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Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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Dear Miss Wong,

Electronic Health Record Sharing System Bill

Thank you for your letter dated 12 May 2014. Our responses to the legal and drafting issues and those to the comments on the Chinese text are set out in Annexes I and II respectively.

Yours sincerely,

(Ida Lee)

for Secretary for Food and Health

c.c. Clerk to Bills Committee
Department of Justice

(Ms Maisie Lam)
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**The Administration's response to
the legal and drafting issues on
Electronic Health Record Sharing System Bill
(Annex I of Letter from Assistant Legal Advisor
of the Legislative Council dated 12 May 2014)**

Clause 1 (Short title and commencement)

1. Subject to the passage of the Bill within this legislative session, we will launch the Electronic Health Record Sharing System (eHRSS) by the end of 2014 the earliest. To allow time for the preparatory work and the enrollment of healthcare recipients and healthcare providers, we aim to commence operation of the Bill as soon as practicable in Q3 of 2014.

Clause 2 (Interpretation)

2. As set out in the Consultation Document, a healthcare recipient's participation in Electronic Health Record (eHR) sharing should be based on "express and informed" consent. The word "informed" implies that there should be a process of providing information to healthcare recipients before they decide to give the consent.

To ensure that a consent is "informed", we would set out clearly in an "Patient Information Notice" (PIN) for participating healthcare recipients the essential information about the conditions of joining eHR sharing.

To cater for the special requirements of the minority groups and visually impaired, eHRC will provide interpretation services upon request to help them understand the terms and conditions of PIN for participation in eHR sharing on need basis. The PIN and relevant information about participation in eHRSS will be made available in the eHRSS website. The eHRSS website will be in conformance to Level AA of the W3C Web Content Accessibility Guidelines 2.0, which will make the Web more accessible to users with disabilities.

As confirmed with the Department of Justice, the element of "informed" is reflected in the definition of "consent". The

requirement of giving of a consent in the Bill implies the giving of a “valid” consent. For a consent to be valid, it must be given voluntarily and on an informed basis.

3. We consider that the ordinary meaning of the two terms should be adopted. In general, “data” is raw, unorganized facts that need to be processed. When data is processed, organised, structured or presented in a given context so as to make it useful, it is called “information”. The Personal Data (Privacy) Ordinance (Cap. 486) (Privacy Ordinance) applies so long as the data or information in question falls within the meaning of “personal data” under the Privacy Ordinance.
4. We take the view that “an individual for whom healthcare is performed” and “接受醫護服務的個人” (an individual who receives healthcare) both reflect the same fact but from different angles only i.e. the giving and receiving ends. If healthcare is “performed” for an individual, it necessitates the fact that the individual “receives” the healthcare performed, otherwise there is arguably no healthcare performed.

Since the Chinese text is not a translation of the English text (and vice versa), we would render the Chinese text according to its own linguistic characteristics or usage. We consider that the existing Chinese text of the definition of “醫護接受者” is appropriate.

5. “Personal particulars”, in the context of eHR, refer to the name, identification document number, and gender, etc. that identify the recipient. The particulars may exist in the form of data or information relating to the recipient.
6. The scope of data to be included in the eHR for sharing is determined based on HA’s professional advice and experience and in consultation with relevant stakeholders. Data within the pre-defined scope is the important ones for the healthcare recipient’s treatment. We consider that the scope of data and information to be

collected under the eHRSS is not excessive and the means of collection are lawful and fair.

The Privacy Commissioner for Personal Data has been consulted in the course of drafting the Bill and has not raised any concern on the compliance of data protection principle 1 of the Privacy Ordinance regarding the scope of the data and information to be collected under the eHRSS.

We have also been conducting Privacy Impact Assessments (PIA) for eHRSS to ensure compliance with the Privacy Ordinance and any privacy issues relating to the eHRSS would be addressed. The findings of the PIA on the System Analysis and Design of the eHRSS confirmed that the scope of data and information collected under the eHRSS is adequate but not excessive (with reference to data protection principles in Schedule 1 of the Privacy Ordinance).

