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By Fax (2537 7319)  
12 May 2014

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Dear Ms LEE,

### Electronic Health Record Sharing System Bill

To assist our scrutiny of the Electronic Health Record Sharing System Bill, we should be grateful for your clarifications on the legal and drafting issues set out at **Annex I**. Our comments on the Chinese text of the Bill are set out at **Annex II**. Please send us your reply in both languages as soon as possible.

Yours sincerely,

  
(Miss Carrie WONG)  
Assistant Legal Adviser

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**Comments on the legal and drafting issues on  
Electronic Health Record Sharing System Bill**

Clause 1 (Short title and commencement)

1. Please advise the expected commencement date of the Bill to be enacted.

Clause 2 (Interpretation)

2. "**Consent**", in relation to an individual, is defined in clause 2(1) as an express consent of the individual. According to paragraph 4.4 of the consultation document entitled "eHealth Record (eHR), Continuity of Care for You" of December 2011 (Consultation Document), only patients who choose to participate on express and informed consent will have their health data shared through the eHR Sharing System. Please advise how the Commissioner will ensure that the joining and/or sharing consent given by the participating patients is informed consent, particularly when not all patients are literate and visually-abled, and whether the element of "informed" is reflected in the definition of "consent".
3. "**Health data**", in relation to a healthcare recipient, is defined in clause 2(1) as the data or information relating to the health condition of, or to the healthcare provided or to be provided to, the recipient. There is no definition of "data" or "information" under the Bill, but "**data**" is defined in section 2(1) of the Personal Data (Privacy) Ordinance (Cap. 486) (Privacy Ordinance) as any representation of information (including an expression of opinion) in any document, and includes a personal identifier, and such definition is to be read together with the Bill to be enacted if the data in question falls within the ambit of the Privacy Ordinance. As Part 4 of the Bill applies to data or information that is personal data as defined by section 2(1) of Privacy Ordinance, please clarify the difference between "data" and "information", and consider whether there is any need to provide definitions for "data" and "information", under the Bill.

4. "**Healthcare recipient**" is defined in clause 2(1) as, among others, an individual for whom healthcare has been performed. Its Chinese rendition (醫護接受者) is however given in the perspective of the person receiving healthcare (i.e. 曾經接受醫護服務的個人). It is also noted that "recipient" and "performed" bearing different meanings in the English text are both rendered as "接受" in the Chinese text. Could the drafting of the bilingual texts be reviewed?
5. "**Index data**", in relation to a healthcare recipient, is defined in clause 2(1) as the personal particulars of the recipient that identify the recipient for the operation of the eHR Sharing System. Please explain the meaning of "personal particulars", and clarify the differences between "personal particulars", "data" and "information", under the Bill?
6. "**Sharable data**" is defined in clause 2(1) as the index data and the health data of the healthcare recipient. It is mentioned in the Report on Public Consultation on the Legal, Privacy and Security Framework for eHR Sharing of June 2012 (Consultation Report) that there are divergent views on the issue of allowing additional access control or exclusion of particular data from eHR sharable scope in other countries where eHR sharing systems are being implemented<sup>1</sup>. It is proposed in the Consultation document that –
  - (a) there should not be safe deposit box<sup>2</sup> in the eHR Sharing System<sup>3</sup>; and
  - (b) participating healthcare providers will be required to make available health data in their electronic medical/patient record

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<sup>1</sup> Please see paragraph 14 of the Consultation Report.

<sup>2</sup> Safe deposit box is an electronic data feature which allows the separate storage of certain patient data with enhanced access control. In the context of eHR, this would mean allowing patients to prevent some categories of eHR sharable data from being automatically viewable by healthcare providers even with the general consent of the patients. Normally, the existence of such box would be indicated by a flag. Healthcare providers would need special consent for opening the box.

<sup>3</sup> Please see paragraph 4.30 of the Consultation document.

(eMR/ePR) systems<sup>4</sup> falling within the eHR sharable scope for uploading to the eHR Sharing System, and no exclusion would be allowed<sup>5</sup>.

Please clarify whether the scope of data and information to be collected for the eHR Sharing System complies with the data protection principle 1 in Schedule 1 to the Privacy Ordinance, and whether healthcare recipients have any discretion to decide on the scope of data to be covered in their eHR (say psychiatric history, etc. to be excluded from the sharable data).

