Bills Committee on Electronic Health Record Sharing System Bill

Summary of issues involving major proposed amendments to the Bill raised by members and/or the Privacy Commissioner for Personal Data and the Administration's position

Views from members and/or the Privacy	The Administration's latest position	Draft Committee Stage
Commissioner for Personal Data		amendments to the Bill
Clause 16 - Sharing consent taken to be given		
Pursuant to clause 16(1) and (2), a healthcare recipient ("HCR") or a substitute decision maker ("SDM") of an HCR was taken to have given a sharing consent to the Hospital Authority ("HA") and the Department of Health ("DH") when the HCR or SDM concerned gave a joining consent. Some members were of the view that the above provision should be amended to the effect that an HCR or his/her SDM was allowed to opt out from this arrangement.	in the public sector serving the largest number of patients, held a vast amount of health data which would be the essential building blocks of the life-long electronic health record ("eHR") of registered HCRs. While the opt-out arrangement (the implementation of which would require modifying the design of the Electronic Health	Nil

Please refer to item (b) of LC Paper No. CB(2)2308/13-14(02) for details of the Administration's response.

Views from members and/or the Privacy		The Administration's latest position	Draft Committee Stage
Commissioner for Personal Data			amendments to the Bill
Proposed new Division 3A: Sharing restriction			
(a) The Privacy Commissioner for Personal Data	(a)	The full development plan of the System was	Draft CSAs proposed by the
("the Privacy Commissioner") and some		a 10-year programme which straddled from	Administration, which
members were of the strong view that		2009-2010 to 2018-2019 and comprising two	according to the
registered HCRs should be provided with		stages. The "safe deposit box" feature was	Administration, was
additional access control over their health		not included as an item in the scope of Stage	agreeable to the Privacy
data contained in their eHR (viz. the		One of the Electronic Health Record	Commissioner, are in
provision of a "safe deposit box" feature for		Programme (from 2009-2010 to 2013-2014).	Annex I.
separate storage of certain health data), in		The Administration would conduct, in the	
order to uphold their right not to disclose		first year of Stage Two of the Programme, a	
certain health data to the prescribed HCPs and		study on enhancing HCRs' choice along a	
protect them from discrimination which		positive direction, with a view to developing	
otherwise could result from inadequate access		and implementing some form of new device	
control of particularly sensitive health data.		or arrangement enabling additional choice for	
Specifically, the Privacy Commissioner		registered HCRs over the disclosure of their	
suggested (i) adding a new subclause to		data. The Administration would introduce	
clause 12 to allow a registered HCR to		Committee Stage amendments ("CSAs") to the	
exercise control over the consent given by		Bill to add a definition for "sharing restriction	
him/her to share his/her data; and (ii) adding a		request" under clause 2; and a new division	
definition for "sharing control" under clause 2		3A in the Bill in order to stipulate the spirit of	
to allow the Secretary for Food and Health to		fostering HCRs' choice over data sharing in	
determine or specify the appropriate form of		the Bill, but at the same time not pre-empting	
control by way of gazette. ²		the future design of the relevant feature. ³	
(b) There was a question from members as to	(b)	While the issue of withholding otherwise	
whether clause 12(6) as presently drafted		sharable data in the System would be	

Please refer to paragraphs 9 to 11 of LC Paper No. CB(2)1580/13-14(03), pages 4-7 of LC Paper No. CB(2)2045/13-14(01) and LC Paper No. CB(2)436/14-15(01) for details of the Privacy Commissioner's views.

Please refer to item (a) of LC Paper No. CB(2)404/14-15(02) and item (ii) of LC Paper No. CB(2)808/14-15(02) for details of the Administration's response.

