Bills Committee on Electronic Health Record Sharing System Bill

The Administration's Draft Committee Stage Amendments to the Electronic Health Record Sharing System Bill

This paper provides the full set of the Administration's draft proposed Committee Stage Amendments (CSAs) to the Electronic Health Record Sharing System Bill for members' reference.

2. Brief descriptions of the draft CSAs are set out in the table below. The draft CSAs are at <u>Annex A</u>. A marked-up copy incorporating amendments¹ proposed by the CSAs is at <u>Annex B</u>.

Brief descriptions of the draft CSAs

(Note: ALA = Assistant Legal Advisor of the Bills Committee; eHRC = Commissioner for the Electronic Health Record; eHRSS = Electronic Health Record Sharing System; HCP = healthcare provider; HCR = healthcare recipient; PCPD = Privacy Commissioner for Personal Data)

	Provisions to be amended	Brief description of the amendments
1.	Clause 2(1) – definition of "healthcare"; Clause 17 ²	In response to members' suggestion, to relax the geographical restriction in respect of the location of the healthcare performed (i.e. no longer has to be in Hong Kong). This is to allow access to the eHRSS for healthcare in overseas under certain special circumstances.
2.	Clause 2(1) – definition of "immediate family member"	Textual / minor amendment. In response to ALA and members' suggestion, to amend the English text of the term to "family member" to align with the apparent wording of the Chinese text of the term (i.e. " $\bar{x} \wedge $ ").

¹ The marked-up copy is for reference only. It would be necessary to check against the final version of the full set of CSAs to be moved by the Administration.

² Consequential amendments to definition of "healthcare recipient" in Clause 2(1) and Clause 19

	Provisions to be amended	Brief description of the amendments
3.	Clause 2(1) – definition of "使用" in the Chinese text	Textual / minor amendment.
		In response to ALA's suggestion, a technical amendment to add " $\cdot \pi$ " after the definition of " $\notin \pi$ " in the Chinese text.
4.	Clause 2(1) – definition of "醫護接受者" in the	Textual / minor amendment.
	Chinese text	In response to ALA's suggestion, to amend the Chinese text to better align the apparent wording of the bilingual texts of the definition of the term "醫護接受者" / "healthcare recipient".
5.	Clause 3	In response to members' suggestion, to amend Clause 3 to add a person "residing with" a healthcare recipient "who accompanies the healthcare recipient at the relevant time" as an eligible "substitute decision maker" of the HCR.
6.	Clause 3	Textual / minor amendment.
		In response to ALA's suggestion, to replace "法 庭" with "法院" in the Chinese text so as to tally with the wording used in the Guardianship of Minors Ordinance (Cap. 13).
7.	Clauses 10 and 22	In response to ALA's suggestion, to amend Clauses 10 and 22 to provide for a time limit of the suspension period of the registration of an HCR/HCP for the sake of clarity. The suspension would be for an initial period of not more than 28 days, and can be extended once only for not more than 28 days if the eHRC considers appropriate.

	Provisions to be amended	Brief description of the amendments
8.	Clauses 11 and 23	In response to ALA's suggestion, to amend Clauses 11 and 23 to provide expressly that an HCR/HCP would be given an opportunity to make representation before the eHRC made a decision on cancellation of the registration of the HCR/HCP.
9.	Clauses 16A and 16B (new) ³	In response to members and PCPD's suggestion, to add the new clauses to stipulate the spirit of fostering patient choice over data sharing in the bill. The new provisions will take effect 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 ready. To address Dr Hon Leung Ka-lau's concern expressed at the meeting on 26 May 2015, we will now add "Despite anything contained in sections 12 and 16" at the beginning of the new Clause 16A(1) to provide more clarity that the new clauses would have effect notwithstanding relevant existing clauses.
10.	Clause 17(5)(g)	In response to PCPD's suggestion, to remove the sub-clause, which is a residual provision that allows registration as an HCP by a specified entity that, in the opinion of the eHRC, directly or indirectly provides healthcare to any HCR.

³ Consequential amendments to Clause 3

	Provisions to be amended	Brief description of the amendments
11.	Clause 20(1) ⁴	In response to PCPD's suggestion, to amend Clause 20(1) to subject Government departments to similar criteria on the provision of healthcare as required of other HCPs for registration for eHRSS under Clause 17.
12.	Clause 21(1)	Textual / minor amendment. To amend the Chinese text to better align with the English text on "a registration" (i.e. "登記醫 護提供者可要求讓其該提供者就其某登記 出互通系統。").
13.	Clause 35	In response to members' suggestion, to delete the clause for better clarity and conciseness. The deletion of the clause would not affect the operation of Clauses $22(1)(e) / 23(1)(e)$.
14.	Clause 35A (new)	In response to members and PCPD's suggestion, to add the new clause to reflect better the "need-to-know" principle in the bill.
15.	Clauses 37(2) and 38	In response to members and PCPD's suggestion, to delete Clauses 37(2) and 38 to remove the prohibition on a person authorized in writing by the data subject (HCR) from making a data access request / data correction request to data of the HCR contained in eHRSS. This re-aligns with the practice of the Personal Data (Privacy) Ordinance (Cap. 486).

