RESPONSE TO THE PERSONAL DATA PROTECTION COMMISSION'S CONSULTATION PAPER ON PROPOSED ADVISORY GUIDELINES FOR THE HEALTHCARE SECTOR

Contact partner: Jeffrey Lim
d: +65 6416 8250
e: jeffrey.lim@wongpartnership.com
WongPartnership LLP
12 Marina Boulevard Level 28
Marina Bay Financial Centre Tower 3
Singapore 018982
www.wongpartnership.com

1. SUMMARY OF MAJOR POINTS

1.1. Thank you for the opportunity to comment on the Consultation Paper on the Proposed Advisory Guidelines for the Healthcare Sector ("**Proposed Healthcare Guidelines**").

1.2. Our comments on the Proposed Healthcare Guidelines are summarised as follows:

(a) The Proposed Healthcare Guidelines mainly consider the applicability of 'deemed consent' to the provision of medical services.

(b) We suggest that the guidelines may need to be clarified in respect of the types of 'teaching purposes' for which personal data may be used, and the consents to be obtained in respect of the same.

(c) We would strongly urge the PDPC to consider the issue of research and the use of personal data for research purposes.

2. DEEMED CONSENT

2.1. The Proposed Healthcare Guidelines discuss the application of 'deemed consent' to various common scenarios faced in the healthcare industry, using a number of examples to illustrate the concept.

2.2. Paragraph 2.3 of the Proposed Healthcare Guidelines states that the deemed consent of the individual may extend to the collection, use and disclosure of their personal data for the purpose of the individual's visit to a clinic and medical care which is provided in relation to the visit. At the same time, this example is very clear on the fact that deemed consent would not cover purposes outside of those for which the personal data was provided.

2.3. As such, if the clinic in question intended to use or disclose the personal data beyond the immediate purpose of the individual's visit and the 'provision of healthcare in relation to that visit', it is less likely to be covered by deemed consent and the clinic should then 'notify [the individual] of such purposes and obtain his consent'.

2.4. Paragraph 2.6 of the Proposed Healthcare Guidelines also states that where there are 'additional purposes' which are not 'reasonably required' to provide the individual with the service of medical care, the healthcare organisation cannot require the individual to consent to their personal data being used for these other purposes as a condition of providing them with the medical care services. For example, where the healthcare organisation intends to use the personal data for 'teaching purposes', then the healthcare organisation should notify the individual of these purposes and obtain consent where the data cannot be anonymised.

2.5. The examples used in the Proposed Healthcare Guidelines generally indicate that 'deemed consent' may be applied in situations where the individual approaches the healthcare organisation for medical services and treatment.

3. CONSENT FOR EDUCATIONAL PURPOSES

3.1. Based on the examples used in the Proposed Healthcare Guidelines, it would seem that 'deemed consent' would not apply in situations falling outside the scope of the provision of medical services and medical treatment.

3.2. In particular, the examples set out in the Proposed Healthcare Guidelines state that where personal data is used for teaching purposes, consent for these purposes should be obtained.

3.3. We note that in Singapore, a number of the healthcare organisations are active teaching hospitals and may run programmes as part of their mandate as teaching hospitals including hosting visiting students on attachments. In the course of these attachments, the personal data of patients may be disclosed to these students.

3.4. On the examples provided, it would appear that the consent of the patients whose personal data is being used by these students would have to be obtained by the healthcare organisations.

3.5. The Proposed Healthcare Guidelines are not clear on the type of consent which is to be obtained from the patients. If it is express specific consent which has to be obtained from every single patient for this type of educational purpose, this may be rather difficult for each healthcare organisation to manage.

3.6. Practically speaking it will be extremely difficult for the hospital to track these consents and arrange a student attachment around the scope of such consents since the manner in which an attachment is conducted may mean that students may be introduced to a number of different patients and files in the course of a single day. It would be extremely prohibitive to have to actively track and limit the patient data which is shown to students based on specific consents obtained.

3.7. Indeed, we note that if the use of personal data for educational purposes are considered purposes for which the consent of the patient cannot be required (on the basis that this would be beyond what is reasonable to provide healthcare services to the patient), then in practical terms:

(a) Academic medicine and the education and qualification of future doctors, nurses or healthcare professionals could well be based on dwindling patient records especially where patients do not opt-in to the use of their personal data for such purposes (here, we should bear in mind that there is a limit to how much anonymisation can be applied before impacting the teaching and pedagogical dependencies on data);

(b) The long established tradition of "on the job" training of students (who are not necessarily employees) such as (what were previously referred to as) housemen may be adversely impacted.