Views from members and/or the Privacy Commissioner for Personal Data	The Administration's latest position	Draft Committee Stage amendments to the Bill
would render it not viable for HCRs to request prescribed HCPs and referral HCPs to which they had given a sharing consent, not to provide to the System certain parts of their health data within the sharable scope.	addressed in the above study, it should be noted that clause 12(6) as presently drafted did not preclude HCRs from making requests for withholding particular data. Whether such request would/could be entertained was a matter to be considered by the HCP concerned, depending on the professional clinical judgment of the relevant healthcare professionals, the particular clinical workflow of the HCP concerned, and whether the local electronic medical record ("eMR") system of that HCP was technically capable of doing so. ⁴	
Clauses 17 and 20 - Application by HCPs for reg	istration and registration of Government bureaux	and departments as HCPs
Clause 17(5)(g) provided that an HCP provided healthcare at one service location if the HCP	(a) Subject to members' views, the	Draft CSAs proposed by the Administration are in
concerned was a specified entity that, in the opinion of the Commissioner for the Electronic	delete clause 17(5)(g).	Annex II.
Health Record ("the Commissioner"), directly or indirectly provided healthcare to any HCR at one premises. The HCP concerned might apply to the Commissioner to be registered as an HCP for the System for that location. Clause 20(1) provided that the Commissioner might register a Government bureau or department as an HCP for the System if the Commissioner was satisfied that the operation of the bureau or department involved providing	(b) Clause 20 was drafted mainly to cater for Government departments which would provide healthcare to detainees, such as the Immigration Department and the Correctional Services Department. Subject to members' views, the Administration would introduce CSAs to amend the clause to subject Government departments to similar criteria on the provision of healthcare as required of	

Please refer to item (b) of LC Paper No. CB(2)404/14-15(02) for details of the Administration's response.

Views from members and/or the Privacy Commissioner for Personal Data	The Administration's latest position	Draft Committee Stage amendments to the Bill
healthcare. The Privacy Commissioner and some members were concerned that the above arrangements were too loose which would in effect widen the sharing of the HCR's eHR. They suggested that clauses 17(5)(g) and 20 should be deleted. In addition, the definition of "specified entity" under clause 17(6) should be expanded to subject Government bureaux or departments to similar criteria on the provision of healthcare as required of other HCPs for registration for eHRSS under clause 17(5)(f). ⁵		
Proposed new clause 35A: Prescribed HCP's dut	ty to restrict access to sharable data	
were of the view that the cardinal principle that access to eHR in the System by individual healthcare professionals would only be made on a	0	Draft CSAs proposed by the Administration, which according to the Administration, was agreeable to the Privacy Commissioner, are in Annex III.

Please refer to paragraph 12 of LC Paper No. CB(2)1580/13-14(03) and pages 7 and 8 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views.

Please refer to paragraphs 7 to 9 of LC Paper No. CB(2)1580/13-14(02), pages 3 and 4 of LC Paper No. CB(2)2045/13-14(01), LC Paper Nos. CB(2)2317/13-14(01) and CB(2)436/14-15(01) for details of the Privacy Commissioner's views.

Please refer to item (iii) of LC Paper No. CB(2)1775/13-14(02), Annex to LC Paper No. CB(2)2308/13-14 (02) and item (i) of LC Paper No. CB(2)808/14-15(02) for details of the Administration's response.

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Views from members and/or the Privacy	The Administration's latest position	Draft Committee Stage
Commissioner for Personal Data		amendments to the Bill
Clause 38: Access to and correction of data or in		
Pursuant to section 17A of the Personal Data (Privacy) Ordinance (Cap. 486) ("the Privacy Ordinance"), a person authorized in writing by the data subject could make a data access request or data correction request on behalf of the data subject. Clause 38 specifically excluded the application of section 17A of the Privacy Ordinance to eHR kept in the System. The Privacy Commissioner objected to clause 38, as rights to data access or data correction were crucial for the protection of individuals' personal data. Clause 38 would also give rise to an inconsistent treatment of health data under the Bill and the Privacy Ordinance which would cause confusion.	The Administration was open to views as to whether clause 38 should be retained or removed. Subject to members' views, it would introduce CSAs to delete clause 38 and the related clause 37(2)(a). 10	Draft CSAs proposed by the Administration are in Annex IV.
Clause 41: Offences relating to accessing, damag	ing or modifying data or information	
Unauthorized access by non-computer means		
(a) Pursuant to clause 41(1), it would be an offence if a person knowingly caused a computer to perform a function so as to obtain unauthorized access to data or information contained in an eHR. The Privacy Commissioner considered that unauthorized access by means other than the use of a computer should also be an offence.	(a) Access to the System was mainly through computers. Unauthorized access to an eHR alone by non-computer means was not a premeditated act. To criminalize the mere act of "unauthorized access" not followed by any malicious act could arguably be disproportionate.	Nil

Please refer to paragraphs 13 to 15 of LC Paper No. CB(2)1580/13-14(03) and pages 8 and 9 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views. Please refer to item (vi) of LC Paper No. CB(2)1775/13-14(02) and Annex to LC Paper No. CB(2)2308/13-14 (02) for details of the Administration's response.