 $^{^4}$ Consequential amendments to definitions of "registered healthcare provider" and "registration" in Clause 2(1) and to Clause 22(3)

	Provisions to be amended	Brief description of the amendments
16.	Clause 43	Textual / minor amendment.
		In response to ALA's suggestion, a technical amendment to replace "捏改" with "捏改" in the Chinese text.
17.	Clauses 46(8) and 46(9)	Textual / minor amendment.
		In response to ALA's suggestion, to amend "healthcare services" to "health care services" and make it clear that the term has the same meaning as in Sections 35B and 35I of Cap. 486.
18.	Clause 50	In response to members' suggestion, to expand the scope of records or documents that eHRC could require an HCP to provide to cover those "in the possession or under the control" of the HCP.
		In response to ALA suggestion, to subject the Hospital Authority and the Department of Health, in addition to registered HCPs, to the requirement to provide records or documents.
19.	Clause 53	Arising from the Bills Committee's discussion on the membership composition of the Electronic Health Record Research Board, to add new sub-clause (2A) to elaborate on the specific requirements for the "not more than 10 other members" appointed by the Secretary for Food and Health" under sub-clause (2)(c).
		In response to ALA suggestion, to amend sub-clause (3) and add new sub-clauses (3A), (5A) and (5B) to provide expressly in the bill the term of appointment, re-appointment, removal

	Provisions to be amended	Brief description of the amendments
		and notice of appointment of the aforementioned members.
20.	Clause 57(1)	In response to ALA's suggestion, to amend the formulation "is not liable" to "does not incur any civil liability" to make it clear that the liability that Clause 57(1) seeks to limit is only civil liability.
21.	Clause 57(2)	In response to PCPD's suggestion, to delete the sub-clause, which provides that the eHRC is not obliged to inspect the local electronic medical record systems of HCPs to ascertain compliance with the eHRSS Ordinance or accuracy of data provided to eHRSS and was intended for preventing possible unmeritorious litigations against the Government.
22.	Clause 58(3)(b)	In response to ALA's concern on the scope of protection of this sub-clause, to replace "a person appointed by the Commissioner under section 48(3)" with "an employee of the Hospital Authority, or an employee of a body corporate established by the Hospital Authority under Section 5(n) of the Hospital Authority Ordinance (Cap. 113), appointed by the Commissioner under section 48(3)" so as to narrow down the persons to be conferred protection under Clause 58.

Food and Health Bureau May 2015

Annex A

Electronic Health Record Sharing System Bill

Committee Stage

Amendments to be moved by the Secretary for Food and Health

<u>Clause</u>	Amendment Proposed
2(1)	In the definition of <i>healthcare</i> , by deleting "in Hong Kong".
2(1)	In the definition of <i>healthcare recipient</i> , by adding "in Hong Kong" after "be performed".
2(1)	In the definition of <i>registered healthcare provider</i> , in paragraph (b), by deleting "bureau or".
2(1)	In the definition of <i>registration</i> , in paragraph (c), by deleting "bureau or" (wherever appearing).
2(1)	In the Chinese text, in the definition of <i>使用</i> , by adding "、 <i>用</i> " after " <i>使用</i> ".
2(1)	In the Chinese text, in the definition of 醫護接受者 , by deleting everything after "指" and substituting "屬已經、正在或相當可能會在香港進行的醫護服務的對象的個人;".
2(1)	By deleting the definition of <i>immediate family</i> member.
2(1)	By adding in alphabetical order—
	"family member (家人), in relation to a healthcare recipient, means an individual who is related to the recipient by blood, marriage, adoption or affinity;
	sharing restriction request (互通限制要求) means a request

made under section 16A(1)(a);".

- 3(2)(d) By deleting "an immediate family member of the healthcare recipient" and substituting "a family member of the healthcare recipient, or a person residing with the healthcare recipient,".
- 3(3)(d) By deleting the full stop and substituting a semicolon.
- 3(3) By adding—
 - "(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).".
- 3(4)(f) By deleting "an immediate family member of the healthcare recipient" and substituting "a family member of the healthcare recipient, or a person residing with the healthcare recipient,".
- 3(5) In the definition of *relevant time*, in paragraph (f), by deleting the full stop and substituting a semicolon.
- 3(5) In the definition of *relevant time*, by adding—
 - "(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.".
- 3 In the Chinese text, by deleting "法庭" (wherever appearing) and substituting "法院".
- 10(1) By adding "for a period of not more than 28 days" before "if the".
- 10 By adding—
 - "(1A) Despite subsection (1), if the Commissioner considers it appropriate, the Commissioner may extend the period of suspension under that subsection for a further period

of not more than 28 days by notice in writing to the specified person.".