As explained at the meeting of the Panel on Health Services on 11 June 2012 (vide LC Paper No. CB(2)2279/11-12(05)), diverse views have been received on the “safe deposit box” feature. There is no “safe deposit” box feature incorporated in the Stage 1 eHRSS. The current design of eHRSS provides sufficient flexibility for healthcare recipients to choose to grant sharing consent only to particular healthcare providers whom they trust and whose records they would like to share in the eHRSS. The issue regarding whether to provide “safe deposit box” for patients will be further studied in Stage 2 of eHRSS.

7. Section 5 of Cap. 1 indeed has the effect of extending a defined expression to include its cognate expressions, but section 5 does not forbid a defined term in an Ordinance to set out explicitly its cognate expressions for clarity sake. Each case has to be decided on its own merits.

In the eHRSS Bill, the Chinese rendition for both “registration” and “registered” is the same term “登記”. We consider it clearer to set out the specific cognate expression in the definition itself instead of simply relying on section 5 of Cap. 1. A recent example for setting out the cognate expression of a defined term can also be found in the

definition of “repeal” in section 1 of Part 1 of Schedule 11 to Cap. 622.

8(a). Data protection principle 3 of the Privacy Ordinance stipulates that “prescribed consent” is required for use for a new purpose (i.e. different from the collection purposes). In the context of eHRSS, the use of the data and information contained in an eHR is clearly set out in Division 1 of Part 3 of the Bill. The purpose of collecting the personal data of healthcare recipients would also be clearly set out in the Information Notice for participating healthcare recipients. Healthcare recipients would be informed that their personal data may be used for (i) Primary Use (for enhancing continuity of healthcare), (ii) Secondary Use (research and statistics, disease surveillance, etc.) and (iii) other uses permitted by the law (e.g. Court proceedings, criminal investigation, etc.). Pursuant to section 3 of the Interpretation and General Clauses Ordinance (Cap. 1), “law” means “any law for the time being in force in, having legislative effect in, extending to, or applicable in, Hong Kong”. Therefore the phrase “as permitted by or under any other law” would be construed accordingly. As law is evolving over time, it is possible that the data and information in the eHRSS may be used for a new purpose. In general we do not envisage a need to use the personal data for a “new” purpose which is not already covered by the mentioned three types of uses.

8(b). “Sharing” of data and information is a key concept in the whole eHR Sharing System. It is important to explain this feature in the provision that provides for the establishment of the system. Although the meaning of “use” may be argued to be wider and include “sharing”, it is undesirable to delete the current references of “sharing” in the Bill or replace it by “use”.

Clause 3 (Substitute decision maker)

9. According to Chapter 10.3 of the Guide, there are words and expressions to be used with caution, and “for the purposes of ...” is

one of the examples cited. We do cautiously consider in each case whether the expression should be used.

In clause 3(1), we take the view that the expression “for the purposes of this Ordinance” serves to set the premises for interpreting the meaning of a substitute decision maker. It is appropriate to keep the expression there. For reference, some recent examples of the use of “for the purposes of this Ordinance” can be found in section 52 of Cap. 612, section 105 of Cap. 618, section 4 of Cap. 620, section 8 of Cap. 621 and section 4 of Cap. 622.

Clause 7 (Giving of joining consent)

10. In the English text of clause 7(3), the meaning of “the consent” is clear as it flows from the contents of the preceding subclauses (1) and (2). Reading the provisions in context we do not consider anything missing and therefore no amendment is necessary.

Clause 8 (Registration of healthcare recipients by Commissioner)

11. The use of “However” as a conjunction to start a new sentence is not a new practice. Examples of similar usage can be found in section 3(2) of Cap. 475 and section 33A(3) of Cap. 485, tracing back at least up to 1997. The expression is more frequently used in plain language drafting to improve readability of the provisions.

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

12. We are in the course of preparing a data retention policy to set out the retention periods for different types of data / information kept inside the eHRSS under different scenarios, with reference to relevant legal and administrative requirements. This policy would be considered in phase 3 of the Privacy Impact Assessment which is being conducted to ensure that it complies with the data protection principles as set out in the Privacy Ordinance.

