

LEGISLATIVE COUNCIL BRIEF

ELECTRONIC HEALTH RECORD SHARING SYSTEM BILL

INTRODUCTION

A At the meeting of the Executive Council on 8 April 2014, the Council ADVISED and the Chief Executive ORDERED that the proposed Electronic Health Record Sharing System Bill (the Bill), at Annex A, should be introduced into the Legislative Council (LegCo).

JUSTIFICATIONS

Electronic Health Record (eHR) Programme

2. An eHR is a record in electronic format containing health-related data or information of an individual. The proposal to develop an eHR sharing system was put forward in the Healthcare Reform Consultation Document “Your Health, Your Life” published in March 2008. It received broad support from the community among other reform proposals. The proposed Electronic Health Record Sharing System (the System), upon commencement of operation, will provide an efficient platform for healthcare providers (HCPs) (e.g. hospitals and clinics) to upload and access individuals’ eHR for healthcare purposes, subject to the individual’s consent.

3. The Government’s road-map is to implement a two-stage programme from 2009-10 to 2018-19 to develop the full System. In July 2009, the Finance Committee of the LegCo approved a capital funding commitment of \$702 million for the first stage of the programme from 2009-10 to 2013-14. The main targets of the first stage are to –

- (a) set up the eHR sharing platform for connecting the participating public and private hospitals;
- (b) make electronic medical record / electronic patient record (eMR/ePR) systems and other health information systems available in the market for private HCPs to connect to the eHR sharing platform; and
- (c) formulate a legal framework to protect data privacy and system security prior to commissioning the System.

To leverage the successful experience and expertise of the Hospital Authority (HA) in developing its Clinical Management System, we have engaged HA as the technical agency for developing the new infrastructure. Subject to the passage of the Bill, we aim to commence operation of the System by end 2014.

Legal, Privacy and Security Framework

4. The Personal Data (Privacy) Ordinance (PDPO) (Cap. 486) sets out the general safeguards for personal data privacy in Hong Kong. There are currently no specific provisions on health-related data. We consider that most provisions of the PDPO should remain applicable to the eHR kept in the new System. However, given the sensitive nature of health records and the unique arrangement of data sharing, we reckon that additional safeguards would be necessary to instill public confidence in the System. We also see the need to set penalties for new offences relating specifically to the operation of the System. A new legislation is therefore prepared to provide for the establishment of the System, sharing and using of data and information contained in the System, the protection of the System, and other incidental and connected matters.

5. Taking into account the requirements of the PDPO, prevailing clinical practices and experience overseas, we formulated a legal, privacy and security framework to govern the sharing of eHR in 2011. We conducted a two-month public consultation on the framework from December 2011 to February 2012. The public responses received reflected general support to the following key concepts and principles –

- (a) Voluntary participation: Only Healthcare Recipients (HCRs) who choose to participate on express and informed consent will have their health data shared through the System. As for HCPs, only those who choose to participate and comply with the requirements for eHR sharing can upload and view data through the System.
- (b) “Patient-under-care” and “need-to-know”: Healthcare professionals of participating HCPs may only access the health data of those HCRs for whom they are delivering care and with consent obtained.
- (c) Pre-defined scope of eHR sharing: Only health data falling within the pre-defined scope for eHR sharing will be shared.
- (d) Identification and authentication of HCR: HCRs will be identified by a centralized HCR Index (HRI) to ensure that health data accessed by HCPs are associated correctly with the HCRs concerned.
- (e) Identification and authentication of HCPs and professionals:

HCPs' eMR/ePR systems will be authenticated. Professionals will also be authenticated by a centralized database compiled on the basis of various professional registers. Different professionals may be granted different extents of access right under the arrangement of role-based access control.

- (f) Role of Government: The Government would take the lead in governing the operation and enforcing the safeguards of the System.
- (g) Versatile and technology-neutral: The legislative framework should be sufficiently versatile and technology-neutral to cater for future advancement in health information technology. Codes of practice (COP) will be devised to provide guidance on the sharing and use of the eHR and set out the operational and security requirements.

We have incorporated these concepts and principles into our legislative proposals and relevant administrative and operational instruments as appropriate.

Legislative Proposals

(A) General provisions

6. The general provisions of the Bill are set out as follows –

- (a) The Bill will define all the key terms including “healthcare”, “healthcare provider”, “healthcare recipient”, “prescribed healthcare provider” (prescribed HCP), and “electronic health record”. Since both patients and healthy individuals may participate in the System, they will be referred to as “registered healthcare recipients” (registered HCRs) rather than “patients”. HCPs participating in the System are referred to as “prescribed HCPs”. Given that the HA and the Department of Health (DH) offer healthcare services to every resident in Hong Kong and that their contribution of HCRs' health information will form the essential building blocks of HCRs' eHR, HA and DH will be stipulated as “prescribed HCPs” by default.
- (b) An HCR's eHR would comprise: (i) the HRI (i.e. the personal particulars of the HCR that identify the HCR, such as name, identity document number and address), (ii) the health data or information of the HCR, and (iii) other data related to the functioning of the System. “Data sharing” refers to the provision and obtaining of the HRI and the health data of a registered HCR through the System.
- (c) Since Government departments may be registered as “prescribed HCPs”, we propose that the Electronic Health

Record Sharing System Ordinance (the Ordinance) should bind the Hong Kong Special Administrative Region Government.

(B) *Establishment of the System*

7. Secretary for Food and Health (SFH) will appoint a public officer as the Commissioner for the Electronic Health Record (eHRC), who will be responsible for the management, operation and further development of the System. The Bill would provide for the establishment of the System by the eHRC. The System will keep a record of every registered HCR and also data or information required for the proper functioning of the System, e.g. access logs.

(C) *Registration of HCR*

“Joining Consent” and “Sharing Consent”

8. We propose that any individual for whom healthcare has been performed, is performed or is likely to be performed, who holds an identity card as defined in the Registration Persons Ordinance (Cap. 177) or any valid identification document as specified by the eHRC, may apply to be registered under the System. Application for registration is based on express and informed consent. This is called the “joining consent”. After giving the “joining consent” to participate in the System, an HCR may give “sharing consent”¹ to any individual prescribed HCP. The proposed arrangement is described as follows –

- (a) An HCR can “authorize” that particular HCP to view and upload his/her eHR.
- (b) The requirement for a prescribed HCP to obtain specific “sharing consent” from an HCR will not be applicable to HA and DH. Consent for HA and DH to view and upload the eHR of any registered HCR is made part and parcel of the HCR’s “joining consent”.
- (c) To cater for healthcare referral, we propose that when a prescribed HCP refers the HCR to another prescribed HCP (e.g. a laboratory to conduct sample tests), the “sharing consent” given to the first-mentioned HCP would cover a consent for the second-mentioned HCP to access the System for particular purposes (e.g. uploading the result of laboratory testing reports).

¹ A sharing consent will be valid either (a) until revocation, or (b) for a one-year period.

Substitute Decision Maker (SDM)

9. Some people may not have the capacity to understand eHR sharing or provide an express consent (e.g. a minor or a person who is mentally incapacitated). We therefore propose introducing the SDM arrangement to facilitate their registration. The key features of the arrangement are as follows -

- (a) In the case of a minor (a person aged below 16 under the Bill), we propose that, in the order of priority, (i) a parent, a guardian², or a person appointed by the Court, or in the absence of the aforementioned, (ii) an immediate family member³ of the minor, who accompanies the HCR at the relevant time, may act as his/her SDM.
- (b) In the case of a person who is mentally incapacitated, incapable of managing his/her own affairs, or incapable of giving a joining consent or a sharing consent, in the order of priority, (i) a guardian⁴ (or a person with guardianship responsibility) or a person appointed by the Court, or in the absence of the aforementioned, (ii) an immediate family member who accompanies the HCR at the relevant time, may act as his/her SDM.
- (c) If none of such SDM is available, we propose that as a last resort, a prescribed HCP providing healthcare to the HCR at the relevant time may act as his/her SDM.

Withdrawal / Suspension / Cancellation

10. Since participation in eHR sharing is on a voluntary basis, a registered HCR or his/her SDM may withdraw his/her joining or sharing consent at any time. Under the circumstances specified in the Bill (e.g. where the registration of an HCR may impair the security or compromise the integrity of the System), the eHRC may suspend or cancel the concerned registration.

(D) Registration of HCP

11. The key provisions on the registration of HCP are as follows –

- (a) Participation of private HCPs in eHR sharing is also on voluntary basis. An HCP that provides healthcare at one or

² For a minor, a guardian appointed under or acting by virtue of the Guardianship of Minors Ordinance (Cap.13) or otherwise appointed by the Court.

³ Defined under the Family Status Discrimination Ordinance (Cap. 527) to be an individual who is related to the healthcare recipient by blood, marriage, adoption or affinity.

⁴ For a mentally incapacitated person, a guardian appointed under the Mental Health Ordinance (Cap. 136), or the Director of Social Welfare.

more than one service locations may apply to the eHRC to be registered as an HCP for the System for all or just a single service location(s). We will allow change of these locations (e.g. address) subject to specific requirements being met. The registration of HCPs would be bound by the administrative COP to be issued by the eHRC and the terms and conditions of participation to be imposed by the eHRC.

- (b) In practice, HCPs providing healthcare may include entities operating hospitals, medical clinics, dental companies, residential care homes, or specified entities⁵ that engage members of the 13 statutorily registered healthcare professionals to deliver healthcare. The list of the statutorily registered healthcare professionals is set out in the Schedule of the Bill. SFH may amend the Schedule by notice in the Gazette.
- (c) A registered HCP may withdraw from the System at any time. On the other hand, the eHRC would also be empowered to suspend or cancel the registration of an HCP under specified circumstances (e.g. contravention of provision of the COP or the HCP no longer provides healthcare at the service location).
- (d) Some Government departments may be involved in healthcare and the eHRC may register these departments as HCPs for the System. They would also need to comply with the COP for HCPs in using the System.