- 11(2) By deleting everything before "the Commissioner" and substituting—
 - "(2) Except for a cancellation under subsection (1)(e),".
- 11(2) By deleting paragraph (a).
- 11(2)(b) By deleting "takes" and substituting "is to take".

11 By adding—

- "(2A) The specified person may, within 14 days after the date of the notice (or such longer period as the Commissioner may allow), make representations to the Commissioner to object to the cancellation in the manner specified in the notice.
 - (2B) The Commissioner must not cancel the registration unless—
 - (a) the specified person has not made any representations under subsection (2A); or
 - (b) the Commissioner has considered the representations and informed the specified person of the decision of cancellation.".

New By adding after Clause 16—

"Division 3A—Sharing Restriction

16A. Request for sharing restriction

- (1) Despite anything contained in sections 12 and 16 and subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may in relation to the health data of the healthcare recipient 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.

- (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 restriction 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 restriction available to the public (in hard copy or electronic form).".
- 17(1) By adding "in Hong Kong" after "service location".
- 17(2) By adding "in Hong Kong" after "service location".
- 17(5)(e) By adding "or" after the semicolon.

- 17(5)(f) By deleting "; or" and substituting a full stop.
- 17(5) By deleting paragraph (g).
- 19(2) By adding "in Hong Kong" after "provides healthcare".
- 20 In the heading, by deleting "**bureaux and**".
- 20(1) By deleting "Government bureau or" and substituting "Government".

20(1) By deleting "operation of the bureau or department involves providing healthcare" and substituting "department provides a healthcare professional to perform healthcare for any healthcare recipient".

- 21(1) In the Chinese text, by deleting "其" and substituting "該提供者就 其某登記".
- 22(1) By adding "for a period of not more than 28 days" before "if the".
- 22 By adding—
 - "(1A) Despite subsection (1), if the Commissioner considers it appropriate, the Commissioner may extend the period of suspension under that subsection for a further period of not more than 28 days by notice in writing to the healthcare provider.".
- 22(3) By deleting "bureau or".

23(2) By deleting everything before "Commissioner" and substituting—"(2) The".

23(2) By deleting paragraph (a).

- 23(2)(b) By deleting "takes" and substituting "is to take".
- 23 By adding—
 - "(2A) The healthcare provider may, within 14 days after the date of the notice (or such longer period as the Commissioner may allow), make representations to the Commissioner to object to the cancellation in the manner specified in the notice.
 - (2B) The Commissioner must not cancel the registration unless—
 - (a) the healthcare provider has not made any representations under subsection (2A); or
 - (b) the Commissioner has considered the representations and informed the healthcare provider of the decision of cancellation.".
- Part 3 In Division 4, in the heading, by deleting "of Electronic Health Record Sharing System" and substituting "for Access to Electronic Health Record".
- 35 By deleting the clause.
- New By adding in Part 3—

"35A. Prescribed healthcare provider's duties to restrict access to health 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 a healthcare professional of the healthcare provider 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.".

- 37(2) By deleting paragraph (a).
- 38 By deleting the clause.
- 43 In the Chinese text, by deleting "捏" and substituting "揑".
- 46(8)(b) In the English text, by deleting "healthcare" and substituting "health care".
- 46(8)(c) In the English text, by deleting "healthcare" and substituting "health care".
- 46(9) In the definition of *direct marketing*, by deleting the full stop and substituting a semicolon.
- 46(9) By adding in alphabetical order—
 "*health care services* (醫護服務) has the same meaning as in sections 35B and 35I of the Privacy Ordinance.".
- 50(1) By deleting "registered" and substituting "prescribed".
- 50(1)(b) By deleting "healthcare provider's possession" and substituting "possession or under the control of the healthcare provider".

53 By adding—

- "(2A) A person may be appointed as a non-ex officio member only if the person is, in the Secretary's opinion, a person—
 - (a) having expertise or experience in healthcare, privacy protection, statistics, research, law or

information technology;

- (b) representing the interests of healthcare recipients; or
- (c) having other experience that would render the person suitable for the appointment.".
- 53(3) By deleting "the period" and substituting "a term of not exceeding 5 years".
- 53 By adding—
 "(3A) A non-ex officio member is eligible for reappointment on the expiry of a term.".

53 By adding—

- "(5A) The Secretary may terminate the office of a non-ex officio member if satisfied that—
 - (a) the member has ceased to be of the capacity because of which he or she was appointed; or
 - (b) the member is otherwise unable or unfit to perform the functions of a member of the Board.
 - (5B) Every appointment or termination under this section is to be notified in the Gazette.".
- 57(1) By deleting "is not liable" and substituting "does not incur any civil liability".
- 57 By deleting subclause (2).
- 58(3) By deleting paragraph (b) and substituting—
 - "(b) an employee of the Hospital Authority, or an employee of a body corporate established by the Hospital Authority under section 5(n) of the Hospital Authority Ordinance (Cap. 113), appointed by the Commissioner under section 48(3)."