Clause 21 (Withdrawal of healthcare provider's registration)

13. Clause 9(7) specifies that “the withdrawal takes effect on that date”. In actual practice, the effects of the withdrawal (e.g. ending of sharing consent) would take effect at a specific point of time, to be determined in accordance with the technical design of the eHRSS and after administrative procedures has been completed as soon as possible. As such, we do not consider it necessary to amend the original wording.

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

14. Compared to registrations as healthcare recipients or healthcare providers, using the data contained in an eHR for research or statistics purpose is less of a fundamental “right” per se, and should be subject to Secretary for Food and Health / the Commissioner’s discretion. A research proposal meeting the basic requirements/qualifications to submit would not and should not guarantee approval. Approval or not of a particular application for use of eHR for research and statistics depends on a number of factors, including but not limiting to the merits of each individual proposal. The eHR Research Board established under clause 53 is in the best position to determine the merits and public interest of applications on a case-by-case basis. For unsuccessful applications, the Secretary or eHRC, as the case may be, will have to notify the applicants of the reasons for the refusal. Taking into account the reasons of refusal, the relevant applicants can always resubmit their applications for consideration. Nevertheless, a person who is aggrieved by the procedural aspect of decisions of the Secretary / the Commissioner may lodge complaints to the Ombudsman.

Clause 31 (Recommendation by Board)

15. Conditions may include authorized use(s), authorized user(s), duty to protect the data, duty to dispose data after use and duty to ensure anonymity of any result or report of research and statistics to be published.

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

16. Healthcare providers are required to observe and follow the Codes of Practice and security guidelines published by the eHR Commissioner. Examples of security best practices and controls to follow for the protection of the eMR system ends of healthcare providers include physical control, access control, remote access control and virus protection. The eHR Commissioner will also monitor the security compliance of eMR systems by means of healthcare providers' security assessments during their first registration to the eHRSS and subsequent periodic assessment.
17. To protect patients' personal data privacy, eHRSS will have access logging for every access to patients' eHR. Healthcare providers are not required to keep a logbook for similar purpose.

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

18. During Stage 1 of the eHR Programme, the eHR sharing platform would only be used by healthcare providers (mainly hospitals or clinics) to access health records for the purpose of delivering more efficient and better quality healthcare.

We consider it necessary to strike a balance between the convenience of healthcare recipients' access and the security of data in developing the eHRSS. There were also concerns about misinterpretation of data by healthcare recipients in the absence of proper medical advice or counseling. We would need to carefully examine the merits and risks of developing the patient portal (there is no "standard" design of "patient portal" but broadly speaking, a patient portal may include functions to allows healthcare recipients to review or update their own information), its functionalities and information to be provided, and the case for providing more channels of access in the Stage 2 of the eHR Programme.

For the time being, healthcare recipient who would like to access the record kept by the concerned healthcare provider can make a Data Access Request (查閱資料要求) under the Privacy Ordinance.

Clause 46 (Offences relating to direct marketing)

19. As far as clause 46(8)(b) and (c) of the Bill is concerned, our intention is to align the wording with sections 35B(b),(c), 35I(b) and (c) of the Privacy Ordinance. It is noted that in above-mentioned sections of the Privacy Ordinance, “health care services” is used. For better alignment with the Privacy Ordinance, we propose to amend “healthcare” in clause 46(8)(b) and (c) of the English text of the Bill to “health care”.

Clause 51 (Commissioner to issue code of practice)

- 20(a). The code of practice (CoP) under clause 51(1) is an administrative instrument for providing guidelines on best practices relating to the use of eHRSS. It is of technical nature and in essence an operation manual. It will help users to better understand the working of the system and how to perform certain functions, e.g. procedures to handle application for registration. While there are no legal requirements to conduct consultation before issuing or amending the CoP, we will consult relevant stakeholders on sections to which their inputs will be useful.
- 20(b). Breach of any provision in the CoP in itself will not directly impose on the person any civil or criminal liability. Following the guidelines in the CoP will help minimise the risk of breaching the future eHRSS Ordinance.
- 20(c). Subject to the usual evidential rules, the CoP, like any other public document, is admissible in legal proceedings.
- 20(d). As the CoP is administrative and operational in nature, it will not be published in the Gazette. We will make the content known to healthcare providers via other means such as providing electronic or hard copies.