(E) *Security requirement*

12. To ensure security and integrity of the System, prescribed HCPs are required to 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.

(F) *Use of eHR*

13. The authorized uses of eHR data or information include –

- (a) the use for improving the efficiency, quality, continuity or integration of healthcare provided, or to be provided, to the registered HCRs.
- (b) the use for (i) researches and statistics related to public health or public safety and (ii) prevention or control of diseases and enhancement of disease surveillance.

⁵ Clause 17(6) of the Bill defines “specified entity” as an individual, a company, a partnership, a statutory body, a body corporate other than a company, or a society.

- (c) other uses currently allowed under the law (e.g. PDPO). Under the PDPO, uses with prescribed consent obtained as per PDPO (such as professors with HCRs' express consent to use their data for clinical teaching) are allowed. Uses without prescribed consent may also be allowed under emergency situations, for Court proceedings or for crime investigation.

In respect of applications for use of HCR non-identifiable data or information, we propose to empower the eHRC to consider and approve such requests. As for the more sensitive HCR identifiable data or information, SFH will be empowered to approve or refuse relevant applications. We will also set up a Research Board to assess the applications and make recommendations to SFH.

(G) *Interaction with PDPO*

14. eHR data would include “personal data” within the meaning of the PDPO. The key features of interaction of the proposed legislation with the PDPO are –

- (a) the performance of functions or exercising of power of the Privacy Commissioner for Personal Data (PCPD) in relation to the personal data and information in the System will not be affected, except that a reference to a minor in the context of eHR sharing is a reference to a person below 16 years of age.
- (b) for the purpose of access or correction of the data or information in the eHR of a registered HCR, Part 5 of the PDPO applies as if the definition of “relevant person” in section 2(1) of that Ordinance were not modified by section 17A of that Ordinance. The implication is that even “a person authorized in writing” would not be allowed to make a Data Access Request (DAR) or Data Correction Request (DCR) on behalf of a data subject for his/her eHR. This arrangement would facilitate better control of access to eHR.
- (c) where the HCP contributing a certain piece of eHR data is unable to comply with a DCR, the eHRC would attach a note to the concerned data to alert other viewers.
- (d) a contravention of a requirement under the PDPO as amended by Part 4 of this Bill is to be regarded as a contravention of a requirement under the PDPO.

(H) *Offences*

15. The decision of HCRs and HCPs to participate in the System will hinge on their confidence in the security and integrity of the System. After reviewing relevant local legislations and overseas practices, we propose that

new offences specific to the operation of eHR sharing should be introduced. The proposed offences are in respect of a person –

- (a) knowingly causing a computer to perform any function so as to obtain unauthorized access to an eHR (e.g. by hacking into the System or using stolen login particulars);
- (b) knowingly damaging an eHR;
- (c) causing access to, modification of or impairment to an eHR, with the intent to commit an offence, deceive, make dishonest gain or cause loss to another;
- (d) knowingly impairing the operation of the System;
- (e) altering, falsifying, concealing or destroying any data or information in an eHR with the intent to evade a DAR or DCR;
- (f) knowingly making an untrue statement to enable the person to give a joining consent or sharing consent;
- (g) knowingly contravening a research condition; and
- (h) using or providing eHR of another person for direct marketing⁶.

(I) Administration

16. SFH will appoint a public officer to be the eHRC to establish, operate, maintain and develop the System. The eHRC would keep a register of prescribed HCPs and make it available for public inspection. The eHRC may require HCPs to produce records or documents under specified circumstances (e.g. contravention of the Ordinance or the COP) for investigation purpose. The eHRC will also be authorized to publish COP and specify forms.

(J) Appeals

17. HCPs or HCRs who are aggrieved by the eHRC's decision regarding their registration may appeal to the Administrative Appeals Board (AAB). Since the eHRC's office would be set up under the Food and Health Bureau (FHB), its actions would be subject to investigations by the Ombudsman pursuant to the Ombudsman Ordinance (Cap. 397).

(K) Access to Card Face Data

18. We have been implementing the Public Private Interface – Electronic

⁶ Services provided by DH, HA, or run, subvented or subsidized by Social Welfare Department are exempted.

Patient Record Programme as a pilot scheme for eHR sharing. The experience acquired is that the use of Hong Kong Identity Card (HKIC) would facilitate the registration process. We will therefore include a provision in the Bill to the effect that the eHRC and the prescribed HCPs would be regarded as having “lawful authority” pursuant to the Registration of Persons Regulations (Cap. 177A) to gain access to the “card face data”⁷ embedded in the HKIC.

(L) Liability of Government and Public Officers

19. We propose that Government and public officers would not be exempted from the criminal liability of the arising from this Bill. To protect highly sensitive eHR data, acts such as unauthorized access to / use / damaging of eHR by any party should be prohibited and should constitute commission of an offence.

20. As regards civil liability, we consider that public officers should not be liable for an act done in exercising a power or the performance of a function under the Bill in good faith. Given that many of the functions (e.g. operating the System) require professional expertise of non-public officers, we propose that persons appointed in writing by the eHRC to perform particular functions would be similarly covered.

THE BILL

21. The key provisions of the Bill are set out as follows –

Part 1

- (a) **Clause 1** sets out the short title and provides for commencement.
- (b) **Clauses 2 and 3** contain definitions that are necessary for the interpretation of the Bill.
- (c) **Clause 4** provides that the Bill applies to the Government.

Part 2

- (d) **Division 2, Clauses 6-11** deal with the registration and withdrawal of HCRs, the giving of joining consent of HCRs, as well as the suspension and cancellation of the registration of HCRs.
- (e) **Division 3, Clauses 12-16** provide that a registered HCR (or an SDM of the HCR) may give a sharing consent to a prescribed HCP. A sharing consent may be given for an indefinite term or for a term of one year.

⁷ “Card face data” refers to the full name of the person in English and Chinese, date of birth, HKIC number and date of issue.

- (f) **Division 4, Clause 17** deals with the application for registration of HCPs. It sets out what is meant by providing healthcare at one service location and provides for the application in respect of one or more service locations.
- (g) **Division 4, Clauses 18 and 19** deal with registration of HCPs and amendment of registration.
- (h) **Division 4, Clause 20** provides that the eHRC may register any department as an HCP for the System if its operation involves the provision of healthcare.
- (i) **Division 4, Clauses 21-23** deal with the withdrawal, suspension and cancellation of registration of HCPs.

Part 3

- (j) **Division 1, Clauses 25-29** provide for the use of data and information in an eHR for improvement of healthcare, research and statistics, disease surveillance and control, or other purposes as permitted by, or under, any other law.
- (k) **Division 2, Clauses 30 and 31** provide that a person may apply to SFH for using HCR identifiable data or information for research or statistics purposes, and that SFH may refer an application to the Research Board for recommendation. The clauses also set out the matters that the Board must consider when making a recommendation.
- (l) **Division 3, Clause 33** provides that a person may apply to the eHRC for using HCR non-identifiable data or information for research or statistics purposes.
- (m) **Division 4, Clause 35** requires a prescribed HCP to take reasonable steps to ensure its eMR system would not impair the security or compromise the integrity of the System.

Part 4

- (n) **Clause 36** provides that Part 4 applies to data or information that is personal data as defined by section 2 of the PDPO.
- (o) **Clauses 37 and 38** provide for the conditions subject to which the PCPD may perform a function or exercise a power under the PDPO in relation to the data or information contained in the System; and deal with modification of the meaning of “relevant person” when Part 5 of the PDPO applies to the access to or correction of the data or information in the eHR of a registered HCR.

Part 5

- (p) **Clauses 41-46** deal with various offences and their penalties

under the Bill.

Part 6

- (q) **Division 1, Clauses 47 and 48** deal with the appointment, functions and powers of the eHRC.
- (r) **Division 1, Clause 50** empowers the eHRC to require HCPs to produce records or documents in certain circumstances.
- (s) **Division 1, Clauses 51 and 52** enable the eHRC to issue a COP and specify forms.
- (t) **Division 2, Clauses 53 and 54** provide for the establishment and functions of the Research Board.
- (u) **Division 3, Clause 55** provides that a person who is aggrieved by a decision of the eHRC specified in the clause may appeal to the AAB.
- (v) **Division 3, Clause 56** provides for how the eHRC or a prescribed HCP is to be regarded as having lawful authority to gain access to the card face data of the HKIC of a HCR for the purposes of regulation 12(1A) of the Registration of Persons Regulations (Cap. 177 sub. Leg. A).
- (w) **Division 3, Clauses 57 and 58** deal with limitation of public liability and protection of a person performing a function or exercising a power under the Bill in good faith.

Part 7

- (x) **Clauses 62** deals with the amendment to the Schedule to the Administrative Appeals Board Ordinance (Cap. 442).

Schedule

- (y) **The Schedule** sets out the list of healthcare professionals for the purpose of clause 17(5)(d), (e) and (f) of the Bill.

LEGISLATIVE TIMETABLE

22. The legislative timetable will be as follows–

Publication in the Gazette	17 April 2014
First Reading and commencement of Second Reading Debate	30 April 2014
Resumption of Second Reading Debate, Committee Stage and Third Reading	To be notified

IMPLICATIONS OF THE PROPOSAL

23. The proposal is generally in conformity with the Basic Law, including the provisions concerning human rights. There is no productivity or environmental implications. The economic, sustainability, financial and civil service implications are set out at Annex B. As regards family implications, the proposal for the SDM arrangement will allow immediate family members to give substitute joining or sharing consent on behalf of HCR. The proposal will have positive sustainability impact on fostering mutual care of family members, including those with special needs.