Annex B

<u>The Administration's Draft Proposed Committee Stage Amendments</u> to the Electronic Health Record Sharing System Bill

Marked-up copy

2. Interpretation

2. 釋義

- (1) In this Ordinance—
- (1) 在本條例中——

...

. . .

- *healthcare* (醫護服務), in relation to an individual, means an activity performed-in Hong Kong by a healthcare professional for the individual for—
- **醫護服務** (healthcare)就個人而言,指醫護專業人員為以下目的 在香港-對該人 進行的活動 —
- ...

. . .

- *healthcare recipient* (醫護接受者) means an individual for whom healthcare has been performed, is performed, or is likely to be performed<u>in Hong Kong;</u>
- **醫護接受者** (healthcare recipient)指 曾經、正在或相當可能接受醫護服務的個人 屬已經、正在或相當可能會在香港進行的醫護服務的對象的個人;
- •••
- *immediate family member* (家人), in relation to a healthcare recipient, means an individual who is related to the recipient by blood, marriage, adoption or affinity;
- **家人** (immediate family member) 就某醫護接受者而言,指與該接受者有血緣、 婚姻、領養或姻親關係的個人;

•••

...

registered healthcare provider (登記醫護提供者) means—

(b) a Government bureau or department that is registered as a healthcare provider for the System under section 20(1);

登記醫護提供者 (registered healthcare provider) 指——

- (b) 已根據第 20(1) 條,登記為互通系統的醫護提供者的政府 政策局或 部門;
- registration (登記)—

. . .

(c) in relation to a Government-bureau or department, means the registration of the bureau or department as a healthcare provider for the System under section 20(1),

and *registered* (登記) is to be construed accordingly;

登記 (registration) ——

- •••
- (c) 就政府某 政策局或 部門而言,指該 局或 部門根據第 20(1) 條,登記 為互通系統的醫護提供者,

而登記 (registered) 作為形容詞使用時,亦須據此解釋;

•••

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

互通限制要求 (sharing restriction request)指根據第 16A(1)(a)條提出的要求;

使用<u>用</u> (use) 就電子健康紀錄所載的資料或資訊而言,包括披露或移轉該資料或資訊; [Chinese text only]

•••

3. Substitute decision maker

3. 代決人

•••

- (2) For a healthcare recipient who is a minor, the following are eligible persons for the purposes of subsection (1)—
- (2) 如醫護接受者是幼年人,則以下的人屬第(1)款所指的合資格人士——
 - •••
 - (b) 根據《未成年人監護條例》(第 13 章)委任或憑藉該條例而行事的 該接受者的監護人,或獲法 <u>庭-院</u>在其他情況下委任的該接受者的監 護人,而該人在有關時間是陪伴該接受者的;[Chinese text only]
 - (c) 獲法 <u>庭</u>一院委任以處理該接受者的事務的人,而該人在有關時間是陪 伴該接受者的;[Chinese text only]
 - (d) in the absence of the persons mentioned in paragraphs (a), (b) and (c), an immediate family member of the healthcare recipient a family member of the healthcare recipient, or a person residing with the healthcare recipient, who accompanies the healthcare recipient at the relevant time;
 - (d) 如沒有(a)、(b) 及(c)段所述的人——該接受者的家人 · 而該人 · 或 與該接受者同住的人士,而該家人或人士 在有關時間是陪伴該接受 者的;
- •••
- (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)—
- (3) 如醫護接受者年滿 16 歲,並符合任何以下說明,則第(4) 款指明的人屬 第(1) 款所指的合資格人士——

•••

- (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).
- (d) 在第(5) 款的**有關時間**的定義的(d)、(e) 或(f) 段所提述的時間,無能 力給予互通同意 --;
- (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).
- (e) 在第(5)款的**有關時間**的定義的(g)或(h)段所提述的時間,無能力提出 互通限制要求。
- (4) The following are persons specified for the purposes of subsection (3)—
- (4) 為施行第(3)款,現指明以下人士——
 - (e) 獲法 庭 院委任以處理有關醫護接受者的事務的人,而該人在有關時間是陪伴該接受者的;[Chinese text only]
 - (f) in the absence of the persons mentioned in paragraphs (a), (b), (c), (d) and (e), an immediate family member of the healthcare recipient a family member of the healthcare recipient, or a person residing with the healthcare recipient, who accompanies the healthcare recipient at the relevant time;
 - (f) 如沒有(a)、(b)、(c)、(d)及(e)段所述的人——有關醫護接受者的家人 <u>,而該人、或與該接受者同住的人士,而該家人或人士</u>在有關時 間是陪伴該接受者的;
- (5) In this section—
- (5) 在本條中——

...

...

relevant time (有關時間) means—

有關時間 (relevant time)——

- (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-;
- (f) 就根據第 15(1) 條撤銷的互通同意而言,指作出該項撤銷的時間<u>~;</u>
- (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.
- (h) 就根據第 16A(1)(b)條提出的移除限制的要求而言,指提出該要求的 時間。

10. Suspension of healthcare recipient's registration

- The Commissioner may suspend the registration of a healthcare recipient for a period of not more than 28 days if the Commissioner reasonably suspects that—
 ...
- (1A) Despite subsection (1), if the Commissioner considers it appropriate, the Commissioner may extend the period of suspension under that subsection for a further period of not more than 28 days by notice in writing to the specified person.

