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Bills Committee on Electronic Health Record Sharing System Bill

Background brief prepared by the Legislative Council Secretariat

Purpose

This paper provides background information on the Electronic Health Record Sharing System Bill which seeks to provide for the establishment of an Electronic Health Record Sharing System ("the System"), the sharing and using of data and information contained therein, the protection of the System and other incidental and related matters. It also gives a brief account of the discussion by the Panel on Health Services ("the Panel") on the legislative proposal.

Background

2. Further to the public consultation on the future service delivery model of the healthcare system[1] and the launch of the Public Private Interface - Electronic Patient Record Sharing Pilot Project to test the feasibility and acceptability of electronic health record ("eHR") sharing, the Government proposed to develop eHR sharing as an infrastructure for healthcare reform in the Healthcare Reform Consultation Document entitled "Your Health, Your Life" published in March 2008. Based on the positive response received in the consultation exercise, the Government rolled out a 10-year two-stage programme in 2009 to develop the System. Its plan is to launch the System by the end of 2014 to enable the sharing of eHRs between healthcare providers ("HCPs") in the public and private sectors with patients' consent. One of the main targets of the first stage programme which spans from 2009-2010 to 2013-2014 is to formulate a legal framework to protect data privacy and system security prior to commissioning the System.

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[1] The Health and Medical Development Advisory Committee released a Discussion Paper entitled "Building a Health Tomorrow" on 19 July 2005 proposing the future service delivery model of the healthcare system, in which the development of a territory-wide patient record system was proposed for the first time for public consultation.

3. At present, the Personal Data (Privacy) Ordinance (Cap. 486) ("PDPO") sets out the provisions for protection of personal data privacy but there is no specific provision on health-related data. General offences against unlawful access to and use of computer and data are provided in the Telecommunications Ordinance (Cap. 106) and the Crimes Ordinance (Cap. 200). In view of the unique arrangement of data sharing, the sensitive nature of health records and the need to provide additional safeguards to instill public confidence in the System, the Government considers it necessary to introduce a new legislation to cater for the new circumstances brought about by the System. In December 2011, the Government conducted a public consultation on the legal, privacy and security framework ("the framework") for the System. Based on the results of the consultation which came to an end in February 2012, the Government sets out the concepts and principles governing the framework of the System which covers, among others, voluntary participation for both healthcare recipients ("HCRs") and HCPs; "patient-under-care" and "need-to-know" principles for data access of HCPs; a pre-defined scope of data sharing; identification and authentication of HCRs and HCPs; the governance of the System; and the provision of a versatile and technology-neutral legal framework and codes of practice to set out the operational and security requirements.

The Bill

4. The Administration introduced the Bill into the Legislative Council on 30 April 2014 to establish the System, to provide for the sharing and using of data and information contained therein and the protection of the System, and to provide for incidental and related matters. The Bill covers, among others, the establishment of the System; the appointment of the Commissioner; registration of HCR and HCP; use of eHR; system security and integrity; interaction with PDPO; new offences specific to the operation of eHR sharing; complaints and appeal mechanism; access to card face data; and liability of Government and public officers. The key features of the Bill are set out in paragraphs 6 to 20 of the Legislative Council Brief (File Ref: FH CR 1/1/3781/10).

Deliberations of the Panel

5. The Panel held five meetings between 2009 and 2013 to discuss the development and the framework of the System and the legislative proposal. It received the views of deputations at one of the meetings. Members of the Panel also observed a demonstration of the operation of the System on 28 February 2014. The deliberations and concerns of members are summarized below.

Privacy and security safeguards

6. Members were concerned about the protection of the privacy of personal data contained in, and the integrity and security of, the System. Some members suggested that it should be made a criminal offence for any person who knowingly or recklessly, without the consent of HCRs, obtained or disclosed HCRs' information stored in the System or subsequently sold the information so obtained for profits. They urged the Administration to take measures to protect the privacy of eHR data as well as guard against data loss and damage.

7. The Administration advised that it had been working closely with the Office of the Privacy Commissioner for Personal Data in the course of developing the System and the drafting of the proposed legislation. The eHR Office had also completed the first and second phases of Privacy Impact Assessment. The third phase of the Privacy Impact Assessment was expected to commence in the first quarter of 2014. This apart, a Privacy Compliance Audit would be commenced after the System came into operation in late 2014. It was proposed that access to eHR data by participating HCPs had to comply with the "patient-under-care" and "need-to-know" principles. In addition, new offences specific to guard against unauthorized access to the System with a malicious intent would be introduced to enhance deterrent effect.

8. On the protection of data integrity and security, the Administration advised that a central data repository approach would be adopted for the System. The eHR core architecture would be based on a centralized eHR sharable data store and all data uploaded by participating HCPs to the central eHR data store would be transformed, restructured, standardized and re-formatted where appropriate before storage to the System. A secondary data centre would also be established, so that two sets of synchronized data would be maintained to guard against data loss and damage. The System as a whole would be hosted in a secure platform with multiple firewalls, intrusion detection tools and industry leading encryption technology to protect patients' health data.

9. Members noted that the System would comprise standalone electronic medical/patient record ("eMR/ePR") systems adopted by individual HCPs and a central electronic platform as the sharing infrastructure for such eMR/ePR systems to interconnect for sharing of eHR among them. They were concerned about how the Administration could prevent system or data input errors in individual eMR/ePR systems from affecting the accuracy of patients' health data in the System. Pointing out that it would make available the system expertise and technical know-how of the Hospital Authority ("HA") to facilitate the development of the private sector's eMR/ePR systems, the Administration reassured members that a comprehensive security and audit framework would be established to ensure safe and secure operation of the System. Individual

HCPs should also take reasonable steps to ensure that their local eMR/ePR systems connecting to the sharing platform would not impair the security or compromise the integrity of the System, and conduct data checks after inputting or correcting eHR data to ensure data accuracy.

