立法會
Legislative Council

LC Paper No. CB(2)2219/14-15
(These minutes have been seen by the Administration)

Ref : CB2/BC/6/13

Bills Committee on Electronic Health Record Sharing System Bill

Minutes of the fifteenth meeting held on Tuesday, 31 March 2015, from 8:30 am to 10:30 am in Conference Room 2A of the Legislative Council Complex

Members present	:	Hon Charles Peter MOK, JP (Chairman) Hon Emily LAU Wai-hing, JP Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN Hon Alan LEONG Kah-kit, SC Hon WU Chi-wai, MH Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung Ir Dr Hon LO Wai-kwok, BBS, MH, JP
Members absent	:	Hon Cyd HO Sau-lan, JP Dr Hon LEUNG Ka-lau Hon CHEUNG Kwok-che Hon CHAN Han-pan, JP Hon Alice MAK Mei-kuen, JP Dr Hon Helena WONG Pik-wan Dr Hon Elizabeth QUAT, JP
Public Officers attending	:	Item I Mr Sidney CHAN, JP Head (eHealth Record) eHealth Record Office Food and Health Bureau

Ms Ida LEE
Deputy Head (eHealth Record)
eHealth Record Office
Food and Health Bureau

Mr Michael FUNG
Chief Systems Manager (eHealth Record)
Hospital Authority

Mrs Juliet CHENG
Chief Systems Manager (eHealth Record)
eHealth Record Office
Food and Health Bureau

Dr W N WONG
Senior Health Informatician (eHealth Record) Special Duties
eHealth Record Office
Food and Health Bureau

Ms Rayne CHAI
Acting Senior Assistant Law Draftsman
Department of Justice

Mr Patrick YEUNG
Senior Government Counsel
Department of Justice

Miss Queenie WU
Acting Senior Government Counsel
Department of Justice

Clerk in attendance : Ms Maisie LAM
Chief Council Secretary (2) 5

Staff in attendance : Miss Carrie WONG
Assistant Legal Adviser 4

Ms Janet SHUM
Senior Council Secretary (2) 5

Ms Louisa YU
Clerical Assistant (2) 5

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I. Meeting with the Administration

[File Ref.: FH CR 1/1/3781/10, LC Paper Nos. CB(2)1515/13-14(01), CB(2)1551/13-14(01), CB(2)2308/13-14(02), CB(2)436/14-15(01), CB(2)808/14-15(02), CB(2)837/14-15(01), CB(2)911/14-15(01), CB(2)956/14-15(01), CB(2)986/14-15(01), CB(2)1019/14-15(02), CB(2)1145/14-15(01) to (03), CB(2)1151/14-15(01) and CB(3)575/13-14]

The Bills Committee deliberated (index of proceedings attached at **Annex**).

Continuation of clause-by-clause examination of the Bill

2. Members noted the written submissions from organizations and individuals in response to the invitation of the Bills Committee on the major proposed amendments to the Bill as set out in Appendices I to IX to LC Paper No. CB(2)1145/14-15(03).

3. Members also noted the Committee stage amendments ("CSAs") proposed by the Administration to clauses 11 and 23 to provide that a healthcare recipient ("HCR") and a registered healthcare provider ("HCP") would be given an opportunity to make representation before the Commissioner for the Electronic Health Record ("eHRC") made a decision on cancellation of registration of the HCR or HCP concerned, details of which were set out in the Annex to LC Paper No. CB(2)1145/14-15(02). Members agreed to consider the above CSAs together with the Administration's response to be provided in respect of paragraph 5(a) below at a future meeting.