B

PUBLIC CONSULTATION

24. We formed a Working Group on Legal, Privacy and Security Issues (WG) under the Steering Committee on eHR Sharing (Steering Committee)⁸. The Steering Committee and the WG comprise representatives of relevant healthcare professional bodies, patient groups, the Office of the PCPD, the Consumer Council, HA, the Office of the Government Chief Information Officer, and DH. The WG and the Steering Committee generally supported the legislative proposals as outlined in paragraphs 6 to 20 above.

25. As mentioned in paragraph 5 above, we have completed a two-month public consultation on the proposals in the legal, privacy and security framework for the System. We briefed the LegCo Panel on Health Services on the outcome of the public consultation and the key features of the Bill on 11 June 2012 and 18 March 2013 respectively. Members were generally supportive of the implementation of the eHR programme and the legal framework proposed.

26. Since September 2013, we have conducted around 50 engagement meetings with healthcare professional bodies, private hospitals, major group practices, non-governmental organisations providing healthcare services, HA, DH, patient groups and academic bodies. We have been explaining to them the legal, privacy and security framework and updating them on the progress of the programme. Responses are generally positive.

PUBLICITY

27. A press release will be issued on 17 April 2014 (gazettal date). A spokesperson will be made available to answer media and public enquiries. Information related to the Bill will be made available online on the eHR Office website.

⁸ To take forward the development of the System, SFH established the Steering Committee on eHR sharing in July 2007 to provide advice to the FHB on the formulation of strategies for the development of the System and the implementation of eHR sharing.

ENQUIRY

28. Any enquiry on this brief can be addressed to Ms Ida Lee, Deputy Head (eHR), at 3509 8912.

Food and Health Bureau
16 April 2014

Electronic Health Record Sharing System Bill

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A BILL

To

Provide for the establishment of the Electronic Health Record Sharing System, the sharing and using of data and information contained in the System, and the protection of the System, data and information; and to provide for incidental and related matters.

Enacted by the Legislative Council.

Part 1

Preliminary

1. Short title and commencement

- (1) This Ordinance may be cited as the Electronic Health Record Sharing System Ordinance.
- (2) This Ordinance comes into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

2. Interpretation

- (1) In this Ordinance—

Board (研委會) means the board established under section 53 with the name “Electronic Health Record Research Board”;

Commissioner (專員) means the public officer appointed under section 47 to be the Commissioner for the Electronic Health Record;

company (公司) means a company as defined by section 2(1) of the Companies Ordinance (Cap. 622);

consent (同意), in relation to an individual, means an express consent of the individual;

data access request (查閱資料要求) has the meaning given by section 2(1) of the Privacy Ordinance;

data correction request (改正資料要求) has the meaning given by section 2(1) of the Privacy Ordinance;

data sharing (資料互通) means the act of providing or obtaining any sharable data of a registered healthcare recipient through the System;

electronic health record (電子健康紀錄)—

- (a) in relation to a registered healthcare recipient, means the record for the recipient that is kept under section 5(2); and
- (b) in relation to a healthcare recipient who was once registered, but is no longer registered, means the record for the recipient that was kept under section 5(2);

electronic medical record system (電子醫療紀錄系統), in relation to a healthcare provider, means an information system used by the healthcare provider to keep the medical record of a healthcare recipient electronically for the recipient's healthcare purpose;

health data (健康資料), in relation to a healthcare recipient, means the data or information relating to the health condition of, or to the healthcare provided or to be provided to, the recipient;

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—

- (a) assessing, recording, maintaining or improving the individual's health;

- (b) diagnosing the individual's illness or disability; or

- (c) treating the individual's illness or disability, or suspected illness or disability;

healthcare professional (醫護專業人員) means a person specified in the Schedule;

healthcare provider (醫護提供者) means a person that provides healthcare;

healthcare recipient (醫護接受者) means an individual for whom healthcare has been performed, is performed, or is likely to be performed;

healthcare referral (醫護服務轉介), in relation to a registered healthcare recipient, means a recommendation made by a prescribed healthcare provider for the provision of healthcare to the recipient by another prescribed healthcare provider;

identifiable data (可識辨身分資料)—see subsection (2)(a);

identity card (身分證) has the meaning given by section 1A(1) of the Registration of Persons Ordinance (Cap. 177);

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;

index data (索引資料), in relation to a healthcare recipient, means the personal particulars of the recipient that identify the recipient for the operation of the System;

joining consent (參與同意) means a consent given under section 7(1) or (2);

minor (幼年人) means a person below 16 years of age;

non-identifiable data (非可識辨身分資料)—see subsection (2)(b);

parent (家長), in relation to a child, means—

- (a) the natural father or natural mother of the child (whether or not the natural father and natural mother are married to each other);
- (b) a parent of the child by adoption under, or recognized as valid by, law; or
- (c) a stepfather or stepmother of the child;

prescribed healthcare provider (訂明醫護提供者) means—

- (a) the Department of Health;
- (b) the Hospital Authority; or
- (c) a registered healthcare provider;

Privacy Commissioner (私 隱 專 員) means the Privacy Commissioner for Personal Data established under section 5(1) of the Privacy Ordinance;

Privacy Ordinance (《私隱條例》) means the Personal Data (Privacy) Ordinance (Cap. 486);

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

- (a) a healthcare provider that is registered as a healthcare provider for the System under section 18(1) for a service location; or
- (b) a Government bureau or department that is registered as a healthcare provider for the System under section 20(1);

registered healthcare recipient (登記醫護接受者) means a healthcare recipient who is registered under section 8(1);

registration (登記)—

- (a) in relation to a healthcare recipient, means the registration of the healthcare recipient as a registered healthcare recipient under section 8(1);
- (b) in relation to a healthcare provider, means the registration of the healthcare provider as a healthcare

provider for the System under section 18(1) for a service location;

- (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;

Secretary (局長) means the Secretary for Food and Health;

sharable data (可互通資料), in relation to a registered healthcare recipient, means both of the following—

- (a) the index data of the healthcare recipient;
- (b) the health data of the healthcare recipient;

sharing consent (互通同意) means a consent given under section 12(1);

substitute decision maker (代決人)—see section 3;

System (互 通 系 統) means the information infrastructure established under section 5(1) with the name “Electronic Health Record Sharing System”;

use (使用), in relation to data or information contained in an electronic health record, includes disclose or transfer the data or information.

(2) In this Ordinance—

- (a) any data or information of a healthcare recipient is **identifiable data** if the identity of the healthcare recipient is ascertainable from the data or information; and
- (b) any data or information of a healthcare recipient is **non-identifiable data** if the identity of the healthcare recipient is unascertainable from the data or information.

- (3) In this Ordinance, a reference to a form specified by the Commissioner is a reference to a form so specified under section 52.

3. Substitute decision maker

- (1) For the purposes of this Ordinance, a person is a substitute decision maker of a healthcare recipient if the person is an eligible person under subsection (2) or (3).
- (2) For a healthcare recipient who is a minor, the following are eligible persons for the purposes of subsection (1)—
- (a) a parent of the healthcare recipient who accompanies the healthcare recipient at the relevant time;
 - (b) a guardian of the healthcare recipient appointed under or acting by virtue of the Guardianship of Minors Ordinance (Cap. 13), or otherwise appointed by the court, who accompanies the healthcare recipient at the relevant time;
 - (c) a person appointed by the court to manage the affairs of the healthcare recipient who accompanies the healthcare recipient at the relevant time;
 - (d) in the absence of the persons mentioned in paragraphs (a), (b) and (c), an immediate family member of the healthcare recipient who accompanies the healthcare recipient at the relevant time;
 - (e) in the absence of the persons mentioned in paragraphs (a), (b), (c) and (d), the prescribed healthcare provider that provides, or is about to provide, healthcare to the healthcare recipient at the relevant time.
- (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)—

- (a) being mentally incapacitated as defined by section 2(1) of the Mental Health Ordinance (Cap. 136);
 - (b) being incapable of managing his or her own affairs;
 - (c) being incapable of giving a joining consent at the time referred to in paragraph (a), (b) or (c) of the definition of **relevant time** in subsection (5);
 - (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).
- (4) The following are persons specified for the purposes of subsection (3)—
- (a) a person appointed under the Mental Health Ordinance (Cap. 136) to be the guardian of the healthcare recipient who accompanies the healthcare recipient at the relevant time;
 - (b) if the healthcare recipient is placed under the guardianship of the Director of Social Welfare or any other person under section 44A(1)(i) of that Ordinance, the Director of Social Welfare or that other person;
 - (c) if the guardianship of the healthcare recipient is vested in the Director of Social Welfare under section 44B(2A) or 59T(1) of that Ordinance, the Director of Social Welfare;
 - (d) if the functions of guardian of the healthcare recipient are to be performed by the Director of Social Welfare or any other person under section 44B(2B) or 59T(2) of that Ordinance, the Director of Social Welfare or that other person;
 - (e) a person appointed by the court to manage the affairs of the healthcare recipient who accompanies the healthcare recipient at the relevant time;

- (f) in the absence of the persons mentioned in paragraphs (a), (b), (c), (d) and (e), an immediate family member of the healthcare recipient who accompanies the healthcare recipient at the relevant time;
 - (g) in the absence of the persons mentioned in paragraphs (a), (b), (c), (d), (e) and (f), the prescribed healthcare provider that provides, or is about to provide, healthcare to the healthcare recipient at the relevant time.
- (5) In this section—
- relevant time** (有關時間) means—
- (a) in relation to an application that is made under section 6(1) for the healthcare recipient to be registered as a registered healthcare recipient, the time at which the application is made;
 - (b) in relation to a joining consent that is required under section 7(1) or (2) for such an application, the time at which the joining consent is required;
 - (c) in relation to a healthcare recipient's registration that is withdrawn from the System by the operation of section 9, the time at which the request for withdrawal is made;
 - (d) in relation to a sharing consent that is given under section 12(1), the time at which the sharing consent is given;
 - (e) in relation to a sharing consent that is renewed under section 14(2), the time at which the sharing consent is renewed;
 - (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.

