
June 2014

The right information, at the right place and at the right time – proposal for a new Patient Data Act

On 30 April 2014, with the bold heading *The right information at the right place at the right time*, the Ministry of Health and Social Affairs announced its final report on the right information in the health care sector (SOU 2014:23). Since the enactment of the current Patient Data Act ("PDA", Sw. *patientdatalagen*), we have seen an enormous development of the possibilities for information handling as well as the potential risks it may convey. The public awareness has increased significantly which means that patients demand efficient coordination between different players in the health care sector, at the same time as the amount of information which is collected may be perceived as a privacy violation in itself. In the midst of this development, we welcome a comprehensive take on the data protection issues in the health care sector and social services.

The proposal constitutes a new Health Care Data Act (Sw. *hälso- och sjukvårdsdatalag*) and a corresponding Social Services Data Act (Sw. *socialtjänstdatalag*). Some of the provisions from the PDA will be directly transferred to the new Health Care Data Act. The purpose of this article is to summarize the primary changes and news in the new Health Care Data Act.

New concepts mean smoother handling, but uncertainties regarding responsibilities

The PDA and the secrecy legislation applicable to the health care sector, focus on how a health care provider's operation is organized as regards the division of responsibilities and restrictions on the exchange of information. By also taking into consideration the entity responsible for the provision and the financing of the health care, the concept of "principal" is introduced to the health care data act. The concept, which is familiar from the Swedish Health Care Act (*hälso- och sjukvårdslagen*), refers to the municipality or county council responsible for providing health care and may contain one or several health care providers within the principal's geographical area.

According to the proposed bill, the principal must be data controller regarding the treatment of personal data which take place in the principal's operation. The concept of principal is thereby likely to facilitate the practical application of the health care data act since it can often be difficult to distinguish between different health care providers under the same principal. However, the current problems regarding the distinction between different health care providers do not disappear altogether since health care providers may continue to be data controllers parallel with their principal. The fact that the problems have been addressed is very welcomed, but certain problems still remain as regards the health care provider concept and potential new problems concerning the double data controller responsibilities.

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One of the most difficult challenges in all handling of personal data is to enable smooth handling without violating personal privacy. This challenge becomes particularly clear in the healthcare sector, where the personal data which is handled is very sensitive and the personal privacy must be weighed against patient safety and the healthcare providers' need for quick and smooth access to information and personal data handling.

The proposed bill means that the signing requirement is abolished, which is a clear example that the report has taken the health care providers' need for easier information handling into consideration. The proposal will probably be appreciated by the health care sector and from a patient safety point of view it can very well be deemed to have been balanced by the fact that the health care provider still bears full responsibility for the correctness of the health records.

The bill also proposes that patients are deprived of the possibility to block information from other health care providers regarding prescribed medication or warnings about the patient's intolerance or hyper sensitivity. At the same time as the access to such data naturally is critical in order to provide the right care at the right time, it is an infringement of the patient's right to dispose freely of information about him/her. The Swedish Data Inspection Board's expert has taken a very critical stand against the changes which are deemed to constitute a too far-reaching reduction of the patient's privacy, and it is therefore possible that the proposal will be adjusted in this respect.

The proposed bill also contains requirements that health care providers, which are to provide each other with direct access or be part of a system for coordinated record keeping, will carry out a joint risk and vulnerability assessment. The health care providers will thereafter agree on how the information security and the personal data responsibilities are to be divided between the health care providers. To a certain degree, this type of agreement will remove the delineation problems concerning the concept of health care provider, which in turn means that personal data processor agreements can be given the right scope and be entered into between the right players.

It should, however, be mentioned that in practice, the health care providers themselves do not develop the IT systems which are used in the health care sector. When a supplier develops services, the supplier may carry out a risk and vulnerability assessment and decide on how the information security is to be handled. Thus, the requirements regarding a comprehensive view on the risk and vulnerability assessment should still be reflected already at the procurement of IT systems.