4. The Bills Committee continued clause-by-clause examination of the Bill from clause 25 and examined up to clause 32.

Follow-up actions required of the Administration

Admin

5. The Bills Committee requested the Administration to -

(a) in respect of clauses 10 and 22, which provided for the suspension of an HCR and an HCP by eHRC under the circumstances specified, consider specifying in the Bill a time limit on how long the suspension could last;

(b) advise the relevant ordinances under which the use of data and information contained in an electronic health record ("eHR") kept in the Electronic Health Record Sharing System ("eHRSS") would

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be permitted as provided for in clause 29;

(c) in respect of clauses 30, 31 and 32 concerning the procedures for applying for the use of identifiable data of an HCR contained in an eHR for carrying out research, or preparing statistics, that were relevant to public health or public safety,

(i) advise whether a separate set of guidelines setting out the detailed criteria for the Electronic Health Record Research Board in consideration of an application for using such identifiable data for research or statistics purpose under clause 31 would be formulated and if so, provide a copy of the draft guidelines for consideration by the Bills Committee when available;

(ii) advise whether views of patient groups for rare diseases on the use of identifiable data of HCRs contained in eHRSS for research and statistics purposes had been gauged;

(iii) provide for members' reference information on the number and examples of health and medical research in tertiary institutions and public healthcare sector which involved data collection on the health records of identifiable data subjects;

(iv) provide for members' reference copies of relevant available guidelines of the Hospital Authority ("HA"), the Research Grants Council under the University Grants Committee and the tertiary institutions relating to the use of identifiable data of data subjects for health and medical research purpose, in particular information on whether the data subjects concerned had to give separate consent to the use of their data for the research being carried out; and

(v) advise whether there had been any complaints lodged against the data users, such as HA, for providing identifiable data of the data subjects for health and medical research purpose without obtaining separate consent from the data subjects concerned;

(d) provide a response to address the concern raised by Professor John Bacon-Shone in his submission dated 18 March 2015 (Appendix VII to LC Paper No. CB(2)1145/14-15(03)) about the re-identification risk of the non-identifiable data of an HCR contained in an eHR being used for research or statistics purpose;

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and

(e) advise the respective circumstances under which eHRC and the HCP would be exposed to legal liability in the use of data or information contained in eHRSS, particularly where the activity or service was performed outside Hong Kong by the HCP for the HCR.

II. Any other business

6. There being no other business, the meeting ended at 10:41 am.

Council Business Division 2
Legislative Council Secretariat
9 October 2015

Annex

Proceedings of the fifteenth meeting of the Bills Committee on Electronic Health Record Sharing System Bill held on Tuesday, 31 March 2015, from 8:30 am to 10:30 am in Conference Room 2A of the Legislative Council Complex

Time marker	Speaker	Subject(s)/Discussion	Action required
Agenda item I: Meeting with the Administration			
000454 - 000642	Chairman	Opening remarks	
000643 - 001006	Chairman Admin	Briefing by the Administration on its response to issues raised at the meeting on 13 March 2015 (LC Paper No. CB(2)1145/14-15(02)).	
001007 - 001725	Chairman Dr KWOK Ka-ki Admin	Dr KWOK Ka-ki's concern that the interest of a registered healthcare recipient ("HCR") might be undermined if the registration of the registered healthcare provider ("HCP") taking care of him or her had been cancelled that his or her electronic health record ("eHR") would no longer be made available to the HCP concerned through the Electronic Health Record Sharing System ("eHRSS"). The Administration's advice that according to the Personal Data (Privacy) Ordinance (Cap. 486) ("PDPO"), the HCR concerned could approach the office of the Commissioner for the Electronic Health Record ("eHRC") to make a data access request ("DAR") concerning his or her electronic health record ("eHR") and provide the copy of such record to the HCP concerned. On Dr KWOK Ka-ki's view that a performance pledge on the time required for processing a DAR should be set and the charges for obtaining a copy of an eHR should be set at reasonable levels, the Administration's advice that it would not take a long time for the office of eHRC to process a DAR as the data and information was in electronic form. Depending on whether the copy of the eHR was in paper or electronic form, the charges for a copy of an eHR would be about several tens of dollars.	
001726 - 003622	Chairman ALA4 Admin Dr KWOK Ka-ki	The Legal Adviser to the Bills Committee's view that since there was no reference to the time limit on how long the suspension of an HCR and a registered HCP by eHRC could last in clauses 10 and 22, it was undesirable that no express provisions would be made to provide that the HCR or HCP concerned would be given an opportunity to make representation before eHRC made a decision on whether or not to suspend or cancel their registration. The Administration's reiteration of its rationale for not providing for the representations by an HCR or registered HCP before eHRC made a decision on suspension of registration as detailed in LC Paper No. CB(2)1145/14-15(02); and its advice that eHRC would not unduly prolong	

