Bills Committee on Electronic Health Record Sharing System Bill

The Administration's Response to the draft Committee Stage Amendments proposed by Dr Hon Leung Ka-lau

This paper sets out the Administration's response to the draft Committee Stage Amendments (CSAs) to the Electronic Health Record Sharing System (eHRSS) Bill proposed by Dr Hon Leung Ka-lau in his letter to the Bills Committee dated 20 May 2015 (vide LC Paper No CB(2)1543/14-15(01)).

The Administration's stance

2. The Administration ***objects in principle*** to the proposed CSAs as it will: (a) seriously undermine our policy objective to promote ***two-way sharing*** amongst public and private healthcare providers; (b) completely alter the fundamental design principles and consent arrangement previously agreed via due consultation process; and (c) render the already developed Stage 1 eHRSS not operable. Our detailed explanations are set out in the ensuing paragraphs.

Design principles of the developed eHRSS

3. After almost 5 years of design and development work, our technical team has completed the Stage 1 eHRSS. The underlying concept of the eHRSS has incorporated two tiers of consent. First, all patients (including the patients of the Hospital Authority (HA) and the Department of Health (DH)) are free to decide whether to give "joining consent" to join the eHRSS. Second, for those patients (i.e. healthcare recipients (HCRs)) who have joined, they could choose to selectively give "sharing consent" for individual private healthcare providers (HCPs) to view and upload their electronic health record (eHR).

4. Broadly speaking, Dr Hon Leung Ka-lau's proposed CSAs would bring about the following direct impact:

(a) the original "sharing consent" will be "split". "Joining consent"

is redefined as a consent from a HCR (i.e. patient) for the eHR Commissioner (eHRC) to obtain eHR from all prescribed HCPs (i.e. HCPs need not obtain a separate direct specific "sharing consent" from HCR). "Sharing consent" is redefined as a consent from a patient for the concerned HCP to obtain his/her eHR from eHRSS (i.e. it will not cover uploading); and

(b) a patient would no longer be taken to have given a "sharing consent" to DH and HA when he/she gives a "joining consent"

5. From Hon Leung's letter, it seems that his concern is that there may be circumstances where a patient only wishes to allow an private HCP to view his eHR in HA/DH but not to upload his/her data to eHRSS for HA/DH to view; or where a patient may not wish his private HCP to view his/her eHR contributed by HA/DH but wants HA/DH to view his/her eHR contributed by that private HCP. In other words, these are scenarios involving ***one-way sharing*** of data.

Policy objectives and formulation process

6. As previously explained to the Bills Committee, the eHRSS is a Government-funded sharing platform of which ***the fundamental objective is to foster the two-way sharing of eHR between public and private HCPs for the benefit of patients***. It is indeed in line with our policy intention and a reasonable arrangement that "sharing consent" should cover both viewing and uploading of eHR.

7. The Public Private Interface – Electronic Patient Record sharing Pilot Project (PPI-ePR) currently being implemented is essentially a one-way sharing **pilot**. It is useful in testing relevant technologies and popularity of concept. The two-way sharing eHRSS would facilitate participating HCPs to both ***benefit from eHRSS (by viewing data) and contribute to it (by uploading data)***. Compared with the one-way pilot, it would bring both patients and HCPs greater benefits. The splitting of the original sharing consent to create one-way arrangement as a default setting would greatly undermine our policy objective.

8. On the proposed deletion of Clause 16 regarding consent for DH

and HA, we have previously explained to the Bills Committee that HA and DH are the largest HCPs in Hong Kong possessing vast amount of health data. These data would be ***the essential building blocks of patients' life-long eHR***, conducive to the continuity of care of the patients. Without these data, the content of patients' eHR may become much more flimsy, and ***the value and benefits of joining the eHRSS would be substantially undermined***. The Bills Committee has deliberated this arrangement and the Administration's clarification, and subsequently agreed on retaining the existing Clause 16 at the meeting on 13 March 2015.