Lifting secrecy makes it possible to follow up on private health care providers

Under the current secrecy legislation, it is possible for public health care providers which carry out health care in the same municipality or county council to exchange information regarding patients. The same support to lift the secrecy is not to be found for private health care providers whose activities are financed by public health care providers. This

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means that the public health care provider's possibility of following up the health care which it has financed is limited. Follow-ups are today regulated in so-called health care agreements, but these do not provide support for lifting the secrecy, but only for follow-ups which do not involve any disclosure of secrecy regulated data. This appears to be very unpractical and in reality follow-ups are in many cases carried out in direct conflict with the applicable secrecy legislation.

Therefore, the bill proposes an amendment to the secrecy legislation to the effect that a private health care provider for certain purposes may disclose information regarding patients to the public principal which finances the private health care provider's health care operation. We are of the opinion that the introduction of such a lifting of the secrecy is very positive for the health care sector since it allows private health care providers and public principals to cooperate as regards the care of patients and follow-ups thereof.

Direct access without coordinated record keeping – eagerly awaited but debated

One of the most central changes in order to achieve the motto *the right information at the right place at the right time* deals with the expansion of the possibilities to direct access of patients' personal data. Under the PDA, direct access between health care providers is only permitted through systems for coordinated record keeping, which entails requirements regarding information to the patient and the patient's consent. In practice, this means that it is very complicated to use direct access under the current legislation.

The bill proposes that direct access shall be permitted between health care providers with the same principal. No system for coordinated record keeping (*Sw. system för sammanhållen journalföring*) is required in the proposal and there is no requirement for information to the patient or the patient's consent. According to the proposal, patients will have the possibility of blocking their data for other health care providers, but since the information requirement is abolished it is less likely that a patient will be aware that several health care providers have access to the data.

This is a good example of when the balance between the patient's privacy, patient safety and the health care sector's need for quick and easy exchange of information is brought to a head. The patient's consent is central from a privacy point of view at the same time as the obtainment of consent limits the possibility of an efficient information handling. The Swedish Data Inspection Board's expert has expressed strong criticism of the above mentioned type of direct access since it is deemed to constitute great privacy risks and it is therefore likely that the proposal will be adjusted in this part.

For health care providers which do not have the same principal, the patient data may only be made available through direct access if the rules regarding systems for coordinated record keeping are followed. The requirement to inform the patient that his/her data is part of a system for coordinated record keeping will be transferred from the PDA while the consent requirement is abolished. Also in this part, the Swedish Data Inspection Board has criticized that the lack of consent, despite the maintaining of the information requirement, constitutes a too great a risk for violation of the patient's privacy.

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It should also be noted that the application will be rather difficult in practice for certain private health care providers. A private health care provider which operates in different parts of the country with financing from different principals may have direct access within the own private health care provider, but only the entity which is financed by a certain principal may have direct access to the other health care providers within that principal. In other words, the difficulty lies in drawing the lines of authority right as regards the various types of direct access.

Concluding comments

The proposed bill constitutes an attempt to abolish many of the obstacles regarding information handling and coordination which exist in the current legislation, especially as regards between private and public health care providers where the public health care provider finances the private health care provider's operation. The introduction of the concept of principal, the lifting of secrecy for private health care providers and the new possibilities of direct access for health care providers with the same principal are clear examples of this.

The proposal contains reliefs throughout as regards the requirements put on the health care providers which at the same time result in weaker privacy protection for the patients. The Swedish Data Inspection Board's critical attitude towards certain parts of the proposal will likely result in adjustments in favour of the privacy protection. However, it is clear that the proposal expresses the position that efficient and safe health care may outweigh the privacy concerns in some cases. What the interest balance will lead to in the end is difficult to foresee at this point, but there are many reasons to follow the development in the near future and we will therefore have reason to return to this topic in the time to come.



Henrik Almström,
Associate



Angelica Lundqvist,
Associate