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		the suspension period given the requirement under section 70 of the Interpretation and General Clauses Ordinance (Cap. 1) which stipulated that "where no time is prescribed or allowed within which any thing shall be done, such thing shall be done without unreasonable delay, and as often as due occasion arises". The Chairman and Dr KWOK Ka-ki's view that the suspension period should not be indefinite and eHRC should decide whether to proceed with cancellation or not within a certain timeframe. The time limit for the suspension period, which could be extended if eHRC considered appropriate, should be provided expressly in the Bill. In view of members' concern, the Administration undertook to consider amending clauses 10 and 22 to such effect.	**Admin**
003623 - 005000	Chairman Admin Dr KWOK Ka-ki	On Dr KWOK Ka-ki's concern about the legal liability of eHRC and registered HCPs (and their healthcare professionals) for any damages to registered HCRs due to the inability of the HCPs to obtain from eHRSS any sharable data of the HCRs when eHRC suspended or cancelled their registration; and his view that the use of sharable data of a registered HCR for the performance of healthcare to that HCR outside Hong Kong should be allowed given the increasing number of Hong Kong residents residing and/or working on the Mainland, the Administration's advice that - (a) while eHRC would be responsible for operating and maintaining eHRSS, it was the responsibility of HCPs and their healthcare professionals to maintain medical records of HCRs under their care; (b) under the Bill, overseas HCPs without any service locations in Hong Kong were ineligible for registration for eHRSS. This apart, "healthcare", in relation to an individual, meant "an activity performed in Hong Kong by a healthcare professional for the individual" for improving the individual's health. Hence, any access to eHRSS for the purpose of using the data of a registered HCR for improving the healthcare provided to that HCR had to be by a healthcare professional registered under the relevant ordinances in Hong Kong and for an activity performed in Hong Kong. These restrictive arrangements would help safeguard the privacy of registered HCRs, as the ordinance (if enacted), like other local legislations, could not be enforced outside Hong Kong; and (c) statutory registered healthcare professionals engaged by the prescribed HCPs could access eHRSS outside Hong Kong by using notebooks or mobile devices through their electronic medical record systems subject to compliance with the security requirements defined by eHRC. In response to the Chairman's enquiry, the Administration's advice that the code of practice and guidelines to be issued to	