7. The definition of "**registration**" includes the provision that "**registered**" is to be construed accordingly. "登記" is adopted for the Chinese rendition of (i) "registration", (ii) "registered" used as an adjective, and (iii) "registered" when used as past tense. By virtue of section 5 of the Interpretation and General Clauses Ordinance (Cap. 1), the definition of "**registration**" extends to "registered" and "registering" being its cognate expressions. Is it necessary to provide that "**registered** (登記) is to be construed accordingly"? Similarly, is it necessary to provide in the Chinese text of the definition of "registration" that "登記 (registered) 作為形容詞使用時，亦須據此解釋"?
8. "Use", in relation to data or information contained in an eHR, is defined in clause 2(1) to include disclose or transfer the data or information. Part 3 deals with "Use of eHR". It is noted that the proposed uses include (i) use for improvement of healthcare, (ii) use for research and statistics, (iii) use for disease control and surveillance etc., and (iv) use as permitted by, or under, any other law.<sup>6</sup>
  - (a) Clause 29 provides that the data and information contained in an eHR may be used as permitted by, or under, any other law.

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<sup>4</sup> eMR/ePR systems are information systems deployed by individual healthcare providers for storing their patients' medical records for their own healthcare purposes. Such systems do not automatically or necessarily provide sharing capabilities. Sharing of eHR by such systems will require compliance with set standards and protocols for sharing and connection to a sharing platform based on such standards and protocol for interconnecting other eMR/ePR systems similarly equipped.

<sup>5</sup> Please see paragraph 4.31 of the Consultation document.

<sup>6</sup> Please see clauses 26 to 29 of the Bill.

Please clarify what is meant by the "as permitted by, or under, any other law". Would there be any use for a new purpose in the proposed use of data or information contained in the eHR Sharing System? If so, is it necessary to build in the element of "prescribed consent" (i.e. express consent to be given voluntarily), as "prescribed consent" is required from the data subject for use of personal data for a new purpose.

- (b) Under clause 5(1)(b), the Commissioner must establish and maintain an information infrastructure for keeping certain specified records, and sharing and using data and information contained in those records. Please clarify what is meant by "sharing" of data and information, and the extent to which it is different from "using" of data and information. It appears that the "use" of data and information as defined in clause 2(1) (i.e. including disclosure or transfer of data and information) is wide enough to cover the "sharing" of data and information as envisaged in clause 5(1)(b). If so, please consider deleting all references to "sharing" of data and information in the Bill.

Clause 3 (Substitute decision maker)

9. In view of paragraph 10.3.12 of "A Guide to Styles & Practices" published by the Department of Justice in 2012, is the use of "For the purposes of this Ordinance" in clause 3(1) too general and uninformative. Please consider deleting it from the text.

Clause 7 (Giving of joining consent)

10. The meaning of "有關同意，是指醫護接受者同意" in clause 7(3) appears to be missing in its corresponding English text.

Clause 8 (Registration of healthcare recipients by Commissioner)

11. "However" is used to start a new sentence in clause 8(2). Is the use of "however" to begin a sentence in the clause necessary? Is this a new drafting style? The same comment also applies to clauses 18(3) and 27(2).

Clause 9 to 11 (Withdrawal/suspension/cancellation of healthcare recipient's registration)

12. Will there be different retention periods for the eHR of withdrawn/suspended/cancelled patients to comply with section 26(1) of, and the data protection principle 2(2) in Schedule 1 to, the Privacy Ordinance?

Clause 21 (Withdrawal of healthcare provider's registration)

13. Clause 21(4) of the Bill provides that if a sharing consent is given to the healthcare provider, the sharing consent ceases to have effect once the withdrawal takes effect (i.e. at a specific point of time). The relevant Chinese rendition is "在有關退出生效之時起失效". Clause 9(7) provides that the withdrawal of healthcare recipient's registration takes effect on a certain date, (i.e. not at a specific time). Similarly, clause 23(3) provides that the sharing consent ceases to have effect once the cancellation takes effect (在有關取消生效之時起失效) but clause 11(3) provides that the cancellation of a health recipient's registration on the ground of death takes effect on the date on which the Commissioner is satisfied that the healthcare recipient has died (在該日生效). Please clarify the policy intent as to whether the withdrawal or cancellation should take effect on a date or at a specified time.