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10. 暫時吊銷醫護接受者的登記

. . .

- (1) 專員如合理地懷疑有以下情況,可暫時吊銷某醫護接受者的登記,<u>為期不</u> 超過28日—
- (1A) 儘管有第(1)款的規定,專員如認為適當,可藉向指明人士發出書面通知, 將該款所指的暫時吊銷的期間,延長一段為期不超過28日的期間。

11. Cancellation of healthcare recipient's registration

- •••
- (2) After cancelling a registration under subsection (1)(a), (b), (c) or (d), Except for a cancellation under subsection (1)(e), the Commissioner must notify the specified person in writing of—
 - (a) the cancellation;
 - (b) the date on which the cancellation takes is to take effect; and
 - (c) the reasons for the cancellation.
- (2A) The specified person may, within 14 days after the date of the notice (or such longer period as the Commissioner may allow), make representations to the Commissioner to object to the cancellation in the manner specified in the notice.
- (2B) The Commissioner must not cancel the registration unless-
 - (a) the specified person has not made any representations under subsection (2A); or
 - (b) the Commissioner has considered the representations and informed the specified person of the decision of cancellation.

•••

11. 取消醫護接受者的登記

- •••
- (2) 專員在根據第(1)(a)、(b)、(c)或(d)款取消登記後,除在根據第(1)(e)款取消 登記的情況外,專員須將以下事宜,以書面通知指明人士 — (a) 該項取消;
 - (ba) 該項取消 的生效日期 將會於何日生效; 及
 - (eb) 該項取消的理由。
- (2A) 有關指明人士可在上述通知的日期後的 14 日(或專員容許的較長限期)內, 以上述通知指明的方式,向專員作出申述,以反對上述取消。

<u>(2B) 除非 —</u>

 (a) 有關指明人士沒有根據(2A)款作出任何申述;或
 (b) 專員已考慮有關申述,並已將有關取消登記的決定,通知有關指明人 土,
 否則專員不得取消有關登記。

Adding clauses 16A and 16B after clause 16-

Division 3A—Sharing Restriction

16A. Request for sharing restriction

- (1) Despite anything contained in sections 12 and 16 and subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may in relation to the health data of the healthcare recipient 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.
- (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 restriction 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 restriction available to the public (in hard copy or electronic form).

在第16條後加入新的第16A及16B條—

<u>第3A分部—互通限制</u>

<u>16A. 要求限制互通</u>

- (1) 儘管有第 12 及 16 條所載的任何規定及除第(2)及(3)款另有規定外,登記 醫護接受者或登記醫護接受者的代決人,可就該接受者的健康資料,提出 以下要求——(1) 要求許容別互達第第一,又以唱作1: 求
 - (a) 要求對資料互通範圍,予以限制;或

(b) 要求移除對資料互通範圍的限制。

- (2) 如醫護接受者是幼年人,則除非專員信納該接受者有能力提出上述要求, 否則該要求須由該接受者的代決人提出。
- (3) 如醫護接受者年滿 16 歲,並且無能力提出上述要求,則該要求須由該接 受者的代決人提出。
- (4) 由登記醫護接受者的代決人提出的要求,是該代決人代表該接受者提出 的,並且是以該接受者的名義提出的。
- (5) 登記醫護接受者的代決人在提出要求時,須顧及該接受者在有關情況下的 最佳利益。
- (6) 要求須按專員指明的格式及方式,向專員提出。
- (7) 專員須將所要求的限制的生效日期,或所要求的限制移除的生效日期,以 書面通知提出要求者。

16B. 專員指明互通限制

- (1) 某人可根據第16A(1)條就何種類限制提出要求,須由專員指明。
- (2) 專員須以印本或電子形式,將列出指明的限制種類的文件的文本,提供予 公眾。

17. Application by healthcare providers for registration

- (1) A healthcare provider that provides healthcare at one service location in Hong Kong may apply to the Commissioner to be registered as a healthcare provider for the System for that location.
- (2) A healthcare provider that provides healthcare at more than one service location in Hong Kong may apply to the Commissioner to be registered as a healthcare provider for the System for those locations as provided in subsection (3).
- • •
- (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.
- •••

17. 醫護提供者申請登記

- (1) 在某一 <u>香港境内的</u>服務地點提供醫護服務的醫護提供者,可向專員提出 申請,要求就該地點,登記為互通系統的醫護提供者。
- (2) 在多於一個 <u>香港境內的</u>服務地點提供醫護服務的醫護提供者,可按第(3) 款的規定,向專員提出申請,要求就該等地點,登記為互通系統的醫護提 供者。