3.8. The guidelines should be further clarified as to the manner and type of 'teaching purposes' for which consent would need to be obtained. In addition, further guidance and elaboration is needed on the type of consent which should be obtained for such teaching purposes.

4. CONSENT FOR RESEARCH

4.1. Various examples in the Proposed Healthcare Guidelines discuss the issue of deemed consent not covering purposes beyond the provision of medical care. For example, paragraph 2.3 of the Proposed Healthcare Guidelines states that if the healthcare organisation intends to market healthcare products to the individual which are unrelated to the individual's condition, the notified consent should be obtained since there is 'no nexus' between this purpose and the medical care being provided, or the individual's initial visit to the healthcare institution.

4.2. A number of healthcare organisations conduct research using patient personal data. In some situations it may not be possible to anonymise the data before it is used, since personal data may be necessary for the meaningful conducting of this research. Indeed, the ability to validate the research results through the personal data records used whether under an independent audit or by granting access to a verification body to the full records to confirm the scientific reliability of any findings may also be a key step before breakthrough treatments / discoveries can be achieved.

4.3. The Proposed Healthcare Guidelines do not cover the issue of research or the use of patient personal data for research. However, to use the language of the Proposed Healthcare Guidelines, to the extent that there is similarly 'no nexus' between the research and the immediate purpose of the patient's visit (i.e. provision of medical care), it would seem that notified consent would have to be obtained.

4.4. The guidelines should be clarified as to the type of consent which is to be obtained in respect of research, and provide examples on how this consent should be obtained from the patients.

4.5. There is a number of exceptions from consent which are specific to the healthcare industry, and one specific exception from consent available under the PDPA which may apply in the research situation, i.e., 'the personal data is used for a research purpose, including historical or statistical research' (Third Schedule, para 1(j), Fourth Schedule, para 1(q) read with Second Schedule, para 1(r)).

4.6. However, in order to fall within this exception from consent, the organisation must meet a number of criteria, including:

(a) The research purpose cannot be reasonably accomplished unless the personal data is provided in an individually identifiable form;

(b) It is impracticable for the organisation to seek the consent of the individual for the use (or disclosure, as the case may be);

(c) The personal data will not be used to contact persons to ask them to participate in the research; and

(d) Linkage of the personal data to other information is not harmful to any individuals identified by the personal data and the benefits to be derived from the linkage are clearly in the public interest.

4.7. It will be very difficult for the healthcare organisation to fall within this exception from consent and to continue their research studies.

4.8. It is often the case that the personal data records which are being used for the research study are historical patient records which have been accumulated over the years. It may not always be clear from the records whether patient consent had been obtained for the use of this personal data for research studies and it may now be very difficult for the organisation to contact these patients again to ask for consent.

4.9. An example of research studies that depend on this type of data include retrospective studies where often researchers reconsider and access the database of personal data that was collected originally for treatment purposes, to identify / investigate patterns or other discoveries that could lead to key steps / improvements to be undertaken. Not all retrospective studies can proceed on the basis of anonymised data, and it may be that anonymised data may increase the risk of errors or invalidate / jeopardise the validity of findings under scientific / empirical standards of accuracy and proof.

4.10. We note that the threshold for the second limb of the research exception is that it must be 'impracticable' for the healthcare organisation to seek the consent of the individual for the use of the personal data. However, the standard of impracticability is not clear and the Proposed Healthcare Guidelines do not provide any examples or discuss this in any detail.