4. Ordinance applies to Government

This Ordinance applies to the Government.

Part 2

Electronic Health Record Sharing System

Division 1—Establishment

5. Establishment of System

- (1) The Commissioner must establish and maintain an information infrastructure with the name “Electronic Health Record Sharing System” in English and “電子健康紀錄互通系統” in Chinese for—
 - (a) keeping the records required by subsection (2); and
 - (b) sharing and using data and information contained in those records.
- (2) The System must keep a record of every registered healthcare recipient containing the following—
 - (a) the index data of the recipient;
 - (b) the health data of the recipient provided to the Commissioner in the form and manner specified by the Commissioner;
 - (c) any other data or information of the recipient that is, in the Commissioner’s opinion, necessary for the proper functioning of the System.

Division 2—Registration of Healthcare Recipients

6. Application by healthcare recipients for registration

- (1) Subject to subsections (2) and (3), a healthcare recipient to which this section applies, or a substitute decision maker of a healthcare recipient, may apply to the Commissioner for the

healthcare recipient to be registered as a registered healthcare recipient.

- (2) If the healthcare recipient is a minor, the application must be made by a substitute decision maker of the healthcare recipient unless the Commissioner is satisfied that the recipient is capable of giving a joining consent.
- (3) If the healthcare recipient is aged 16 or above and is incapable of giving a joining consent, the application must be made by a substitute decision maker of the healthcare recipient.
- (4) An application made by a substitute decision maker of a healthcare recipient is made on behalf of and in the name of the recipient.
- (5) In making an application, a substitute decision maker of a healthcare recipient must have regard to the best interests of the recipient in the circumstances.
- (6) An application—
 - (a) must be made in the form and manner specified by the Commissioner;
 - (b) must be accompanied by the information specified by the Commissioner; and
 - (c) must be accompanied by a joining consent.
- (7) This section applies to a healthcare recipient—
 - (a) who holds an identity card; or
 - (b) who does not hold an identity card but holds—
 - (i) a certificate of registration of birth issued under the Births and Deaths Registration Ordinance (Cap. 174);
 - (ii) a proof of identity as defined by section 17B(1) (other than an identity card) of the Immigration Ordinance (Cap. 115);

- (iii) a certificate of exemption as defined by section 17G(1) of the Immigration Ordinance (Cap. 115); or
- (iv) any other identification document specified by the Commissioner.

7. Giving of joining consent

- (1) For an application made by a healthcare recipient under section 6(1), the recipient must give a consent specified in subsection (3).
- (2) For an application made by a substitute decision maker of a healthcare recipient under section 6(1), the substitute decision maker must give a consent specified in subsection (3) on behalf of and in the name of the recipient.
- (3) The consent is for the Commissioner—
 - (a) to obtain from, and to provide to, a prescribed healthcare provider to which the healthcare recipient has given a sharing consent any sharable data of the recipient; and
 - (b) if the prescribed healthcare provider has made a healthcare referral to another prescribed healthcare provider, to obtain from, and to provide to, that other prescribed healthcare provider any sharable data of the recipient relevant to the healthcare referral,

for the operation of the System after the registration of the recipient.
- (4) A joining consent must be given in the form and manner specified by the Commissioner.
- (5) A joining consent is revoked if—
 - (a) the healthcare recipient's registration is withdrawn from the System by the operation of section 9; or

- (b) the healthcare recipient's registration is cancelled under section 11(1).

8. Registration of healthcare recipients by Commissioner

- (1) On receiving an application made under section 6(1), the Commissioner, if satisfied that, on the face of it, the application complies with section 6(6), may—
 - (a) register the healthcare recipient as a registered healthcare recipient; and
 - (b) impose the conditions that the Commissioner considers appropriate for registering the healthcare recipient.
- (2) However, the Commissioner must not register the healthcare recipient if the Commissioner is satisfied that doing so may impair the security or compromise the integrity of the System.
- (3) After approving or refusing an application, the Commissioner must notify the healthcare recipient in writing of the decision and—
 - (a) if the application is approved—the date on which the registration takes effect and the conditions for the registration; or
 - (b) if the application is refused—the reasons for the refusal.

9. Withdrawal of healthcare recipient's registration

- (1) Subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may request that the registration of the recipient be withdrawn from the System.
- (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 giving a joining consent, 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) After granting a request, the Commissioner must notify the requestor in writing of the date on which the request is granted. The withdrawal takes effect on that date.

10. Suspension of healthcare recipient's registration

- (1) The Commissioner may suspend the registration of a healthcare recipient if the Commissioner reasonably suspects that—
 - (a) the application for registration did not comply with section 6(6);
 - (b) the healthcare recipient holds none of the documents specified in section 6(7);
 - (c) the healthcare recipient contravenes—
 - (i) a provision of this Ordinance; or
 - (ii) a condition for the registration; or
 - (d) the registration may impair the security or compromise the integrity of the System.
- (2) After suspending the registration, the Commissioner must notify the specified person in writing of—

- (a) the suspension;
 - (b) the date on which the suspension takes effect; and
 - (c) the reasons for the suspension.
- (3) When the registration of a healthcare recipient is suspended—
 - (a) new data or information of the recipient may still be provided by a prescribed healthcare provider to the System; but
 - (b) the electronic health record of the recipient is not to be made available to a prescribed healthcare provider through the System.
- (4) After the Commissioner is satisfied that there are no longer any grounds for suspending the healthcare recipient's registration, the Commissioner must notify the specified person in writing of—
 - (a) the Commissioner's decision; and
 - (b) the date on which the suspension ceases to take effect.
- (5) In this section—

specified person (指明人士) means—

- (a) if the healthcare recipient is a minor and the application for the healthcare recipient's registration was made by a substitute decision maker, that substitute decision maker;
- (b) if the healthcare recipient is aged 16 or above and is, in the Commissioner's opinion, incapable of giving a joining consent and the application for the healthcare recipient's registration was made by a substitute decision maker, that substitute decision maker; or
- (c) in any other case—
 - (i) the healthcare recipient; or

- (ii) the substitute decision maker of the healthcare recipient who made the application for the healthcare recipient's registration.

11. Cancellation of healthcare recipient's registration

- (1) The Commissioner may cancel the registration of a healthcare recipient if the Commissioner is satisfied that—
 - (a) the application for registration did not comply with section 6(6);
 - (b) the healthcare recipient holds none of the documents specified in section 6(7);
 - (c) the healthcare recipient contravenes—
 - (i) a provision of this Ordinance; or
 - (ii) a condition for the registration;
 - (d) the registration may impair the security or compromise the integrity of the System; or
 - (e) the healthcare recipient has died.
- (2) After cancelling a registration under subsection (1)(a), (b), (c) or (d), the Commissioner must notify the specified person in writing of—
 - (a) the cancellation;
 - (b) the date on which the cancellation takes effect; and
 - (c) the reasons for the cancellation.
- (3) A cancellation under subsection (1)(e) takes effect on the date on which the Commissioner is satisfied that the healthcare recipient has died.
- (4) In this section—

specified person (指明人士) means—

- (a) if the healthcare recipient is a minor and the application for the healthcare recipient's registration was made by a substitute decision maker, that substitute decision maker;
- (b) if the healthcare recipient is aged 16 or above and is, in the Commissioner's opinion, incapable of giving a joining consent and the application for the healthcare recipient's registration was made by a substitute decision maker, that substitute decision maker; or
- (c) in any other case—
 - (i) the healthcare recipient; or
 - (ii) the substitute decision maker of the healthcare recipient who made the application for the healthcare recipient's registration.

Division 3—Sharing Consent

12. Giving of sharing consent

- (1) Subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may give a consent specified in subsection (6) to a prescribed healthcare provider that provides healthcare to the healthcare recipient.
- (2) If the healthcare recipient is a minor, the sharing consent must be given by a substitute decision maker of the healthcare recipient unless the Commissioner is satisfied that the recipient is capable of giving the sharing consent.
- (3) If the healthcare recipient is aged 16 or above and is incapable of giving a sharing consent, the sharing consent must be given by a substitute decision maker of the healthcare recipient.

- (4) A sharing consent given by a substitute decision maker of a registered healthcare recipient is given on behalf of and in the name of the recipient.
- (5) In giving a sharing consent, a substitute decision maker of a registered healthcare recipient must have regard to the best interests of the recipient in the circumstances.
- (6) The consent is for—
 - (a) the prescribed healthcare provider—
 - (i) to provide to the System any sharable data of the healthcare recipient in the form and manner specified by the Commissioner;
 - (ii) to obtain from the System any sharable data of the healthcare recipient in the form and manner specified by the Commissioner; and
 - (iii) to provide to a referral healthcare provider any sharable data of the healthcare recipient relevant to the healthcare referral and in the form and manner specified by the Commissioner; and
 - (b) a referral healthcare provider—
 - (i) to provide to the System any sharable data of the healthcare recipient relevant to the healthcare referral and in the form and manner specified by the Commissioner; and
 - (ii) to obtain from the System any sharable data of the healthcare recipient relevant to the healthcare referral and in the form and manner specified by the Commissioner.
- (7) A sharing consent must be given in the form and manner specified by the Commissioner.
- (8) A sharing consent may be given for an indefinite term or a one-year term.