- •••
- (5) 就本條而言,某醫護提供者如符合以下說明,即屬在某一服務地點提供醫 護服務 —
 - •••
 - (e) 持有根據《殘疾人士院舍條例》(第 613 章)第 7(2)(a)條就某一殘疾人 士院舍發出的牌照,或持有根據該條例第 11(2)(a)條就某一殘疾人士 院舍發出的豁免證明書,並有聘用醫護專業人員,在該院舍從事醫護 服務;或
 - (f) 有聘用醫護專業人員,在某一處所從事醫護服務的指明實體;;或。
 - (g) 專員認為符合以下說明的指明實體:在某一處所,直接或間接向醫護 接受者提供醫護服務。

19. Amendment of registration

- •••
- (2) A healthcare provider must not request the registration be amended for a change of the service locations unless the healthcare provider would, after the change, still be registered for all of the service locations at which the healthcare provider provides healthcare <u>in Hong Kong</u>.

•••

19. 修訂登記

- •••
- (2) 醫護提供者要求就服務地點的更改而修訂有關登記,須符合以下先決條件:在該項更改後,該提供者仍會是就所有其 <u>在香港</u>提供醫護服務所在的服務地點登記。

20. Registration of Government-bureaux and departments as healthcare providers

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

20. 將政府 政策局及 部門登記為醫護提供者

- (1) 專員如信納,政府某 政策局或部門 的運作,涉及提供醫護服務 提供醫護 專業人員,以對醫護接受者進行醫護服務,則可將該 局或部門登記為互 通系統的醫護提供者。
- (2) 在第(1)款中提述部門,並不包括衞生署。

21. 醫護提供者退出互通系統 [Chinese text only]

- (1) 登記醫護提供者可要求讓 其該提供者就其某登記 退出互通系統。
- •••

22. Suspension of healthcare provider's registration

- (1) The Commissioner may suspend a registration of a registered healthcare provider for a period of not more than 28 days if the Commissioner reasonably suspects that—
- (1A) Despite subsection (1), if the Commissioner considers it appropriate, the Commissioner may extend the period of suspension under that subsection for a further period of not more than 28 days by notice in writing to the healthcare provider.
 - •••

...

- (3) When the registration of a healthcare provider (including a Government-bureau or department) is suspended—
 - (a) new data or information of a registered healthcare recipient may still be provided by the healthcare provider to the System; but
 - (b) the electronic health record of a registered healthcare recipient must not be made available to the healthcare provider through the System.
- •••

22. 暫時吊銷醫護提供者的登記

- (1) 專員如合理地懷疑有以下情況,可暫時吊銷某登記醫護提供者的登記,<u>為</u> <u>期不超過28日</u>—
- •••
- (1A) 儘管有第(1)款的規定,專員如認為適當,可藉向有關醫護提供者發出書面 通知,將該款所指的暫時吊銷的期間,延長一段為期不超過 28 日的期 <u>間。</u>
 - (3) 在某醫護提供者(包括政府某 政策局或部門)的登記被暫時吊銷期間 —
 - •••

. . .

23. Cancellation of healthcare provider's registration

- ...
- (2) After cancelling a registration under subsection (1), the <u>The</u> Commissioner must notify the healthcare provider in writing of—

(a) the cancellation;

- (b) the date on which the cancellation takes is to take effect; and
- (c) the reasons for the cancellation.
- (2A) The healthcare provider may, within 14 days after the date of the notice (or such longer period as the Commissioner may allow), make representations to the Commissioner to object to the cancellation in the manner specified in the notice.
- (2B) The Commissioner must not cancel the registration unless-
 - (a) the healthcare provider has not made any representations under subsection (2A); or
 - (b) the Commissioner has considered the representations and informed the healthcare provider of the decision of cancellation.

(3) If a sharing consent is given to the healthcare provider, the sharing consent ceases to have effect once the cancellation takes effect.

23. 取消醫護提供者的登記

- •••
- (2) 專員 在根據第(1)款取消登記後,須將以下事宜,以書面通知有關醫護提供者
 - (a) 該項取消;
 - (ba) 該項取消 的生效日期 將會於何日生效; 及
 - (eb) 該項取消的理由。
- (2A) 有關醫護提供者可在上述通知的日期後的 14 日(或專員容許的較長限期) 內,以上述通知指明的方式,向專員作出申述,以反對上述取消。
- <u>(2B) 除非 —</u>
 - (a) 有關醫護提供者沒有根據第(2A)款作出任何申述;或
 - (b) 專員已考慮有關申述,並已將有關取消登記的決定,通知有關醫護提 供者,

否則專員不得取消有關登記。

(3) 如有互通同意給予有關醫護提供者,則該同意在有關取消生效之時起失效。

Part 3

Electronic Health Record

Division 4—Safeguards of Electronic Health Record Sharing System for Access to Electronic Health Record

第3部

電子健康紀錄

第4分部 — 對電子健康紀錄互通系統取覽電子健康紀錄的保障

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.