Clauses 30 and 33 (Application to Secretary/Commissioner for use for research or statistics purpose)

14. It is noted that applications for using identifiable data and non-identifiable data of a healthcare recipient contained in an eHR for research or statistics purpose made under clauses 30 and 33 are to be made to the Secretary and the Commissioner respectively. It appears from clause 55 on right of appeal that a person who is aggrieved by such decisions cannot appeal to the Administrative Appeals Board. Please clarify whether there is any appeal/review mechanism for the decisions of these unsuccessful applications.

Clause 31 (Recommendation by Board)

15. The Board may make recommendations on the conditions of the approval of an application made under clause 30. Please give examples of the conditions that may be imposed on the applicants.

Clause 35 (Prescribed healthcare provider's duties on eMR system)

16. Under clause 35, a healthcare provider is required to take reasonable steps to ensure that the provider's eMR system does not impair the security or compromise the integrity of the eHR Sharing System. Please advise what is meant by "reasonable steps"?
17. Would the participating healthcare provider be required to keep a logbook for recording the details of every access made to the eHR Sharing System for privacy and security protection?

Clause 38 (Access to and correction of data or information)

18. It is mentioned in paragraph 4.40 of the Consultation Document that besides data access requests, other tools (such as patient portal) are planned to be commissioned in the second stage of the eHR Programme to allow patients to access their own eHR more conveniently. Does the plan still hold true? If so, please explain what is meant by "patient portal" and the anticipated implementation date.

Clause 46 (Offences relating to direct marketing)

19. Clause 46(8)(b) provides, among others, that the purpose is the offering, or the advertising of the availability, of healthcare services provided or administered by the Department of Health or the Hospital Authority. "**Healthcare**" is defined in clause 2(1) as an activity performed in Hong Kong by a professional for the individual for certain specified purposes. Its Chinese rendition (醫護服務) includes the meaning of "services". Please clarify whether the defined meaning of "healthcare" has already covered "healthcare services". If so, please consider expanding the definition of "healthcare" in clause 2(1) to include an activity or a service. The same comment also applies to the rendition of "social or healthcare services" in clause 46(8)(c) as "社會或醫護服務". If "healthcare"

includes the element of "services", please consider amending the English text to "social services or healthcare".

Clause 51 (Commissioner to issue code of practice)

20. The Commissioner may issue a code of practice under clause 51(1). Please clarify –

- (a) whether there are any consultation requirements (whether legal or administrative) to be fulfilled before the issuance or amendment of the code of practice; and if so, please specify the persons who are likely to be consulted before its issuance or amendments;
- (b) whether a person's failure to observe any provision of the code of conduct will render him liable for any civil or criminal proceedings;
- (c) the admissibility of the code of practice in evidence;
- (d) whether the code of practice, including its amendments or revocation, are to be published in the Gazette;
- (e) the reasons why the code of practice is not subsidiary legislation;
- (f) the expected date for the issuance of the code of practice;
- (g) whether a draft code of practice has been prepared; if so, please provide a copy of the same for the Bills Committee's consideration; and
- (h) whether the Commissioner may issue guidelines, best practices etc.

Clause 47 (Appointment of Commissioner)

21. Please consider whether the Bill needs further provisions on the following matters –

- (a) What is the term of office of the Commissioner? Is the Commissioner's term of office renewable? If so, for how long, and renewable for how many times?



- (b) Can the Commissioner hold any office of profit other than his office as Commissioner or engage in any occupation for reward outside the functions of his office?
- (c) What if the person appointed to be the Commissioner dies, resigns, is removed from office, is absent from Hong Kong, is for any other reason unable to perform functions of his office?

Clause 48 (Functions and powers of Commissioner)

22. Under clause 35, a prescribed healthcare provider must take reasonable steps to ensure that the provider's eMR system does not impair the security or compromise the integrity of the eHR Sharing System. Since the eHR Sharing System would be accessible by different participating healthcare providers, it is important to check against unauthorized access and authentication of healthcare providers. Please consider whether the Bill needs further provisions on the following matters –

- (a) Does the Commissioner need the power to inspect the systems holding eMR of the healthcare providers, and investigate, on possible contravention of the requirements of the Bill to be enacted? If so, does he need the power of entry and search on premises for an inspection or investigation? Would the suspected healthcare provider be informed of the result of such inspection or investigation? If so, how?
- (b) Does the Commissioner need the power to collect evidence on contravention of the Bill to be enacted?
- (c) Can the Commissioner charge fees for any promotional activities in the course of performance of his functions?
- (d) Can the Commissioner employ staff and determine their terms of service?
- (e) Can the Commissioner's functions or powers be delegated to any prescribed officers?

