

中華人民共和國香港特別行政區政府總部食物及衞生局 Food and Health Bureau, Government Secretariat The Government of the Hong Kong Special Administrative Region The People's Republic of China

6 February 2015

Ms Maisie LAM Clerk to the Bills Committee on the Electronic Health Record Sharing System Bill

Dear Ms LAM,

## <u>Draft proposed amendments</u> <u>in relation to (i) "need-to-know" principle and</u> <u>(ii) patient choice over data sharing</u>

To facilitate the Bills Committee's scrutiny of the Electronic Health Record Sharing System (eHRSS) Bill we set out below the draft amendments, proposed by the Administration and agreed by the Privacy Commissioner for Personal Data (PCPD), in relation to (i) the "need-to-know" principle and (ii) patient choice over data sharing. The drafts are marked in revision mode on extracts of the bill at <u>Annexes A and B</u> respectively.

## (i) "Need-to-know" principle

As explained previously to the Bills Committee, the "need-to-know" principle has been adopted in the design of the eHRSS, and reflected in the relevant legislative provisions <sup>1</sup> and system operation/workflows. Nevertheless, in response to the suggestion of the PCPD and some members, we proposed for discussion a draft amendment to the bill (a new Clause 35A) in our written response following the 6<sup>th</sup> meeting on 29 July 2014. The PCPD subsequently suggested some refinements to the proposed new clause vide his letter to the Bills Committee dated 8 December 2014.

<sup>&</sup>lt;sup>1</sup> Clauses 25 and 26 of the bill together would guard against the use of data and information by any person who has nothing to do with improving the efficiency, quality, continuity or integration of the healthcare provided to a healthcare recipient. In addition, as set out in Clause 12, a healthcare recipient has the choice over giving sharing consent only to those healthcare provider(s) that has (have) a "need to know" his/her health data in the eHRSS, and can also revoke the sharing consent given to a particular provider at any time should he consider that the provider no longer has the need.

We have eventually worked out with the PCPD and the Department of Justice (DoJ) a revised draft Clause 35A that takes into account the PCPD's suggestion to reflect the principle more specifically while maintaining consistency in drafting style with the remainder of the bill. The refined draft, on which the PCPD has no further comment and agreeable to the Administration, is set out in <u>Annex A</u>.

#### (ii) Patient choice over data sharing

In previous Bills Committee meetings and our written responses, we explained to Members that there had been diverse views on the provision of "safe deposit box". It had not been included as an item in the scope of Stage 1 eHRSS and the Administration would conduct a study on this issue at Stage 2 of the eHRSS. In view of the concern expressed by the PCPD and some members, we undertook at the 8<sup>th</sup> meeting of the Bills Committee on 11 November 2014 that we would conduct the future study on enhancing patient choice along a positive direction, with a view to developing and implementing some form of new device/arrangement enabling additional choice for patients over the disclosure of their data. The study will be conducted in the 1<sup>st</sup> year of Stage 2 Electronic Health Record (eHR) Programme.

We note that the Bills Committee generally welcomes the positive direction of our future study. It was also accepted that pending the future study on enhancing patient choice, we could not stipulate the provision of a particular form of a "safe deposit box" in the bill. Notwithstanding, the PCPD and some members suggested that we should explore stipulating the spirit of fostering patient choice over data sharing in the bill, but at the same time not pre-empting the future design of the relevant feature. It was also suggested that the new provisions might be arranged to take effect only upon completion of the future study and after such feature was technically ready, instead of from Day 1 of eHRSS operation. In this regard, the PCPD proposed some draft new provisions in his letter dated 8 December 2014 to the Bills Committee.

We have carefully studied the PCPD's suggestion. Along the suggested approach and line of thinking, we have worked out with the PCPD and the DoJ a set of refined proposed amendments as set out in <u>Annex B</u>. For clarity and better alignment with the flow and drafting style of the bill, we propose to set out the sharing restriction on the scope of data sharing in a new standalone division in the bill (division 3A). Making reference to the PCPD's proposed amendments to empower the Secretary for Food and Health (SFH) to specify the form of sharing control, we propose that the future eHR Commissioner (eHRC) should be so designated. The consideration is that the eHRC is the public officer under the eHRSS Ordinance to establish, operate,

maintain and develop the eHRSS. It is therefore more appropriate for the eHRC to perform such duties instead of SFH. We also agree with the PCPD that there is no need for any clauses on provisions of discretion for the eHRC to grant or refuse the request on sharing restriction made by a healthcare recipient. The overall spirit of our proposed provisions is to foster patient choice. The eHRC is obliged to notify the healthcare recipient in writing on the effective date of the sharing restriction. In the future design of the relevant new feature, we will ensure that the sharing restriction request may take effect as soon as completion of necessary identification and processing.