35. 訂明醫護提供者在電子醫療紀錄系統方面的責任

訂明醫護提供者須採取合理步驟,以確保其電子醫療紀錄系統,不會損害互通 系統的保安,或危害互通系統的完整性。

35A. Prescribed healthcare provider's duties to restrict access to health 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 a healthcare professional of the healthcare provider 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.

35A. 訂明醫護提供者限制取覽健康資料的責任

- (1) 如登記醫護接受者或登記醫護接受者的代決人,給予訂明醫護提供者互通 同意,則本條適用。
- (2) 有關醫護提供者須採取合理步驟,以確保
 - (a) 只有可能會對有關醫護接受者進行醫護服務的、該醫護提供者的醫護 專業人員,方可取覽該接受者的健康資料;及
 - (b) 該項取覽的範圍,只限於可能攸關對該接受者進行的醫護服務的健康 資料。
- (3) 然而,為遵守《私隱條例》第5部之下的查閱資料要求或改正資料要求, 即使有醫護專業人員以外的人,獲准取覽有關健康資料,有關醫護提供者 並不視作違反第(2)款的規定。

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;

- (b) a word or an expression used in this Part, and defined or otherwise explained in section 2 of the Privacy Ordinance, has the same meaning as in that section; and
- (c) despite paragraph (b), a reference to a minor in the Privacy Ordinance is a reference to a person below 16 years of age.
- (3) Subsection (2)(b) does not apply to the word "Commissioner".

37. 私隱專員就 資料或資訊執行職能或行使權力

- (1) 如私隱專員根據《私隱條例》,就互通系統所載的資料或資訊,執行職能 或行使權力,則私隱專員須在第(2)款指明的條件的規限下,如此行事。
- (2) 有關條件是 (a)—<u>《私隱條例》第5部按第38條的規定具有效力;</u>
 - (b) 在本部中使用的字或詞句,如在《私隱條例》第2條中有所界定或以 其他方式解釋,則該字或詞句的涵義,與該字或詞句在該條中的涵義 相同;及

- (c) 儘管有(b)段的規定,在《私隱條例》中提述未成年人,即提述未滿 16歲的人。
- (3) 第(2)(b)款不適用於"專員"一詞。

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.

38. 查閱和改正資料或資訊

《私隱條例》第 5 部適用於登記醫護接受者的電子健康紀錄所載的資料或資訊 的查閱或改正, 猶如該條例第 2(1)條中有關人士的定義, 沒有經該條例第 17A 條修改一樣。

43. 關乎查閱資料要求及改正資料要求的罪行 [Chinese text only]

- (1) 任何人——
 - (a) 更改、<u>提提</u>改、隱藏或銷毀電子健康紀錄所載的資料或資訊;或
 - (b) 指示另一人作出(a)段所述的任何事情,

而該人如此行事的意圖,是就該資料或資訊,規避某查閱資料要求或改正資料要求,該人即屬犯罪。

(2) 任何人犯上述罪行,一經循簡易程序定罪,可處第6級罰款。

46. Offences relating to direct marketing

- •••
- (7) This section does not apply in relation to the use or provision of data or information contained in an electronic health record, or a copy (in whatever format) of the data or information, by a person if, not for gain, the person uses or provides the data or information, or the copy, for a purpose specified in subsection (8).
- (8) The purpose is the offering, or the advertising of the availability, of—
 - (a) social services run, subvented or subsidized by the Social Welfare Department;
 - (b) <u>healthcare health care</u> services provided or administered by the Department of Health or the Hospital Authority; or [English text only]
 - (c) any other social or <u>healthcare-health care</u> services that, if not provided, would be likely to cause serious harm to the physical or mental health of—
 - (i) the individual to whom the services are intended to be provided; or
 - (ii) any other individual. [English text only]
- (9) In this section—
- (9) 在本條中——
- *direct marketing* (直接促銷) has the meaning given by section 35A(1) of the Privacy Ordinance-;

直接促銷 (direct marketing) 具有《私隱條例》第 35A(1) 條給予該詞的涵 義一;

<u>health care services (醫護服務)</u> has the same meaning as in sections 35B and 35I of the Privacy Ordinance.

醫護服務 (health care services) 的涵義與該詞在《私隱條例》第 35B 及 35I 條 中的涵義相同。

50. Commissioner to require production of records or documents in certain circumstances

- (1) If it appears to the Commissioner that there are circumstances suggesting the happening of an event specified in subsection (2), the Commissioner may in writing require a registered prescribed healthcare provider to produce the record or document—
 - (a) that is or may be relevant to the event; and
 - (b) that is in the <u>healthcare provider's possession possession or under the</u> <u>control of the healthcare provider</u>.