- 20(e). As aforementioned, the CoP is in nature an administrative and operation manual of best practices.
- 20(f). Subject to the passage of the Bill within this legislative session, we aim to commence operation of eHRSS by the end of 2014 the earliest. The CoP will be issued before the commencement of the new system.
- 20(g). The draft CoP is under preparation. We may later provide a note setting out the framework and key features of the CoP to the Bills Committee for reference.
- 20(h). Yes. Depending on operational needs, the Commissioner may issue guidelines and best practices relating to, e.g. new IT system security guidelines or revised administrative procedures to follow etc.

Clause 47 (Appointment of Commissioner)

- 21(a). The Commissioner will be a public officer appointed by the Secretary for Food and Health (SFH).

Section 42 of the Interpretation and General Clauses Ordinance, Cap.1 states that where any Ordinance confers a power or imposes a duty upon any person to make any appointment, then the person having such power or duty shall also have the general power to remove, suspend, dismiss or revoke the appointment of, and to re-appoint or reinstate, any person appointed in exercise of such power or duty; and to specify the period for which any person appointed in exercise of such power or duty shall hold such appointment.

By virtue of the above provision, SFH has sufficient power to exercise his control on the office of the Commissioner.

- 21(b). The Commissioner, being a public officer, would be subject to the usual regulations in the Government regarding whether a public officer can take up outside employment, whether paid or unpaid.
- 21(c). Section 39(2) of the Interpretation and General Clauses Ordinance (Cap. 1) provides that where any Ordinance confers any power or imposes any duty on the holder of any public office as such, then the

power may be exercised and the duty shall be performed by the holder for the time being of that public office. SFH may appoint a public officer to be the Commissioner. Section 54 of Cap. 1 provides that any reference to a public officer shall include a reference to any person for the time being discharging the functions of that office and any person appointed to act in or perform the duties of such office for the time being. If a “person” dies, resigns, is removed from office, absent from Hong Kong or is for other reasons unable to perform the functions, whoever is holding that public office (e.g. by acting appointment) would assume the power / duty.

Clause 48 (Functions and powers of Commissioner)

22(a). The Commissioner supervises connections of the eMRs of healthcare providers to the eHRSS. Individual healthcare providers’ own eMRs may be used by them for other internal operational and business purposes which are outside the purview of the Commissioner. Under circumstances as specified under clause 51(2), the Commissioner may require healthcare providers to produce record or document to facilitate investigation. We do not envisage the need to include a clause in the Bill for the Commissioner to physically inspect the eMRs of the healthcare providers.

The Bill stipulates certain offences that carry criminal sanction (clauses 41-46 refer). The Commissioner does not have the law enforcement expertise for conducting inspections and investigations in relation to such serious offenses (e.g. entry and search of premises). For suspected criminal offences under the Bill, the Police will be the agency to investigate. In relation to any suspected breaches of the Privacy Ordinance regarding the use of personal data in an eHR, the Office of the Privacy Commissioner for Personal Data will be the lawful authority to follow up.

22(b). Further to the response to (a) above, for non-compliance of the Bill or the code of practice issued by the Commissioner which does not constitute criminal offenses per se, the Commissioner may request

relevant information from healthcare providers pursuant to clause 51(1).

- 22(c). The eHRSS is operated and maintained by the Commissioner who is a public officer. It is under the Government set-up and is not of a commercial nature. The Commissioner will not charge fees for the promotional activities of the eHRSS.

Healthcare providers and healthcare recipients need not pay fee to join the eHRSS. In the operation of eHRSS, there are only two likely circumstances that the Commissioner may need to charge fees. First, a fee will be levied on handling Data Access Request (DAR) (查閱資料要求) from patient in accordance with the Privacy Ordinance. As the administrative cost for generating electronic copies would unlikely be substantial, we envisage that the DAR fee will not be high. Second, the Commissioner may need to charge administrative fee for compiling and providing data to researchers whose research proposals have been approved.