Views from members and/or the Privacy Commissioner for Personal Data	The Administration's latest position	Draft Committee Stage amendments to the Bill
(b) During the public consultation for the review of the Privacy Ordinance in 2010, a more stringent regulatory regime for sensitive personal data (including health data) was proposed but the proposal was not taken forward by the Administration. One of the reasons was that there were no mainstream views in the community on the scope of sensitive personal data. There should, however, be little argument that health data was sensitive in nature. ¹¹	(b) Data not directly obtained from the System should not be governed by any offence provision under the Bill. At present, the mere act of accessing one's personal data without consent was not an offence under the Privacy Ordinance. If it was considered that unauthorized access of personal data without subsequent malicious act in general should be criminalized, amendments should be made to the Privacy Ordinance. 12	
Misuse of eHR data in general		
(a) The Privacy Commissioner proposed that misuse of data or information contained in an eHR for purposes unrelated to the healthcare of an HCR (in addition to the use of eHR data for direct marketing purpose as provided under clause 46) should be made an offence given the sensitivity of health data. In particular, the person misusing the data could be different from the person making the unauthorized access in the first place.	 (a) It might not be appropriate to impose an offence on misuse of eHR in general, as there were different extents and various scenarios of "misuse" which carried a broad meaning. In addition, it was debatable whether all "misuses" should be penalized or even criminalized. (b) Misuse of personal data was generally governed by the Data Protection Principle ("DPPs") under the Privacy Ordinance. In 	Nil
(b) Section 64(1) of the Privacy Ordinance provided that it was an offence for a person to disclose any personal data of a data subject	particular, contravention of DPP3 was not an offence unless the data user failed to comply with the relevant enforcement notice issued	

Please refer to paragraph 16 of LC Paper No. CB(2)1580/13-14(03) and pages 9 and 10 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views.
Please refer to paragraphs 34 to 36 under item (vii) of LC Paper No. CB(2)1775/13-14(02) for details of the Administration's response.

Views from members and/or the Privacy Commissioner for Personal Data which was obtained from a data user without the data user's consent if certain conditions were fulfilled. Its application to small HCPs was further limited where the wrongdoer was the data user and hence, the issue of consent would not arise. 13	by the Privacy Commissioner. While making contravention of a DPP an offence was proposed in the public consultation for the review of the Privacy Ordinance in 2010, the proposal was not pursued as the majority view received was against it. ¹⁴	Draft Committee Stage amendments to the Bill
Penalty for unauthorized access by non-computer in The Privacy Commissioner proposed that if the Administration considered that the criminal sanction for unauthorized access by non-computer means and misuse of eHR data was too harsh, consideration could be given to introducing other penalties. The practice in Australia where misuse of eHR could be subject to civil penalty might serve as a reference. 15	It might not be appropriate to empower the Commissioner, a non-judicial authority, to impose monetary penalty generally on "misuses of eHR data" couched in broad terms. In addition, the imposition of a financial penalty similar to "civil penalty" in Australia was not common in the legal regime of Hong Kong. 16	Nil
Clause 53(2): Establishment of the Electronic He Some members suggested that the precise composition of members of the Electronic Health Record Research Board should be specified under clause 53(2) with a view to ensuring that the 10 non-ex officio members to be appointed by the Secretary for Food and Health would be drawn from various fields.	The Administration would introduce CSAs to amend clauses 53(2) to elaborate on the specific requirements for the 10 non-ex officio members of the Electronic Health Record Research Board. ¹⁷	3

Please refer to paragraphs 17 and 18 of LC Paper No. CB(2)1580/13-14(03) and pages 11 and 12 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views. Please refer to paragraphs 37 and 38 of LC Paper No. CB(2)1775/13-14(02) and paragraphs 13 to 15 of LC Paper No. CB(2)2045/13-14(03) for details of the Administration's response. Please refer to page 10 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views. Please refer to paragraphs 13 and 15 of LC Paper No. CB(2)2045/13-14(03) for details of the Administration's response. Please refer to item (d) of LC Paper No. CB(2)1775/13-14(03) for details of the Administration's response.