•••

50. 在某些情況下,專員可要求交出紀錄或文件

- (1) 專員如覺得有情況顯示有第(2)款指明的任何事件發生,可藉書面要求 登 記<u>訂明</u>醫護提供者,交出符合以下說明的紀錄或文件—
 - (a) 攸關或可能攸關該事件的;及
 - (b) 由該提供者管有 <u>或控制</u>的。
- •••

53. Establishment of Board

- (1) A board is established with the name "Electronic Health Record Research Board" in English and "電子健康紀錄研究委員會" in Chinese.
- (2) The Board is to consist of the following members—
 - (a) the Permanent Secretary for Food and Health (Health), as ex officio member and chairman;
 - (b) the Commissioner, or a person nominated by the Commissioner as representative, as ex officio member; and
 - (c) not more than 10 other members appointed by the Secretary.
- (2A) A person may be appointed as a non-ex officio member only if the person is, in the Secretary's opinion, a person—
 - (a) having expertise or experience in healthcare, privacy protection, statistics, research, law or information technology;
 - (b) representing the interests of healthcare recipients; or
 - (c) having other experience that would render the person suitable for the appointment.
 - (3) A non-ex officio member may hold office for the period a term of not exceeding <u>5 years</u> and on the terms specified in his or her letter of appointment by the Secretary.

(3A) A non-ex officio member is eligible for reappointment on the expiry of a term.

- (4) A non-ex officio member may resign from the Board by notice in writing to the Secretary.
- (5) Except as provided in this Ordinance, the Board may regulate its procedure and may make standing orders for that purpose.
- (5A) The Secretary may terminate the office of a non-ex officio member if satisfied <u>that</u>
 - (a) the member has ceased to be of the capacity because of which he or she was appointed; or
 - (b) the member is otherwise unable or unfit to perform the functions of a member of the Board.
- (5B) Every appointment or termination under this section is to be notified in the Gazette.
 - (6) In this section—
 - non-ex officio member (非當然委員) means a member of the Board appointed under subsection (2)(c).

53. 研委會的設立

- (1) 現設立一個委員會,其中文名稱為"電子健康紀錄研究委員會",而英文名稱為"Electronic Health Record Research Board"。
- (2) 研委會由以下委員組成
 - (a) 擔任當然委員及主席的食物及衞生局常任秘書長(衞生);
 - (b) 擔任當然委員的專員或由專員提名為其代表的人;及
 - (c) 由局長委任的不多於 10 名的其他委員。
- (2A) 只有符合下述條件的人,方可獲委任為非當然委員
 - (a) 局長認為,該人在醫護服務、私隱保障、統計、研究、法律或資訊 科技方面,具有專長或經驗;
 - (b) 局長認為,該人代表醫護接受者的利益;或
 - (c) 局長認為,該人具有其他經驗而適合獲委任。
 - (3) 非當然委員的任期<u>不超逾5年,</u> 及委任條款 · 由局長在該委員的委任函 中指明。
- (3A) 非當然委員在任期屆滿時,有資格獲再度委任。
- (4) 非當然委員可向局長發出書面通知,辭任委員。
- (5) 除本條例另有規定外,研委會可規管其程序,並可為此訂立會議常規。
- (5A) 局長如信納有以下情況,可終止某非當然委員的職務
 - (a) 該委員因某身分獲委任,但已不再具有該身分;或
 - (b) 該委員因其他原因,不能夠或不適合執行研委會委員的職能。
- (5B) 根據本條作出的每項委任或終止委任,均須在憲報公布。
- (6) 在本條中 —
- 非當然委員 (non-ex officio member)指根據第(2)(c)款委任的研委會委員。

57. Limitation of public liability

- (1) The Government or a public officer-is not liable does not incur any civil liability only because—
 - (a) data or information contained in an electronic health record is used in accordance with this Ordinance;
 - (b) the participation of a healthcare recipient or healthcare provider in the System is subject to the approval by a public officer; or
 - (c) the use of data and information contained in an electronic health record referred to in section 27 is subject to the approval of the Secretary or the Commissioner.
- (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.

57. 限制公職人員的法律責任

- (1) 政府或公職人員不會僅因為以下情況,而 承擔 招致任何民事 法律責任—
 - (a) 按照本條例,使用電子健康紀錄所載的資料或資訊;
 - (b) 醫護接受者或醫護提供者參與互通系統,須獲得公職人員的批准;或
 - (c) 使用電子健康紀錄所載的資料及資訊(第 27 條所提述者),須獲得局 長或專員的批准。
- (2)—專員並無責任檢查或承諾檢查電子醫療紀錄系統,以確定——
 - (a) 本條例是否獲遵守;或
 - (b) 向互通系統提供的任何可互通資料,是否準確。

58. Protection of public officers etc.

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- (3) This section applies to—
 - (a) a public officer; and
 - (b) a person an employee of the Hospital Authority, or an employee of a body corporate established by the Hospital Authority under section 5(n) of the <u>Hospital Authority Ordinance (Cap. 113)</u>, appointed by the Commissioner under section 48(3).

58. 保障公職人員等

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- (3) 本條適用於
 - (a) 公職人員;及
 - (b) <u>獲</u>專員根據第 48(3)條委任的 人醫院管理局僱員,或獲如此委任的、 根據《醫院管理局條例》(第 113 章)第 5(n)條成立的法團的僱員。