4.11. Indeed, scenarios may arise where the healthcare organisation is in fact not in a position to ascertain for certain whether in fact a situation of impracticability has arisen. Take the following example. Patient A consults a Doctor B to treat an ongoing condition. After a few consultations, a patient record is developed and the personal data is of interest for research. Patient A is scheduled to meet Doctor B again and Doctor B plans to seek his consent for use of Patient A's personal at the next consultation. However, before the next consultation arises, Patient A changes his doctor without informing Doctor B and so, not only misses the next appointment with Doctor B, but in fact ceases to see Doctor B altogether. Doctor B has not been told of Patient A's decision. In that situation (which is not altogether uncommon), Doctor B would be aware that Patient A has missed his appointment, but does not know whether in fact Patient A would return for further consultation in the future where the opportunity to seek consent may arise. We note that though Patient A may indeed one day return to see Doctor B, this could happen in a matter of years, or it may not happen at all. A state of uncertainty has therefore arisen, over whether he may in fact now consider, without evidence / supporting information that it is now impractical to obtain consent? We note in particular, that to come under the research exemption Doctor B would in any case have to refrain from using the patient's personal data to contact Patient A to ask him to participate in the research.

4.12. In order to provide healthcare organisations with greater clarity on the research exception, we would urge the PDPC to provide examples of what would constitute impracticability in the healthcare industry as well as to set out a test to assist in ascertaining the threshold of impracticability.

4.13. We also wish to add that many healthcare institutions have indeed established well developed and robust safeguards in place, quite independently of any requirements under the PDPA, to ensure that weighing and evaluating the ethical aspects and interests of the patient are fully considered in handling research proposals before a determination that the consent of a patient is not required. These safeguards can include / take the form of submitting research proposals to an experienced panel / committee that scrutinises proposals for research, and which take into account the welfare of the individuals as a key consideration in their

evaluation when considering whether a waiver of consent by the data subject can be granted to allow a research project to proceed.

5. RETENTION OF MEDICAL RECORDS – PATIENT HEALTH RECORDS

5.1. We note that the PDPC has stated at paragraph 4.3 of the Proposed Healthcare Guidelines that, "Generally speaking, retaining personal data of existing patients for the purpose of having access to their consultation history would be considered a valid business purpose."

5.2. There is a clear interest for a doctor to have as complete a medical record as possible since in establishing an appropriate diagnosis the full patient history may aid in the provision of safer / appropriate treatment or assist in preventative measures. So, to illustrate, it is for this reason that it is not uncommon for doctors seeing a patient for the first time to provide previous medical records for a particular condition, if any. A patient may, for this reason, be better served if he can contact previous / other doctors to retrieve case files, sometimes reaching back over long periods of time.

5.3. We also note that paragraph 4.4 of the Proposed Healthcare Guidelines reiterates the general position that an organisation should not keep records in perpetuity or "just in case". However, given the earlier stated need for as complete a record as possible in the case of patient health data, and given that it is not uncommon for a doctor to not see a patient for a significant period of time (including time spans of up to years from last consultation), it may indeed be desirable to retain health records "just in case" a future consultation may occur (e.g. where the earlier information would be valuable case history to a healthcare provider). Again, it may not be clear to the healthcare practitioner (to repeat the example given earlier in paragraph **Error! Reference source not found.** of this submission), that a situation has arisen where the next consultation with a patient may not happen.

5.4. We would therefore urge the PDPC to consider the importance (and potentially life-saving value) of being able to access a full medical history and that, for such reasons, a legitimate purpose for retention of such records could well be for the contingency ("just in case" if you will) of supporting a future consultation (whether by the patient with the same doctor, or on request by another doctor in future / subsequent treatment sessions many years after the records were created). We note here that, patient health data is, in this respect a specialised category of personal data for which the argument for retention is in fact in the interests of he data subject (e.g. for providing an accurate diagnosis, be able to take life-saving measures, improving well-being of the patient).

6. CONCLUSION

6.1. The implementation of the PDPA is still in its nascent stage and it will take healthcare organisations some time to adjust and adapt their practices. It is also necessary to ensure that in doing so, they are not unduly hampered or restricted in carrying on practices and research which would be considered beneficial to their patients and to the healthcare industry in general. The competitive edge, operational efficiencies, and well being of individuals in healthcare operations often relies on ensuring accessibility to complete and accurate personal data and this is a factor that directly impacts the quality of medical care in healthcare institutions.

6.2. It may be extremely difficult for healthcare organisations to continue with these beneficial practices without further clarity and guidance from the PDPC. It would be beneficial for certainty (and key for the continued development and maintenance of Singapore's position as a leading healthcare hub) that the PDPC take these issues above into consideration. We would therefore urge the PDPC to actively expand the Proposed Healthcare Guidelines in view of the issues raised.

WongPartnership LLP
5 June 2014