Scope of data for eHR sharing

10. Members expressed diverse views on the incorporation of sensitive data into the System. Some members considered that sensitive health data should not be categorized as sharable data in the System, in order to protect HCRs' privacy. Some other members, however, were of the view that the exclusion of certain sensitive health data might affect the quality of care provided to HCRs.

11. The Administration stressed that the voluntary participation of HCRs in the System would provide flexibility for the patients to control access to their health data. Only prescribed HCPs with consent obtained from HCRs could access records in the System on a "need-to-know" basis and their access would be regulated to ensure compliance with the security requirements of the System. On the sharable scope of data, the Administration considered it important to ensure the completeness and integrity of eHR data in order to ensure the quality of healthcare delivery. The Administration would conduct further study on additional access control over sensitive data with reference to overseas experience.

Access to eHR data by HCRs

12. Members were concerned about HCRs' right to access to, and to give or withdraw their consent for sharing of, their own eHR data. They were of the view that HCRs as data subjects should be allowed to access a complete and accurate set of their eHR data. Concern was also raised about the charges imposed upon HCRs for the access to eHR data.

13. According to the Administration, a simple application mechanism would be put in place to allow HCRs to easily gain access to their eHR data. Given that the administrative cost for producing patients' eHR would be minimal, it was envisaged that the fee for data access request would not be high. Given that participation in eHR sharing was on a voluntary basis, registered HCRs might withdraw their joining or sharing consent at any time.

14. On the suggestion that prescribed HCPs should be held legally liable if they failed to input complete records of participating HCRs into the System, the Administration advised that healthcare professionals had the responsibility to maintain a complete and accurate set of medical records of their patients. They should upload the pre-defined scope of health data of the participating HCRs

onto the System. For data that fell outside the scope of sharable eHR, they could be retained in the HCPs' paper records or their own eMR/ePR systems.

Operating body

15. Members noted that the System would be run by an eHR Sharing System operating body ("eHR-OB"). Concern was raised over the governance of eHR-OB and the membership of its management board. Some members considered that eHR-OB should be established as a statutory authority placed under HA to leverage the system expertise of HA to provide support for the development of the System and ensure the security of patients' health data. Some other members however suggested that eHR-OB should be set up as an independent governing body.

16. According to the Administration, eHR-OB would be set up under the proposed legislation and empowered to commission security audits in the relevant electronic record system and the internal access control systems of participating health providers. While eHR-OB would not be placed under HA but the Food and Health Bureau, it would leverage HA's expertise and experience to develop and improve the System. Representatives from the healthcare sector and patient groups would be invited to participate in the institutional set up as appropriate. Members were subsequently advised that a public officer would be appointed as the eHR Commissioner for the management, operation and further development of the System.

Participation of private HCPs

17. Members expressed concern on the readiness of private hospitals and doctors to participate in eHR sharing. There was a suggestion that incentives should be provided for private HCPs, particularly medical practitioners in solo practice who maintained a large volume of paper-based patients' records and had to bear a high cost to convert them into electronic records, to participate in eHR sharing. There was also a view that the architectural design of eHR should enable the processing of Chinese characters in order to facilitate the participation of Chinese Medicine Practitioners ("CMPs") in the future.

18. The Administration advised that the Hong Kong Medical Association and the Hong Kong Doctors Union were supportive of eHR development. The Administration had engaged all private hospitals in a task force concerning the deployment of the Clinical Management System ("CMS") Adaptation modules. To encourage the participation of private doctors, the Administration would bear the costs for developing the System and provide the appropriate training and technical support to private doctors. It was believed that the hardware costs to be borne by private doctors participating in eHR sharing should not be

substantial. In addition, efforts had been and would continuously be made to incorporate the use of eHR in various subsidized healthcare schemes and public-private-partnership projects to promote eHR sharing to private HCPs. It would also ensure the availability of eHR-compatible eMR/ePR systems and other health information systems in the market for private doctors, clinics and other healthcare providers to connect to the eHR sharing platform. While CMPs would not be covered at the initial stage, it was expected that with better standardization of terminologies and the inclusion of CMPs in the Elderly Health Care Voucher Pilot Scheme, more CMPs would become used to storing medical records in electronic mode.

Manpower support for implementing the System

19. Concern was raised as to whether the implementation of the System would lead to a brain drain of health information technology ("health IT") professional from HA to private healthcare providers. There was a view that the Administration should increase engagement of the information technology ("IT") sector in the subsequent stages of the development programme to promote the development of the health IT industry.

20. The Administration advised that while the eHR sharing infrastructure core component would be leveraged upon HA's expertise and know-how, the CMS Extension modules would be developed predominantly by professionals of the IT service sector. It had discussed with tertiary institutions the provision of degree courses in health IT with a view to building up a larger workforce in the health IT field in the future.

Relevant papers

21. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

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Appendix

Relevant papers on the Electronic Health Record Sharing System Bill

Committee	Date of meeting	Paper
Panel on Health Services	9.3.2009 (Item IV)	Agenda Minutes CB(2)1724/08-09(01)
Panel on Health Services	19.6.2009 (Item II)	Agenda Minutes CB(2)2101/08-09(01)
Panel on Health Services	12.12.2011 (Item IV)	Agenda Minutes
Panel on Health Services	11.6.2012 (Item IV)	Agenda Minutes
Panel on Health Services	18.3.2013 (Item VI)	Agenda Minutes
Panel on Health Services	20.1.2014 (Item III)	Agenda Minutes
Panel on Health Services	4 March 2014*	CB(2)993/13-14(01) CB(2)993/13-14(02) *(restricted to the reference of members only)*

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