The refined draft amendments are agreeable to the PCPD. The eventual new feature on enhancement of patient choice over the disclosure of their data will be devised in the future study. After completing the study, we will consult stakeholders including the Steering Committee on eHR Sharing, PCPD, medical professional bodies and patient groups on the proposed new feature before implementation.

Yours sincerely,

(Ms Ida LEE) for Secretary for Food and Health

c.c. Assistant Legal Advisor 4, Legal Service Division
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The Privacy Commissioner for Personal Data
Department of Justice
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(Miss Carrie WONG) (Attn.: Ms Sandra LIU) (Attn.: Ms Rayne CHAI Ms Carmen CHAN Mr Patrick YEUNG)

## Annex A

# Draft proposed amendments in relation to "Need-to-know" principle

(Note: Draft amendments are marked in red on the following extract of the draft bill.)

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# 35. Prescribed healthcare provider's duties on electronic medical record system

A prescribed healthcare provider must take reasonable steps to ensure that the healthcare provider's electronic medical record system does not impair the security or compromise the integrity of the System.

#### **35A.** Prescribed healthcare provider's duty to restrict access to sharable data

- (1) This section applies if a prescribed healthcare provider is given a sharing consent by a registered healthcare recipient or a substitute decision maker of a registered healthcare recipient.
- (2) The healthcare provider must take reasonable steps to ensure that (a) access to any health data of the healthcare recipient is restricted to its healthcare professional who may perform healthcare for the recipient; and (b) the access is restricted to the health data that may be relevant for performing healthcare for the recipient.
- (3) However, for complying with a data access request or data correction request under Part 5 of the Privacy Ordinance, the healthcare provider is not to be treated as contravening the requirement under subsection (2) even if access to the health data is granted to a person other than the healthcare professional.

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## Annex B

## Draft proposed amendments in relation to patient choice over data sharing

(Note: Draft amendments are marked in red on the following extract of the draft bill.)

(Note: The new provisions will be arranged to take effect only upon completion of the future study on enhancing patient choice and after such feature enabling additional choice for patients over the disclosure of their data is technically ready, instead of from Day 1 of eHRSS operation.)

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#### 2. Interpretation

(1) In this Ordinance—

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<u>sharing restriction request</u> (互通限制要求) means a request made under section <u>16A(1)(a);</u>

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# **Division 3A—Sharing Restriction**

#### 16A. Request for sharing restriction

- (1) Subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may make (a) a request to restrict the scope of data sharing; or (b) a request to remove a restriction on the scope of data sharing, in relation to the health data of the healthcare recipient.
- (2) If the healthcare recipient is a minor, the request must be made by a substitute decision maker of the healthcare recipient unless the Commissioner is satisfied that the recipient is capable of making the request.
- (3) If the healthcare recipient is aged 16 or above and is incapable of making the request, the request must be made by a substitute decision maker of the healthcare recipient.
- (4) A request made by a substitute decision maker of a registered healthcare recipient is made on behalf of and in the name of the recipient.
- (5) In making a request, a substitute decision maker of a registered healthcare recipient must have regard to the best interests of the recipient in the circumstances.
- (6) A request must be made to the Commissioner in the form and manner specified by the Commissioner.
- (7) The Commissioner must notify the requestor in writing of the date on which the requested restriction, or the requested removal of restriction, takes effect.

#### 16B. Commissioner to specify sharing restriction

- (1) The Commissioner must specify the types of restrictions in respect of which a person may make a request under section 16A(1).
- (2) The Commissioner must make copies of a document setting out the specified types of restrictions available to the public (in hard copy or electronic form).

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(Note: The following amendments are consequential amendments.)

#### 3. Substitute decision maker

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- (3) For a healthcare recipient who is aged 16 or above and who is of any of the following descriptions, the persons specified in subsection (4) are eligible persons for the purposes of subsection (1)—

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- (d) being incapable of giving a sharing consent at the time referred to in paragraph (d), (e) or (f) of the definition of *relevant time* in subsection (5).
- (e) being incapable of making a sharing restriction request at the time referred to in paragraph (g) or (h) of the definition of *relevant time* in subsection (5).

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(5) In this section—

relevant time (有關時間) means—

•••••

- (f) in relation to a sharing consent that is revoked under section 15(1), the time at which the revocation of the sharing consent is made $\frac{1}{2}$
- (g) in relation to a sharing restriction request that is made under section 16A(1)(a), the time at which the request is made;
- (h) in relation to a request to remove a restriction that is made under section 16A(1)(b), the time at which the request is made.

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