- (9) In this section—

referral healthcare provider (獲轉介醫護提供者) means a prescribed healthcare provider to which a healthcare referral of the healthcare recipient is made by the prescribed healthcare provider to which the consent is given.

13. Indefinite sharing consent

- (1) This section applies to a sharing consent given for an indefinite term.
- (2) The sharing consent is in effect until—
 - (a) the healthcare recipient's registration is withdrawn from the System by the operation of section 9;
 - (b) the healthcare recipient's registration is cancelled under section 11(1); or
 - (c) the consent is revoked under section 15(1).

14. One-year sharing consent

- (1) This section applies to a sharing consent given for a one-year term.
- (2) Subject to subsections (3) and (4), as long as the sharing consent is in effect, the registered healthcare recipient, or a substitute decision maker of the healthcare recipient, may renew the sharing consent for another one-year term.
- (3) If the healthcare recipient is a minor, the sharing consent must be renewed by a substitute decision maker of the healthcare recipient unless the Commissioner is satisfied that the recipient is capable of renewing the sharing consent.
- (4) If the healthcare recipient is aged 16 or above and is incapable of giving a sharing consent, the sharing consent must be renewed by a substitute decision maker of the healthcare recipient.

- (5) A sharing consent renewed by a substitute decision maker of a registered healthcare recipient is renewed on behalf of and in the name of the recipient.
- (6) In renewing a sharing consent, a substitute decision maker of a registered healthcare recipient must have regard to the best interests of the recipient in the circumstances.
- (7) If a sharing consent is renewed for a one-year term under subsection (2), that term is to commence on the date of the renewal.
- (8) The sharing consent is in effect during its term until—
 - (a) the healthcare recipient's registration is withdrawn from the System by the operation of section 9;
 - (b) the healthcare recipient's registration is cancelled under section 11(1); or
 - (c) the consent is revoked under section 15(1).

15. Revocation of sharing consent

- (1) Subject to subsections (2) and (3), a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may revoke a sharing consent given to a prescribed healthcare provider.
- (2) If the healthcare recipient is a minor, the revocation 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 revocation.
- (3) If the healthcare recipient is aged 16 or above and is incapable of giving a sharing consent, the revocation must be made by a substitute decision maker of the healthcare recipient.
- (4) A revocation 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 revocation, a substitute decision maker of a registered healthcare recipient must have regard to the best interests of the recipient in the circumstances.
- (6) A revocation must be made in the form and manner specified by the Commissioner.
- (7) After the revocation is recorded in the System, the Commissioner must notify the person making the revocation in writing of the date on which the record is made. The revocation takes effect on that date.

16. Sharing consent taken to be given

- (1) A healthcare recipient is taken to have given a sharing consent to the Department of Health and to the Hospital Authority when the healthcare recipient gives a joining consent.
- (2) A substitute decision maker of a healthcare recipient is taken to have given a sharing consent on behalf of and in the name of the recipient to the Department of Health and to the Hospital Authority when the substitute decision maker gives a joining consent.
- (3) A sharing consent taken to be given because of a joining consent is in effect as long as the joining consent is in effect.
- (4) Sections 12(7) and (8), 13, 14 and 15 do not apply to a sharing consent taken to be given under this section.

Division 4—Registration as Healthcare Providers for System

17. Application by healthcare providers for registration

- (1) A healthcare provider that provides healthcare at one service location 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 may apply to the Commissioner to be registered as a healthcare provider for the System for those locations as provided in subsection (3).
- (3) For the purposes of subsection (2), a healthcare provider may apply for—
 - (a) a single registration for all of the locations; or
 - (b) a separate registration for each location that the healthcare provider chooses to register.
- (4) An application—
 - (a) must be made in the form and manner specified by the Commissioner; and
 - (b) must be accompanied by the information specified by the Commissioner.
- (5) For the purposes of this section, a healthcare provider provides healthcare at one service location if the healthcare provider—
 - (a) is registered under section 3(4) of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) in respect of one hospital or one maternity home;
 - (b) is registered under section 5(2) of the Medical Clinics Ordinance (Cap. 343) in respect of one clinic;
 - (c) carries on the business of dentistry under section 12 of the Dentists Registration Ordinance (Cap. 156) at one premises;
 - (d) holds a certificate of exemption issued under section 7(2), or a licence issued under section 8(2)(a), of the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459) in respect of one residential care home, and

- engages a healthcare professional to perform healthcare at that home;
 - (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;
 - (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.
- (6) In subsection (5)—
- specified entity*** (指明實體) means—
- (a) an individual;
 - (b) a company;
 - (c) a partnership;
 - (d) a statutory body;
 - (e) a body corporate other than a company; or
 - (f) a society, or a branch of a society, registered under section 5A(1), or exempted from registration under section 5A(2), of the Societies Ordinance (Cap. 151).

18. Registration of healthcare providers by Commissioner

- (1) On receiving an application made under section 17(1) or (2), the Commissioner, if satisfied that the healthcare provider complies with the requirements set out in subsection (2), may—

- (a) register the healthcare provider as a healthcare provider for the System for the service location for which the application is made; and
 - (b) impose the conditions that the Commissioner considers appropriate for registering the healthcare provider.
- (2) The requirements are—
- (a) the requirements specified by the Commissioner for connecting the healthcare provider to the System; and
 - (b) the system requirements on data sharing specified by the Commissioner.
- (3) However, the Commissioner must not register the healthcare provider if the Commissioner is satisfied that—
- (a) the service or business nature of the healthcare provider is not consistent with the purpose of the use of data and information specified in section 26; or
 - (b) registering the healthcare provider may impair the security or compromise the integrity of the System.
- (4) After approving or refusing an application, the Commissioner must notify the healthcare provider in writing of the decision and—
- (a) if the application is approved—the date on which the registration takes effect and the conditions for the registration; or
 - (b) if the application is refused—the reasons for the refusal.

19. Amendment of registration

- (1) Subject to subsection (2), a healthcare provider registered under section 18(1) may request a registration be amended for—
- (a) a change in the particulars of a service location; and

- (b) a change of the service locations for which the healthcare provider is registered.
- (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.
- (3) A request must be made to the Commissioner in the form and manner specified by the Commissioner.
- (4) After granting a request, the Commissioner must notify the requestor in writing of the date on which the request is granted. The amendment takes effect on that date.

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.
- (2) The reference of a department in subsection (1) does not include the Department of Health.

21. Withdrawal of healthcare provider's registration

- (1) A registered healthcare provider may request that a registration of the healthcare provider be withdrawn from the System.
- (2) A request must be made to the Commissioner in the form and manner specified by the Commissioner.
- (3) After granting a request, the Commissioner must notify the healthcare provider in writing of the date on which the request is granted. The withdrawal takes effect on that date.

- (4) If a sharing consent is given to the healthcare provider, the sharing consent ceases to have effect once the withdrawal takes effect.

22. Suspension of healthcare provider's registration

- (1) The Commissioner may suspend a registration of a registered healthcare provider if the Commissioner reasonably suspects that—
 - (a) the healthcare provider contravenes—
 - (i) a provision of this Ordinance;
 - (ii) a provision of a code of practice issued under section 51; or
 - (iii) a condition for the registration;
 - (b) the healthcare provider no longer provides healthcare at the service location to which the registration relates;
 - (c) the healthcare provider no longer complies with—
 - (i) the requirements specified by the Commissioner for connecting the healthcare provider to the System; or
 - (ii) the system requirements on data sharing specified by the Commissioner;
 - (d) the service or business nature of the healthcare provider is no longer consistent with the purpose of the use of data and information specified in section 26; or
 - (e) the registration may impair the security or compromise the integrity of the System.
- (2) After suspending a registration, the Commissioner must notify the healthcare provider in writing of—
 - (a) the suspension;
 - (b) the date on which the suspension takes effect; and

- (c) the reasons for the suspension.
- (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.
- (4) After the Commissioner is satisfied that there are no longer any grounds for suspending the healthcare provider's registration, the Commissioner must notify the healthcare provider in writing of—
 - (a) the Commissioner's decision; and
 - (b) the date on which the suspension ceases to take effect.

23. Cancellation of healthcare provider's registration

- (1) The Commissioner may cancel a registration of a registered healthcare provider if the Commissioner is satisfied that—
 - (a) the healthcare provider contravenes—
 - (i) a provision of this Ordinance;
 - (ii) a provision of a code of practice issued under section 51; or
 - (iii) a condition for the registration;
 - (b) the healthcare provider no longer provides healthcare at the service location to which the registration relates;
 - (c) the healthcare provider no longer complies with—
 - (i) the requirements specified by the Commissioner for connecting the healthcare provider to the System; or

- (ii) the system requirements on data sharing specified by the Commissioner;
 - (d) the service or business nature of the healthcare provider is no longer consistent with the purpose of the use of data and information specified in section 26; or
 - (e) the registration may impair the security or compromise the integrity of the System.
- (2) After cancelling a registration under subsection (1), the Commissioner must notify the healthcare provider in writing of—
 - (a) the cancellation;
 - (b) the date on which the cancellation takes effect; and
 - (c) the reasons for the cancellation.
- (3) If a sharing consent is given to the healthcare provider, the sharing consent ceases to have effect once the cancellation takes effect.

24. Supplementary provision to sections 22, 23 and 50

A reference in sections 22, 23 and 50 to the service location to which a registration relates includes each of the service locations covered by a single registration of a healthcare provider under section 17(3)(a).