Views from members and/or the Privacy	The Administration's latest position	Draft Committee Stage
Commissioner for Personal Data		amendments to the Bill
Clause 57(2): Limitation of public liability		
Clause 57(2) of the Bill stipulated that the	The Administration advised that, subject to	Draft CSAs proposed by the
Commissioner was not obliged to inspect, or	members' views, it would introduce CSAs to	Administration are in
commit to inspect, an eMR system to ascertain	delete clause 57(2).	Annex V.
(a) whether the ordinance was complied with; or		
(b) whether any sharable data provided to the		
System was accurate. The Privacy Commissioner		
objected to this provision, as it called in question		
how the Commissioner could exercise the		
supervisory and oversight role effectively. The		
provision would also reduce the Privacy		
Commissioner's enforcement power that might be		
invoked against the Commissioner to ensure the		
latter's compliance with the Privacy Ordinance.		
In addition, ensuring the integrity of eHR in the		
System was the obligation of the Commissioner		
as a data user under DPP4 and DPP(2)1 of the		
Privacy Ordinance. 18		

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Please refer to paragraphs 19 to 25 of LC Paper No. CB(2)1580/13-14(03) and pages 12 to 15 of LC Paper No. CB(2)2045/13-14(01) for details of the Privacy Commissioner's views.

Draft Committee Stage amendments to the Bill in relation to registered healthcare recipients' choice over data sharing¹

(Note: The proposed amendments are marked in *italic and underline type* or with deletion line)

Add a definition for "sharing restriction request" under clause 2

2. Interpretation(1) In this Ordinance—

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

Add a new subclause (3)(e) and new subclauses (5)(g) and (h) under clause 3

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—

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- (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.

¹ The Administration has advised that the new provisions will be arranged to take effect only upon completion of the future study on enhancing registered healthcare recipients' choice and after such feature enabling additional choice for registered healthcare recipients over the disclosure of their data is technically ready.

Add a new Division 3A

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).

Draft Committee Stage amendments to the Bill in relation to application by healthcare providers for registration and registration of Government departments as healthcare providers

(Note: The proposed amendments are marked in *italic and underline type* or with deletion line)

Delete subclause (5)(g) under clause 17

17. Application by healthcare providers for registration

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- (5) For the purposes of this section, a healthcare provider provides healthcare at one service location if the healthcare provider—
 - (e) holds a licence issued under section 7(2)(a), or a certificate of exemption issued under section 11(2)(a), of the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613) in respect of one residential care home for persons with disabilities, and engages a healthcare professional to perform healthcare at that home; *or*
 - (f) is a specified entity that engages a healthcare professional to perform healthcare at one premises; or.
 - (g) is a specified entity that, in the Commissioner's opinion, directly or indirectly provides healthcare to any healthcare recipient at one premises.

Amend the heading of and subclause (1) under clause 20

20. Registration of Government bureaux and departments as healthcare providers

- (1) The Commissioner may register a Government bureau or department as a healthcare provider for the System if the Commissioner is satisfied that the operation of the bureau or department involves providing healthcare the department provides a healthcare professional to perform healthcare for any healthcare recipient.
- (2) The reference of a department in subsection (1) does not include the Department of Health.

Draft Committee Stage amendments to the Bill in relation to prescribed healthcare provider's duty to restrict access to sharable data

(Note: The proposed amendments are marked in <u>italic and underline type</u>)

Add a new clause 35A

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.

Draft Committee Stage amendments to the Bill in relation to access to and correction of data or information

(Note: The proposed amendments are marked with deletion line)

Delete subclause (2)(a) under clause 37

37. Privacy Commissioner's performance of functions or exercise of powers in relation to data or information

- (1) If the Privacy Commissioner performs a function or exercises a power under the Privacy Ordinance in relation to data or information contained in the System, the Privacy Commissioner must do so subject to the conditions specified in subsection (2).
- (2) The conditions are
 - (a) Part 5 of the Privacy Ordinance has effect as provided under section 38:

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Delete clause 38

38. Access to and correction of data or information

Part 5 of the Privacy Ordinance applies to the access to or correction of the data or information contained in the electronic health record of a registered healthcare recipient as if the definition of *relevant person* in section 2(1) of that Ordinance were not modified by section 17A of that Ordinance.

Draft Committee Stage amendments to the Bill in relation to limitation of public liability

(Note: The proposed amendments are marked with deletion line)

Delete subclause (2) under clause 57

57. Limitation of public liability

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- (2) The Commissioner is not obliged to inspect, or commit to inspect, an electronic medical record system to ascertain
 - (a) whether this Ordinance is complied with; or
 - (b) whether any sharable data provided to the System is accurate.