9. The overall consent arrangement incorporated into the eHRSS now developed has undergone ***due deliberation and consultation*** with the Steering Committee on eHR Sharing and its working groups. They comprise various stakeholders including patient groups, healthcare related professional bodies and experts in particular sectors or representatives of relevant organizations. The arrangement was also put forth in Chapter 4 of the public consultation document on "The Legal, Privacy and Security Framework for Electronic Health Record Sharing" in 2011-12.

10. From international experience, to successfully implement a voluntary eHRSS of such scale, ***simplicity and ease of use for majority*** of the participants, including HCRs and HCPs, is of utmost importance. The present consent arrangement and Stage 1 eHRSS is designed and development with this in mind.

Flexibility of the Administration's new Clauses 16A and 16B "Sharing restriction request"

11. The Stage 1 eHRSS already developed would be able to cater for the majority of the participants. That said, we acknowledge that some patients may have concerns in some circumstances over the sharing of their eHR. Indeed, possible scenarios were raised during the earlier discussion of the "safe deposit box" issue. After considerable discussions at the Bills Committee, the Administration has eventually undertaken to conduct in the 1st year of Stage 2 eHR Programme a 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. It was also agreed that after completing the study, we will consult stakeholders including the Steering Committee on eHR Sharing, Privacy Commissioner for Personal Data (PCPD), medical professional bodies and patient groups on the proposed new feature before implementation. We have accordingly prepared a set of CSAs on "sharing restriction" to provide the legal basis for a patient to make a request to restrict the scope of data sharing [1] in relation to his/her eHR (vide LC Paper No. CB(2)808/14-15(02) – the draft clauses are re-attached at **Annex**). The above arrangement was ***agreeable to PCPD***, and was ***generally accepted by members*** at the meeting on 26 February 2015.

12. In this connection, we wish to highlight that ***the new Clauses 16A and 16B proposed by the Administration could already provide very flexible room to allow different methods of restrictions, including arrangements to address the underlying concern of Hon Leung and different potential scenarios. There would be no need of further amending the bill***.

Consequences of proposed draft CSAs taken forward

13. The existing Clauses 7, 12 and 16 of the bill, together with other clauses, were drafted as an integrated whole to give effect to the Stage 1 system developed and the related operational workflows. ***If Hon Leung's latest proposed draft CSAs were taken forward, the developed eHRSS could not commence operation even if the amended bill is passed. The delay and the negative impact would be most undesirable for many patients.***

14. Members may recall that in our previous written responses, we have mentioned the technical implication of modifying the presently developed eHRSS to accommodate special requests for "opting out" from the default consent arrangement for HA/DH. We indicated that the technical alteration, though not insurmountable, would require ***substantial modification*** such as the redesign of workflows, change of

[1] "Data sharing" is defined in the bill as "the *act* of providing or obtaining any sharable data of a registered healthcare recipient through the System"

system design and logics as well as the programmes and applications involved. We estimated that such change alone would already take ***no less than 12 months*** to complete these work.

15. If on top of the above modification, the consent arrangement is to further alter (viz. splitting the sharing consent), it will ***call for fundamental changes*** of the eHRSS and much more ***serious delay***. Moreover, the capital funding approved by the Finance Committee in 2009 has been mostly expended on development of Stage 1 eHRSS according to agreed principles. There is no funding to fundamentally redevelop a different system.

16. The Stage 1 eHRSS developed can commence operation soon after passage of the eHRSS Bill. Many patients will soon be able to benefit from the two-way sharing of eHR. ***As the aforementioned new clauses on "sharing restriction request" agreed by the Administration, PCPD and Members could in fact provide adequate room for new devices to address special patients' concerns, we object to the latest amendments proposed in the letter***.

Food and Health Bureau
May 2015

Annex

Draft proposed amendments in relation to patient choice over data sharing

(Note: Draft amendments are marked in red and with underline 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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sharing restriction request (互通限制要求) means a request made under section 16A(1)(a);

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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)—

……

(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).

……

(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~~.~~;

(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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