party company in the event that they do not pay their bill.

Similarly, a clause specifying that patient data may be used by partner companies to develop their digital solutions would be too abstract and therefore invalid. The purposes and recipients are not sufficiently defined for the patient to fully understand what is at stake, especially as the data processing has no obvious connection with the doctor-patient relationship.

On the other hand, allowing invoices to be issued by a third-party company is in principle conceivable, provided that the patient is informed what data will be sent to this third party (and that the disclosure complies with the principle of proportionality – see section 4 below). However, caution is still required: if, for example, the patient were to be given an unexpected diagnosis of a serious condition and this diagnosis was going to affect the data transmitted for billing, it may be doubtful whether the consent initially given would be sufficient. In short, this type of consent may only be valid for ‘routine’ billing: the key issue is what the patient can imagine at the time of giving consent.

- freely given: the data subject must be able to express their wishes freely (i.e. they are not under threat or duress and have not been misled). They must therefore have a real choice and be able to refuse or withdraw their consent without suffering disproportionate inconvenience. If the person has no real choice but to accept, their consent is not free.

Consent does not require any particular legal form (subject to certain legislation requiring written consent in certain specific areas, e.g. medically assisted reproduction, human genetic analysis or research on human beings in certain cases). As a general rule, consent does not need to be given in writing. However, despite the lack of any legal requirements, documented consent is preferable for evidentiary purposes.

Finally, where consent provides the legal basis for data processing (this is not the case if the processing is required by law, for example), it may be withdrawn at any time and without having to provide a reason. The controller must offer patients simple ways of exercising their right to withdraw consent.

3. Secure electronic data communications

The FDPIC has observed that several forms contain a clause stating that the patient consents to unsecured electronic communications. This can be problematic. As a general rule, when sensitive data as defined in the FADP is sent, a secure communication channel is required. In relation to medical matters, the mere existence of a relationship with a doctor or therapist can already allow conclusions to be drawn about a person's state of health; this is particularly true of communications with medical specialists (an appointment with an oncologist suggests cancer). As a result, even exchanges relating to purely administrative matters (e.g. making appointments) must be considered sensitive and therefore require secure communication (e.g. encrypted).

However, patients may agree to such administrative exchanges by unsecured electronic means provided they have been informed in advance of the risks associated with this method of

communication and have given their consent freely. The patient must have an effective choice (e.g. in the form of a checkbox on the form).

Finally, it should be noted that service providers can be held liable for any failure to comply with their obligation to ensure that adequate data protection and security measures are in place.

For further information on this topic, please refer to the following page: Copies of medical invoices.

4. Principle of proportionality

According to the principle of proportionality, the data controller must limit data processing to what is strictly necessary for the purpose for which it is being carried out. In a doctor-patient relationship, the aim is, in principle, to provide therapeutic care. The principle of proportionality therefore applies as much to the use made of the data as to the data collection itself. In other words, don't collect more data than is needed and don't use the data more intensively than is needed. In the healthcare sector, questionnaires submitted by doctors and therapists sometimes contain questions that go beyond this limit. These forms should therefore be simplified so that they only request data relevant to the doctor-patient relationship.

For example, the systematic collection of data such as maiden name, marital status, nationality, business telephone number, profession and name of employer may not be necessary. This does not mean that these data cannot be collected in certain cases. If in a particular case, the patient's profession is relevant to the consultation, in that it may have a link with the condition (for example, if the patient complains of back pain), it may be requested. It is the systematic collection of certain data that is problematic.

Deciding what data are and are not necessary depends on the particular case. Whatever the case, the doctor must always be able to justify each specific data processing operation. If, as part of the duty to inform, the doctor decides to use data in a particular way, or if they collect specific data, they must be able to justify this decision and explain to the patient why this is required in connection with the treatment or therapy. This applies all the more so when consent is required.