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		HCPs would stipulate the responsibility of HCPs in using eHR for healthcare. HCRs would also be given an information notice which cover, among others, the scope, purpose, and benefits of eHR sharing upon their registration for eHRSS. The Chairman's suggestion that feasibility of allowing the use of data or information contained in eHRSS for healthcare performed outside Hong Kong should be explored during the second stage of the Electronic Health Record Programme. The Legal Adviser to the Bills Committee's remark that clause 57(1) provided that the Government and public officers would be exempted from civil liability under specified circumstances provided in the Bill. The Administration was requested to advise the respective circumstances under which eHRC and the prescribed HCP would be exposed to legal liability in the use of data or information contained in eHRSS, particularly where the activity or service was performed outside Hong Kong by the HCP for the HCR.	**Admin**
005001 - 005150	Chairman Admin ALA4	Members agreed to examine the Administration's proposed Committee stage amendments ("CSAs") to clauses 11 and 23 together with the CSAs to clauses 10 and 22 to be proposed by the Administration.	
005151 - 005155	Chairman	Continuation of clause-by-clause examination of the Bill	
005156 - 010451	Chairman Admin ALA4 Ms Emily LAU Ir Dr LO Wai-kwok	<u>Examination of clauses 25 to 29</u> The Administration's advice in response to Ms Emily LAU's enquiry that given the general prohibition imposed by clause 25 on the use of the data and information contained an eHR except as provided in clauses 26 to 29, clause 29 served to preserve the status quo of the prevailing uses of data and information pursuant to the legal regime at any point in time. The Legal Adviser to the Bills Committee's concern about the use of data and information contained in an eHR permitted by or under any other law, in particular the relevant ordinances under which the use would be permitted as provided for in clause 29, as detailed in paragraph 8 of her letter dated 12 May 2014 to the Administration (LC Paper No. CB(2)1515/13-14(01)). In response, the Administration undertook to further discuss the matter with the Legal Adviser to the Bills Committee after the meeting and revert in writing.	**Admin**
010452 - 011331	Chairman Admin	<u>Examination of clauses 30 to 32</u> In response to the Chairman's enquiry about what constituted "identifiable data", the Administration's advice that any data or information of an HCR was identifiable data if the identity of the HCR was ascertainable from the data or information. This covered, among others, personal identifiers such as the name and Hong Kong Identity Card number of a registered HCR, as well as the health data of those HCRs suffering from rare diseases.	

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011332 - 011815	Chairman Ms Emily LAU Admin	Referring to clause 31(2)(c) which provided that in considering an application for using the identifiable data of a registered HCR contained in an eHR for carrying out research, or preparing statistics, that were relevant to public health or public safety, due regard would be given by the Electronic Heath Record Research Board ("the eHR Research Board") as to whether it was practicable to obtain the consent of the HCR concerned for the use, Ms Emily LAU's enquiry as to whether the office of eHRC would help the applicant to seek the consent of the HCR concerned. The Administration's advice that registered HCRs would be informed via the information notice for HCRs participating in eHRSS that their personal data might be used for, among others, research or statistics purpose. Hence, there was no need for eHRC to seek separate consent of the registered HCRs for using their eHRs for individual studies. It should be noted that a person who had obtained the consent of an HCR for using his or her health data for research and statistics purpose would still need to make an application to the Secretary for Food and Health ("SFH") under clause 30 if the research required the use of that HCR's identifiable data contained in his or her eHR.	
011816 - 012419	Chairman Ir Dr LO Wai-kwok Admin	In response to Ir Dr LO Wai-kwok's enquiry about whether an applicant who had been given approval for the use of identifiable data of an HCR in his or her eHR could contact the HCR concerned direct, the Administration's advice that under clause 31(3), if the eHR Research Board recommended that SFH approved the application, it might make recommendations on the conditions of approval which might include authorized use(s) and duty to preserve the privacy and confidentiality of the identifiable data so obtained, etc. This apart, clause 27(2) provided that the results of the research or the resulting statistics could not be made available in a form that would enable an HCR to be identified.	
012420 - 013320	Chairman Ms Emily LAU Admin	Ms Emily LAU's enquiry about the factors to be considered by the eHR Research Board in considering whether it was ethical to carry out a research or prepare the statistics under clause 31(2)(a). The Administration's advice that it was expected that most of the applications for the use of identifiable data for research or statistics purpose would be made by researchers of tertiary institutions and public or private hospitals. Ethical approval of the relevant ethics committee of the administering institution should have already been obtained prior to the applicant made the application to SFH under clause 30. For applications from individuals in personal capacity, the eHR Research Board would assess, among others, the merits of the proposal in terms of research ethics.	
013321 - 015340	Chairman Mr Alan LEONG Admin	Mr Alan LEONG's view that only non-identifiable data of the registered HCRs contained in their eHRs should be used for research or statistics purpose. In case there was exceptional	