Part 3

Electronic Health Record

Division 1—Use of Electronic Health Record

25. General rule

The data and information contained in an electronic health record may not be used except as provided in section 26, 27, 28 or 29.

26. Use for improvement of healthcare

The data and information contained in the electronic health record of a registered healthcare recipient may be used for improving the efficiency, quality, continuity or integration of the healthcare provided, or to be provided, to the healthcare recipient.

27. Use for research and statistics

- (1) The data and information contained in an electronic health record may be used for carrying out research, or preparing statistics, that are relevant to public health or public safety.
- (2) However, the results of the research or the resulting statistics must not be made available in a form that would enable a healthcare recipient to be identified.

28. Use for disease control and surveillance etc.

- (1) The data and information contained in an electronic health record may be used by a person specified in subsection (2)—
 - (a) for the prevention or control of disease; or
 - (b) for the enhancement of disease surveillance or investigation.
- (2) The person is—

- (a) the Department of Health;
- (b) the Hospital Authority; or
- (c) a health officer as defined by section 2 of the Prevention and Control of Disease Ordinance (Cap. 599).

29. Use permitted by or under any other law

The data and information contained in an electronic health record may be used as permitted by, or under, any other law.

Division 2—Procedures for Use of Identifiable Data under Section 27

30. Application to Secretary for use for research or statistics purpose

- (1) A person may apply to the Secretary for using identifiable data of a healthcare recipient contained in an electronic health record for carrying out research, or preparing statistics, that are relevant to public health or public safety.
- (2) An application—
 - (a) must be made in the form and manner specified by the Commissioner; and
 - (b) must be accompanied by a proposal specified in subsection (3).
- (3) The proposal is a written proposal setting out—
 - (a) the nature and objectives in respect of the research or statistics;
 - (b) the public or scientific benefit of the research or statistics that the applicant anticipates; and
 - (c) any other information relating to the research or statistics as specified by the Commissioner.

31. Recommendation by Board

- (1) The Secretary may refer an application made under section 30(1) to the Board for a recommendation on whether the application should be approved or refused.
- (2) When making a recommendation, the Board must have regard to—
 - (a) whether it is ethical to carry out the research or prepare the statistics;
 - (b) whether the objectives in respect of the research or statistics are only achievable by using the identifiable data;
 - (c) whether it is practicable to obtain the consent of the healthcare recipient concerned for the use;
 - (d) whether, at the time the research is carried out or the statistics are prepared, adequate safeguards are in place to preserve the confidentiality of the identifiable data;
 - (e) the weighing of—
 - (i) the public interest in carrying out the research or preparing the statistics; and
 - (ii) the public interest in protecting the privacy of the healthcare recipient concerned; and
 - (f) the resource implication in providing the identifiable data.
- (3) If the Board recommends that the Secretary approves the application, the Board may also make recommendations on the conditions of the approval.

32. Decisions of Secretary

- (1) After approving or refusing an application made under section 30(1), the Secretary must notify the applicant in writing of the decision and—
 - (a) if the application is approved—the conditions of the approval; or
 - (b) if the application is refused—the reasons for the refusal.
- (2) If the application is approved, the identifiable data is to be made available to the applicant in the form and manner specified by the Commissioner after the applicant has paid the administrative costs for processing the application.

**Division 3—Procedures for Use of Non-identifiable Data
under Section 27**

33. Application to Commissioner for use for research or statistics purpose

- (1) A person may apply to the Commissioner for using non-identifiable data of a healthcare recipient contained in an electronic health record for carrying out research, or preparing statistics, that are relevant to public health or public safety.
- (2) An application—
 - (a) must be made in the form and manner specified by the Commissioner; and
 - (b) must be accompanied by a proposal specified in subsection (3).
- (3) The proposal is a written proposal setting out—
 - (a) the nature and objectives in respect of the research or statistics;

- (b) the public or scientific benefit of the research or statistics that the applicant anticipates; and
- (c) any other information relating to the research or statistics as specified by the Commissioner.

34. Decisions of Commissioner

- (1) Before approving or refusing an application made under section 33(1), the Commissioner must have regard to—
 - (a) whether it is ethical to carry out the research or prepare the statistics; and
 - (b) the resource implication in providing the non-identifiable data.
- (2) After approving or refusing an application made under section 33(1), the Commissioner must notify the applicant in writing of the decision and—
 - (a) if the application is approved—the conditions of the approval; or
 - (b) if the application is refused—the reasons for the refusal.
- (3) If the application is approved, the non-identifiable data is to be made available to the applicant in the form and manner specified by the Commissioner after the applicant has paid the administrative costs for processing the application.

**Division 4—Safeguards of Electronic Health Record
Sharing System**

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.

Part 4**Application to Data or Information that is Personal
Data under Privacy Ordinance****36. Data or information to which this Part applies**

This Part applies to data or information that is personal data as defined by section 2(1) of the Privacy Ordinance.

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".

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.

39. Commissioner's further duty in certain circumstances

(1) This section applies if—

- (a) a person is required to comply with section 23(1) of the Privacy Ordinance in relation to the data or information of a registered healthcare recipient that was provided to the System by the person as a prescribed healthcare provider; and
- (b) the person—
 - (i) is no longer a prescribed healthcare provider;
 - (ii) no longer has the sharing consent of the healthcare recipient; or
 - (iii) fails to respond to a data correction request in compliance with the Privacy Ordinance.

(2) The Commissioner must make a note, whether annexed to the data correction requested or elsewhere, of the matters in respect of which the data is considered by the requestor to be inaccurate.

(3) The note must be made in such a way that the data cannot be used by a person without the note being drawn to the attention of, and being made available for inspection by, the person.

40. Contravention of requirement under Privacy Ordinance

For the purposes of the Privacy Ordinance, a contravention of a requirement under a provision of that Ordinance that has effect subject to this Part is to be regarded as a contravention of a requirement under that Ordinance.

Part 5**Offences****41. Offences relating to accessing, damaging or modifying data or information**

- (1) A person commits an offence if the person knowingly causes a computer to perform a function so as to obtain unauthorized access to data or information contained in an electronic health record.
- (2) A person who commits an offence under subsection (1) is liable on summary conviction to a fine at level 6.
- (3) For the purposes of subsection (1), access by a person to data or information is unauthorized if—
 - (a) the person is not entitled to control that access;
 - (b) the person has not been authorized by another person who controls that access to obtain that access;
 - (c) the person does not believe that the authorization has been given; and
 - (d) the person does not believe that, even if the person had applied to the appropriate authority, the authorization would have been given.
- (4) A person commits an offence if the person, without lawful excuse, knowingly damages data or information contained in an electronic health record.
- (5) A person who commits an offence under subsection (4) is liable on summary conviction to imprisonment for 2 years.
- (6) A person commits an offence if—
 - (a) the person knowingly—

- (i) causes access to data or information contained in an electronic health record;
 - (ii) causes modification of data or information contained in an electronic health record; or
 - (iii) causes impairment to the accessibility, reliability, security or processing of data or information contained in an electronic health record; and
- (b) the person causes the access, modification or impairment—
 - (i) with intent to commit an offence;
 - (ii) with a dishonest intent to deceive;
 - (iii) with a view to dishonest gain for the person or for another; or
 - (iv) with a dishonest intent to cause loss to another, whether on the same occasion as the person causes the access, modification or impairment or on any future occasion.
- (7) A person who commits an offence under subsection (6) is liable on conviction on indictment to imprisonment for 5 years.
- (8) For the purposes of subsection (6)(b)—
 - (a) a reference to gain includes—
 - (i) a gain in money or other property;
 - (ii) a temporary gain or a permanent gain;
 - (iii) a gain by keeping what one has; and
 - (iv) a gain by getting what one has not; and
 - (b) a reference to loss includes—
 - (i) a loss in money or other property;

- (ii) a temporary loss or a permanent loss;
- (iii) a loss by not getting what one might get; and
- (iv) a loss by parting with what one has.

(9) In this section—

computer (電腦) means a device for storing, processing or retrieving data or information.

42. Offences relating to impairment to System

- (1) A person commits an offence if the person knowingly impairs the operation of the System.
- (2) A person who commits the offence is liable on conviction on indictment to imprisonment for 10 years.

43. Offences relating to data access requests and data correction requests

- (1) A person commits an offence if the person, with intent to evade a data access request or data correction request in relation to any data or information contained in an electronic health record—
 - (a) alters, falsifies, conceals or destroys the data or information; or
 - (b) directs another person to do anything mentioned in paragraph (a).
- (2) A person who commits the offence is liable on summary conviction to a fine at level 6.

44. Offences relating to untrue statements

- (1) A person commits an offence if the person knowingly makes an untrue statement to enable the person to give a joining consent or sharing consent.

- (2) A person who commits the offence is liable on summary conviction to a fine at level 6.

45. Offences relating to contravening conditions for research or statistics purpose

- (1) A person commits an offence if the person knowingly contravenes a condition imposed under section 32(1)(a).
- (2) A person who commits the offence is liable on summary conviction to a fine at level 6.

46. Offences relating to direct marketing

- (1) A person commits an offence if the person uses another person's data or information contained in an electronic health record, or a copy (in whatever format) of the data or information, for direct marketing.
- (2) A person who commits an offence under subsection (1) is liable on conviction on indictment to a fine of \$500,000 and to imprisonment for 3 years.
- (3) A person commits an offence if, for gain, the person provides to others another person's data or information contained in an electronic health record, or a copy (in whatever format) of the data or information, for direct marketing.
- (4) A person who commits an offence under subsection (3) is liable on conviction on indictment to a fine of \$1,000,000 and to imprisonment for 5 years.
- (5) A person commits an offence if, not for gain, the person provides to others another person's data or information contained in an electronic health record, or a copy (in whatever format) of the data or information, for direct marketing.