- 22(d). No. The staff working in the Office of the Commissioner are civil servants or contract staff employed by the Government.

- 22(e). The Commissioner will not delegate his statutory functions and powers to another officer. According to clause 48(3) of the Bill, the Commissioner may appoint someone in writing to assist the Commissioner in performing a function and also exercising a power.

Clause 52 (Commissioner to specify forms)

23. The Commissioner is empowered by clause 52 to specify a format (格式) (which is intangible in nature) adopted in a form (表格) (which is tangible in nature). While the dictionary meaning of the word “form” can be relied on to convey both meanings above, we need the terms “格式” and “表格” in the Chinese text. For reference, similar wording is also adopted in section 67 of the Privacy Ordinance.

24. There is no legal requirement to publish these forms in the Gazette. The forms will be made available for downloading in the website of the Office of the Commissioner.

There will be various forms for administrative / operational purposes. They are under preparation.

Clause 53 (Establishment of Board)

25. We consider it more reader-friendly to set out the bilingual names of the “Electronic Health Record Research Board” in both texts. Similar examples can be found in section 3 of Cap. 581, section 3 of Cap. 601, section 4 of Cap. 604 and section 3 of Cap. 616.
26. Given that at this stage it is difficult to predict the number and nature of the research applications to be received and the mix of expertise required may change over time, we consider it appropriate not to prescribe in the Bill the composition, criteria or background of members to allow flexibility. Apart from the different disciplines of the healthcare sectors, we may also need expert advice on IT or statistical matters.

Food and Health Bureau

16 May 2014

**The Administration's response to
the comments on the Chinese text on
Electronic Health Record Sharing System Bill
(Annex II of Letter from Assistant Legal Advisor
of the Legislative Council dated 12 May 2014)**

Clause 2 (Interpretation)

1. We are of the view that the term “家人” can reflect the policy intent accurately. Besides, the Chinese rendition for “immediate family member” is “家人” in the Personal Data (Privacy) Ordinance (Cap. 486) (see section 63C). As Cap. 486 is highly relevant to our Bill, we consider it preferable to follow its rendition. The same rendition is also used in one of the recent Ordinances, namely the Residential Properties (First-hand Sales) Ordinance (Cap. 621).

Clause 3 (Substitute decision maker)

2. We plan to move amendments to the relevant provisions to replace “法庭” with “法院”.

Clause 9 (Withdrawal of healthcare recipient's registration)

3. The difference in the way of framing the idea in the bilingual texts is intended to achieve the most natural and smooth language flow in their respective texts. A direct translation of the expression “withdrawal of...registration” will result in an odd Chinese expression like “登記的撤回”. We are of the view that “...退出互通系統” is the most readable and accurate expression to convey the meaning.

Clause 25 (General Rule)

4. “不得...用” has been commonly used in our recent legislation as the Chinese equivalent for “may not be used”. Examples include section 412 (7) of Cap. 622 and section 12A(10) of Cap. 575. It

expresses a clearer meaning, especially when the meaning of “prohibition” is conveyed.

Clause 27 (Use for research and statistics)

5. We consider that the bilingual texts in the two clauses cited have conveyed the meaning accurately without inconsistency. The word “identified” referred to in clause 27(2) is not linked to “identifiable data” defined in clause 2(1). The differences in wording as pointed out are acceptable due to the different contexts involved.

Clause 26 (Use for improvement of healthcare)

6. “用於” (instead of “使用於”) is referred to in the cited provisions to smoothen the language flow for easy reading. We plan to move amendment to add “、用” after “使用” for the defined term “use” for the sake of clarity.

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

7. We plan to move an amendment to replace "捏改" with "捏改".

Clause 59 (Service of notice etc.)

8. “Addressed to...” is also commonly rendered as “致予...” in our legislation. Examples include section 22 of Cap. 98, section 206 of Cap. 485A and section 700 of Cap. 622. For the sake of simplicity and clarity, “致予...” is referred to in the lead-in of clause 59(a), (b), (c) and (d) of the Chinese text.

Food and Health Bureau

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