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		genuine need to use the identifiable data of the registered HCRs for such purpose, express and informed consent from the HCRs concerned should be sought as far as practicable. The Administration's advice that - (a) the usage of identifiable health data for research or statistic purpose was very common internationally and locally. While it was envisaged that most of the applications for using the data and information contained in eHRs of the registered HCRs for research or statistics purpose would be related to the use of non-identifiable data, it could not be ruled out that in some cases the use of identifiable data were necessary. Cases in point were registering individual HCRs on a community base for certain disease to evaluate the disease patterns, prognosis and treatment efficacy; studying the relationship between certain health determinants and health status in matched groups of HCRs; and tracking and monitoring the treatment outcome and complications in individual HCRs over time; (b) section 62 of PDPO provided that personal data was exempt from the provisions of data protection principle 3 on use of personal data where (i) the data was to be used for preparing statistics or carrying out research; (ii) the data was not to be used for any other purpose; and (iii) the resulting statistics or results of the research were not made available in a form which identified the data subjects or any of them. Given the need to strike a balance between the public interest in conducting research and protecting privacy of registered HCRs in particular for the cases of using identifiable data contained in an eHR for research or statistics purpose, the Bill had, on top of section 62 of PDPO, provided for a due process to consider applications made in this regard under clauses 30 to 32; (c) the eHR Research Board to be established under clause 53 (as amended by the proposed CSAs set out in the Annex to LC Paper No. CB(2)1151/14-15(01)), which comprised, among others, representatives from different sectors, would assess the merits and public interest of these applications on a case-by-case basis to provide SFH with recommendations on whether to approve or refuse the applications, and where applicable, conditions of approval which might include special requirements on safeguarding privacy; (d) the above mechanism and the drafting of clauses 30 to 32 (and clauses 33 and 34 concerning the procedures for the use of non-identifiable data for research or statistics purpose) had made reference to provisions of the laws in Australia concerning the use of electronic health data for research or statistics purpose; and	

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		(e) it would not be feasible to seek the consent of the HCRs concerned for each research study involving the use of identifiable data of the registered HCRs as some of these HCRs might have passed away or emigrated.	
015341 - 020652	Chairman Admin Mr Alan LEONG Dr Fernando CHEUNG Prof Joseph LEE	The Chairman's decision to extend the meeting for 15 minutes beyond its appointed time. Holding the view that the principles set out in clause 31(2) were too general, Mr Alan LEONG and Dr Fernando CHEUNG's suggestion for the Administration's consideration that a set of administrative guidelines should be formulated setting out the detailed criteria for the eHR Research Board to process the applications. A copy of the draft guidelines should be provided to the Bills Committee for consideration. Prof Joseph LEE's request for the Administration to provide for members' reference - (a) information on the number and examples of health and medical research in tertiary institutions and public healthcare sector which involved data collection on the health records of identifiable data subjects; and (b) copies of available guidelines of the Hospital Authority ("HA"), the Research Grants Council under the University Grants Committee and the tertiary institutions relating to the use of identifiable medical data for research purpose.	**Admin** **Admin**
020653 - 020708	Chairman Ms Emily LAU	Ms Emily LAU's request for the Administration to advise in writing on whether the views of patient groups for rare diseases on the use of identifiable data of HCRs contained in eHRSS for research and statistics purposes had been gauged.	**Admin**
020709 - 021200	Chairman ALA4 Ms Emily LAU Admin Prof Joseph LEE	The Administration undertook to - (a) provide a written response to address the concern raised by Professor John Bacon-Shone in his submission dated 18 March 2015 (Appendix VII to LC Paper No. CB(2)1145/14-15(03)) about the re-identification risk of the non-identifiable data of an HCR contained in an eHR being used for research or statistics purpose; and (b) advise in writing as to whether there had been any complaints lodged against the data users, such as HA, for providing identifiable data of the data subjects for health and medical research purpose without obtaining separate consent from the data subjects concerned.	**Admin**

Time marker	Speaker	Subject(s)/Discussion	Action required
Agenda item II: Any other business			
021201 - 021210	Chairman	Closing remarks	

Council Business Division 2
Legislative Council Secretariat
9 October 2015