- (6) A person who commits an offence under subsection (5) is liable on conviction on indictment to a fine of \$500,000 and to imprisonment for 3 years.
- (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) healthcare services provided or administered by the Department of Health or the Hospital Authority; or
 - (c) any other social or healthcare 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.
- (9) In this section—

direct marketing (直接促銷) has the meaning given by section 35A(1) of the Privacy Ordinance.

Part 6

Administrative and Miscellaneous Provisions

Division 1—Administration

47. Appointment of Commissioner

- (1) The Secretary may appoint a public officer to be the Commissioner for the Electronic Health Record.
- (2) The appointment is to be notified in the Gazette.

48. Functions and powers of Commissioner

- (1) The Commissioner has the following functions—
 - (a) to establish, operate, maintain and develop the System;
 - (b) to regulate and supervise the sharing and using of data and information contained in the System;
 - (c) to supervise the compliance with this Ordinance;
 - (d) to promote the System to healthcare recipients, healthcare providers and the public;
 - (e) to devise and promote, and encourage among healthcare providers, proper standards of conduct, and sound and prudent practices, in data sharing;
 - (f) to advise the Secretary on matters relating to the System;
 - (g) to deal with applications for use of data and information contained in an electronic health record under section 27; and
 - (h) to devise a mechanism for handling complaints relating to the operation of the System.

- (2) The Commissioner may do anything necessary for, or incidental or conducive to, the performance of a function of the Commissioner.
- (3) The Commissioner may appoint in writing a person to assist the Commissioner in performing a function and exercising a power.

49. Commissioner to keep register of prescribed healthcare providers

- (1) The Commissioner must establish and maintain a register of prescribed healthcare providers for the purposes of this Ordinance.
- (2) The register may be kept in a form, and may contain information, that the Commissioner considers appropriate.
- (3) The register must be made available for a member of the public to ascertain—
 - (a) whether a healthcare provider is registered as a healthcare provider for the System under section 18(1); and
 - (b) the service location for which the healthcare provider is registered.
- (4) The register must be made available for public inspection free of charge—
 - (a) through the Internet; and
 - (b) at the office of the Commissioner, or any other Government offices as the Commissioner may direct, during normal office hours.

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 healthcare provider to produce the record or document—
 - (a) that is or may be relevant to the event; and
 - (b) that is in the healthcare provider's possession.
- (2) The event is that—
 - (a) the healthcare provider contravenes—
 - (i) a provision of this Ordinance;
 - (ii) a provision of a code of practice issued under section 51; or
 - (iii) a condition for the registration;
 - (b) the healthcare provider no longer provides healthcare at the service location to which the registration relates;
 - (c) the healthcare provider no longer complies with—
 - (i) the requirements specified by the Commissioner for connecting the healthcare provider to the System; or
 - (ii) the system requirements on data sharing specified by the Commissioner;
 - (d) the service or business nature of the healthcare provider is no longer consistent with the purpose of the use of data and information specified in section 26; or
 - (e) the registration may impair the security or compromise the integrity of the System.
- (3) The requirement must specify the manner in which the record or document must be produced.

51. Commissioner to issue code of practice

- (1) The Commissioner may issue a code of practice—
 - (a) indicating the manner in which the Commissioner proposes to perform a function or exercise a power; or
 - (b) providing guidance on the operation of a provision of this Ordinance.
- (2) The Commissioner—
 - (a) must publish the code of practice in a manner appropriate to bringing it to the notice of persons affected by it; and
 - (b) must make copies of the code of practice available to the public (in hard copy or electronic form).
- (3) The Commissioner may amend or revoke the code of practice. Subsections (2) and (4) apply to an amendment or revocation of the code of practice in the same way as they apply to the code of practice.
- (4) A code of practice issued under this section is not subsidiary legislation.

52. Commissioner to specify forms

- (1) The Commissioner may specify the form of a document required for the purposes of this Ordinance.
- (2) The Commissioner may specify more than one form of the document, whether as alternatives or to provide for different circumstances.
- (3) A form specified under this section—
 - (a) must be completed in accordance with the directions and instructions that are specified in the form; and

- (b) if the completed form is required to be provided to the Commissioner or any other person, must be so provided in the manner specified in the form.

Division 2—Electronic Health Record Research Board**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.
- (3) A non-ex officio member may hold office for the period and on the terms specified in his or her letter of appointment by the Secretary.
- (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.
- (6) In this section—

non-ex officio member (非當然委員) means a member of the Board appointed under subsection (2)(c).

54. Function of Board

The function of the Board is to make recommendations to the Secretary—

- (a) for deciding whether to approve or refuse an application made under section 30(1); and
- (b) for imposing conditions on approving an application made under that section.

Division 3—Miscellaneous Provisions**55. Right of appeal—against decisions of Commissioner**

- (1) A person who is aggrieved by any of the Commissioner's decisions set out in subsection (2) may appeal to the Administrative Appeals Board.
- (2) The decisions are—
 - (a) to refuse to register a healthcare recipient under section 8(1);
 - (b) to suspend the registration of a healthcare recipient under section 10(1);
 - (c) to cancel the registration of a healthcare recipient under section 11(1);
 - (d) to refuse to register a healthcare provider as a healthcare provider for the System under section 18(1);
 - (e) to suspend a registration of a registered healthcare provider under section 22(1); and
 - (f) to cancel a registration of a registered healthcare provider under section 23(1).
- (3) An appeal may only be made within 28 days after the aggrieved person receiving notice of the decision.

- (4) An appeal does not suspend the decision unless the Commissioner decides otherwise.

56. Access to card face data of healthcare recipient

- (1) This section applies if the Commissioner or a prescribed healthcare provider gains access to the card face data of the identity card of a healthcare recipient by using facilities provided by or with the approval of the Government.
- (2) The Commissioner or the prescribed healthcare provider is to be regarded as having lawful authority to gain access to the card face data of the identity card of the healthcare recipient for the purposes of regulation 12(1A) of the Registration of Persons Regulations (Cap. 177 sub. leg. A).
- (3) In this section—

card face data (證面數據) means the data specified in paragraph 1(a), (c), (d) and (e) of Schedule 1 to the Registration of Persons Regulations (Cap. 177 sub. leg. A) that are stored in the chip embodied in an identity card.

57. Limitation of public liability

- (1) The Government or a public officer is not liable 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.

58. Protection of public officers etc.

- (1) A person to whom this section applies is not civilly liable for an act done or omitted to be done by the person in good faith—
- (a) in performing a function or purportedly performing a function under this Ordinance; or
 - (b) in exercising a power or purportedly exercising a power under this Ordinance.
- (2) Subsection (1) does not affect the liability of the Government for the act or omission.
- (3) This section applies to—
- (a) a public officer; and
 - (b) a person appointed by the Commissioner under section 48(3).

59. Service of notice etc.

A notice or document required to be given or sent under this Ordinance is, in the absence of evidence to the contrary, given or sent if—

- (a) for an individual—
 - (i) it is addressed to and delivered personally to the individual;
 - (ii) it is sent to the individual by post addressed to the individual at the individual's last known address;

- (iii) it is sent to the individual by an electronic mail transmission addressed to the individual at the individual's last known electronic mail address; or
 - (iv) it is sent to the individual by a text message addressed to the individual at the individual's last known telephone number;
- (b) for a company—
- (i) it is addressed to the company and delivered to an officer of the company by hand;
 - (ii) it is addressed to the company and left at or sent by post to the registered office of the company; or
 - (iii) it is sent to the company by post addressed to the company at the company's last known address;
- (c) for a partnership—
- (i) it is addressed to the partnership and delivered to a place in Hong Kong at which the partnership carries on business, and given to a person apparently concerned in the management of, or apparently employed by, the partnership by hand; or
 - (ii) it is sent to the partnership by post addressed to the partnership at the partnership's last known address; or
- (d) for a statutory body, a body corporate other than a company, or an unincorporated body of persons other than a partnership—
- (i) it is addressed to the body and delivered to a place in Hong Kong at which the body carries on business, and given to a person apparently concerned in the management of, or apparently employed by, the body by hand; or

- (ii) it is sent to the body by post addressed to the body at the body's last known address.

60. Amendment of Schedule

The Secretary may by notice published in the Gazette amend the Schedule.

Part 7

Amendment to Administrative Appeals Board Ordinance

61. Administrative Appeals Board Ordinance amended

The Administrative Appeals Board Ordinance (Cap. 442) is amended as set out in section 62.

62. Schedule amended

The Schedule—

Add

“74. Electronic
Health Record
Sharing System
Ordinance
(of 2014)

A decision of the Commissioner for
the Electronic Health Record—

- (a) to refuse to register a
healthcare recipient under
section 8(1);
- (b) to suspend the
registration of a
healthcare recipient under
section 10(1);
- (c) to cancel the registration
of a healthcare recipient
under section 11(1);
- (d) to refuse to register a
healthcare provider as a
healthcare provider for
the Electronic Health
Record Sharing System
under section 18(1);

- (e) to suspend a registration of a registered healthcare provider under section 22(1);
 - (f) to cancel a registration of a registered healthcare provider under section 23(1)."
-

Schedule

[ss. 2 & 60]

Healthcare Professionals

1. A registered pharmacist within the meaning of the Pharmacy and Poisons Ordinance (Cap. 138).
2. A registered dentist within the meaning of the Dentists Registration Ordinance (Cap. 156).
3. An enrolled dental hygienist within the meaning of the Ancillary Dental Workers (Dental Hygienists) Regulations (Cap. 156 sub. leg. B).
4. A registered medical practitioner within the meaning of the Medical Registration Ordinance (Cap. 161).
5. A registered midwife within the meaning of the Midwives Registration Ordinance (Cap. 162).
6. A registered nurse or enrolled nurse within the meaning of the Nurses Registration Ordinance (Cap. 164).
7. A registered medical laboratory technologist within the meaning of the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A).
8. A registered occupational therapist within the meaning of the Occupational Therapists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. B).
9. A registered optometrist within the meaning of the Optometrists (Registration and Disciplinary Procedure) Regulation (Cap. 359

sub. leg. F) whose name has been entered in Part I of the register as defined by section 2 of that Regulation.