Clause 52 (Commissioner to specify forms)

23. What is it that the Commissioner seeks to specify – the form or the format? It appears from the Chinese rendition of "form" in clause 52(1) that the format (格式) is to be specified, but the Chinese rendition of "form" (格式的表格) in clause 52(3) seems to suggest that the format of the form is to be specified.
24. Does the specified form need to be published in the Gazette? How will it be made available to the public for use? If a draft specified form has been prepared, please provide a copy of the same for the Bills Committee's consideration.

Clause 53 (Establishment of Board)

25. Is the expression "and 電子健康紀錄研究委員會" strictly necessary in clause 53(1) of the English text? Is the expression "，而英文名稱為 "Electronic Health Record Research Board"" strictly necessary in clause 53(1) of the Chinese text?
26. The Board is to consist of (i) the Permanent Secretary for Food and Health (Health) as ex officio member and chairman, (ii) the Commissioner, or a person nominated by the Commissioner as representative, as ex officio member, and (iii) not more than ten other members appointed by the Secretary. Please consider whether the Bill needs further provisions on the following matters –
  - (a) the intended composition of those other members, and the criteria for appointment of such members;
  - (b) whether public officers can be appointed as members; and if so, whether there is any limit on the maximum number of public officers that can be appointed; and
  - (c) whether a replacement has to be filled for a vacancy or during a member's temporary absence or incapacity.

**Comments on the Chinese text on  
Electronic Health Record Sharing System Bill**

Clause 2 (Interpretation)

1. "**Immediate family member**" is rendered as "家人" in clause 2(1). The meaning of "immediate" is not reflected in the Chinese rendition.

Clause 3 (Substitute decision maker)

2. Under clause 3(2), "appointed by the court" is rendered as "獲法庭委任". Please consider whether "法庭" should be replaced by "法院" as in section 8F(1) of the Guardianship of Minors Ordinance (Cap. 13). The same comment applies to the rendition of "法庭" for "court" in clause 3(4)(e) in a similar context.

Clause 9 (Withdrawal of healthcare recipient's registration)

3. "Withdrawal of ... registration" in clause 9 does not tally with its rendition of "...退出互通系統". Also, the meaning of "registration" in clause 9(1) of the Bill is missing in the corresponding Chinese text. The same comment also applies to clauses 13(2)(a), 14(8)(a) and 21(1) in a similar context.

Clause 25 (General Rule)

4. Please clarify why "may not be used" is rendered as "不得使用", rather than "不可使用" as in Rule 99R of the Bankruptcy Rules (Cap. 6A).

Clause 27 (Use for research and statistics)

5. "**Identifiable data**" is rendered in clause 2(1) of the Bill as "可識辨身分資料". "Must not be made available in a form that would enable a healthcare recipient to be identified" in clause 27(2) is rendered as "不得以能識辨醫護接受者的身分的形式提供". Please review the bilingual drafting of these clauses to achieve consistency.

Clause 26 (Use for improvement of healthcare)

6. "Use" (使用) is defined in clause 2(1). It is noted that "used for" is rendered as "用於" rather than "使用於" in clause 26, and such rendition does not trigger the reader to refer to the Interpretation clause for its definition. The same comment also applies to the rendition of "used for" for "用於" in clauses 27(1), 28(1) and 29.

Clause 43 (Offences relating to data access requests and data correction requests)

7. "Falsifies" is rendered as "捏改" in clause 43. Please consider amending it to "捏改".

Clause 59 (Service of notice etc.)

8. It appears that the meaning of the expression "it is addressed to" or "addressed to" (註明...為收件人) in clause 59(a)(i), (ii), (iii) and (iv), clause 59(b)(i), (ii) and (iii), and clause 59(c)(i) and (ii), and clause 59(d)(i) and (ii) is missing in the corresponding Chinese text.