10. A registered radiographer within the meaning of the Radiographers (Registration and Disciplinary Procedure) Regulation (Cap. 359 sub. leg. H).
 11. A registered physiotherapist within the meaning of the Physiotherapists (Registration and Disciplinary Procedure) Regulation (Cap. 359 sub. leg. J).
 12. A registered chiropractor within the meaning of the Chiropractors Registration Ordinance (Cap. 428).
 13. A listed or registered Chinese medicine practitioner within the meaning of the Chinese Medicine Ordinance (Cap. 549).
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Explanatory Memorandum

The objects of this Bill are to establish the Electronic Health Record Sharing System (*System*), to provide for the sharing and using of data and information contained in the System, and the protection of the System, data and information, and to provide for incidental and related matters.

2. The Bill is divided into 7 Parts and contains a Schedule.

Part 1—Preliminary

3. Clause 1 sets out the short title and provides for commencement.
4. Clauses 2 and 3 contain definitions that are necessary for the interpretation of the Bill, including the expressions *Commissioner*, *electronic health record*, *healthcare*, *healthcare provider*, *healthcare recipient*, *joining consent*, *prescribed healthcare provider*, *registered healthcare provider*, *registered healthcare recipient*, *sharable data*, *sharing consent*, *substitute decision maker* and *System*.
5. Clause 4 provides that the Bill applies to the Government.

Part 2—Electronic Health Record Sharing System

Division 1

6. Clause 5 deals with the establishment of the System, and provides for what are contained in an electronic health record.

Division 2

7. Clause 6 deals with the application for registration of healthcare recipients. An individual for whom healthcare has been performed, is performed or is likely to be performed in Hong Kong may apply to be registered as a registered healthcare recipient. A substitute decision maker of the individual may also make the application on

behalf of and in the name of the individual. If the individual is a minor (except in the circumstances provided in the clause), or is aged 16 or above and is incapable of giving a joining consent, the application must be made by his or her substitute decision maker. Generally speaking, the following persons are eligible to be a substitute decision maker of an individual: a parent, a guardian or an immediate family member of the individual, a person appointed by the court to manage the affairs of the individual, or a prescribed healthcare provider that provides healthcare to the individual.

8. Clause 7 requires a healthcare recipient, or a substitute decision maker of a healthcare recipient, to give a joining consent to the Commissioner for the Electronic Health Record (*Commissioner*) when applying to be registered as a registered healthcare recipient. The joining consent allows the Commissioner to obtain from, and to provide to, a prescribed healthcare provider any index data and health data or information (*sharable data*) of the healthcare recipient, for the operation of the System.
9. Clause 8 deals with the registration of healthcare recipients by the Commissioner.
10. Clause 9 deals with the withdrawal of registration from the System by healthcare recipients.
11. Clauses 10 and 11 respectively provide for the suspension and cancellation of registration of healthcare recipients by the Commissioner.

Division 3

12. Clause 12 provides that a registered healthcare recipient, or a substitute decision maker of a registered healthcare recipient, may give a sharing consent to a prescribed healthcare provider that provides healthcare to the healthcare recipient. The sharing consent allows the prescribed healthcare provider to provide to, and to obtain from, the System any sharable data of the healthcare

recipient. A sharing consent may be given for an indefinite term or a one-year term.

13. Clause 13 deals with an indefinite sharing consent while clause 14 deals with a one-year sharing consent.
14. Clause 15 deals with the revocation of a sharing consent.
15. Clause 16 provides that a healthcare recipient, or a substitute decision maker of a healthcare recipient, is taken to have given a sharing consent to the Department of Health (*Department*) and to the Hospital Authority (*Authority*) when giving a joining consent. The Department and the Authority may share the sharable data of the healthcare recipient with a prescribed healthcare provider for the operation of the System.

Division 4

16. Clause 17 deals with the application for registration of healthcare providers for the System. A healthcare provider that provides healthcare at a service location may apply to the Commissioner to be registered as a healthcare provider for the System for that location.
17. Clause 18 deals with the registration of healthcare providers for the System by the Commissioner.
18. Clause 19 deals with the amendment of registration of healthcare providers.
19. Clause 20 provides that 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.
20. Clause 21 deals with the withdrawal of registration from the System by healthcare providers.

21. Clauses 22 and 23 respectively provide for the suspension and cancellation of registration of healthcare providers by the Commissioner. Clause 24 is a supplementary provision to clauses 22, 23 and 50.

Part 3—Electronic health record

Division 1

22. Clause 25 provides that the data and information contained in an electronic health record may not be used except as provided in clause 26, 27, 28 or 29.
23. Clause 26 provides for the use of data and information for improving the healthcare provided to a registered healthcare recipient.
24. Clause 27 provides for the use of data and information for research and statistics purposes.
25. Clause 28 provides for the use of data and information for disease control and surveillance purposes.
26. Clause 29 provides for the use of data and information as permitted by, or under, any other law.

Division 2

27. Clause 30 enables a person to apply to the Secretary for Food and Health (*Secretary*) for using identifiable data of a healthcare recipient contained in an electronic health record for research or statistics purpose.
28. Clause 31 empowers the Secretary to refer an application made under clause 30(1) to the Electronic Health Record Research Board (*Board*) for a recommendation on whether the application should be approved or refused. The clause also sets out the matters that the Board must consider when making a recommendation to the Secretary.

29. Clause 32 deals with the Secretary's decision to approve or refuse an application made under clause 30(1).

Division 3

30. Clause 33 enables a person to apply to the Commissioner for using non-identifiable data of a healthcare recipient contained in an electronic health record for research or statistics purpose.
31. Clause 34 deals with the Commissioner's decision to approve or refuse an application made under clause 33(1).

Division 4

32. Clause 35 requires a prescribed healthcare provider to 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.

Part 4—Application to data or information that is personal data under Privacy Ordinance

33. Clause 36 provides that Part 4 of the Bill applies to data or information that is personal data as defined by section 2(1) of the Personal Data (Privacy) Ordinance (Cap. 486) (*Privacy Ordinance*).
34. Clause 37 provides for the conditions subject to which the Privacy Commissioner for Personal Data may perform a function or exercise a power under the Privacy Ordinance in relation to data or information contained in the System.
35. Clause 38 deals with modification of the definition of *relevant person* in section 2(1) of the Privacy Ordinance when Part 5 of that Ordinance applies to the access to or correction of the data or information contained in the electronic health record of a registered healthcare recipient.

36. Clause 39 provides for further duty of the Commissioner in certain circumstances.
37. Clause 40 provides that a contravention of a requirement under a provision of the Privacy Ordinance that has effect subject to Part 4 of the Bill is to be regarded as a contravention of a requirement under that Ordinance.

Part 5—Offences

38. Clauses 41, 42, 43, 44, 45 and 46 deal with various offences and their penalties under the Bill. The offences include—
 - (a) offences relating to accessing, damaging or modifying data or information;
 - (b) offences relating to impairment to the System;
 - (c) offences relating to data access requests and data correction requests;
 - (d) offences relating to untrue statements;
 - (e) offences relating to contravening conditions for research or statistics purpose; and
 - (f) offences relating to direct marketing.

Part 6—Administrative and miscellaneous provisions

Division 1

39. Clause 47 deals with the appointment of the Commissioner. Clause 48 deals with the functions and powers of the Commissioner.
40. Clause 49 provides for the duty of the Commissioner to establish and maintain a register of prescribed healthcare providers.
41. Clause 50 empowers the Commissioner to require a registered healthcare provider to produce records or documents in certain circumstances.

42. Clause 51 enables the Commissioner to issue a code of practice and clause 52 enables the Commissioner to specify forms.

Division 2

43. Clause 53 provides for the establishment of the Board and the appointment of its members.
44. Clause 54 provides that the function of the Board is to make recommendations to the Secretary for deciding whether to approve or refuse applications for using identifiable data of a healthcare recipient contained in an electronic health record for research or statistics purpose, and for imposing conditions on approving those applications.

Division 3

45. Clause 55 provides for an appeal against a decision of the Commissioner specified in the clause to be made to the Administrative Appeals Board.
46. Clause 56 allows the Commissioner or a prescribed healthcare provider to be regarded as having lawful authority to gain access to the card face data of the identity card of a healthcare recipient for the purposes of regulation 12(1A) of the Registration of Persons Regulations (Cap. 177 sub. leg. A).
47. Clause 57 deals with the limitation of public liability and clause 58 deals with the protection of a person performing a function or exercising a power under the Bill in good faith.
48. Clause 59 deals with the service of notice under the Bill.
49. Clause 60 provides for the manner of amendment of the Schedule to the Bill.

Part 7—Amendment to Administrative Appeals Board Ordinance

50. Clause 62 deals with an amendment to the Schedule to the Administrative Appeals Board Ordinance (Cap. 442).

Schedule

51. The Schedule sets out a list of healthcare professionals for clause 2.

IMPLICATIONS OF THE PROPOSAL

Economic Implications

1. The sharing of health-related data and information of individuals by the prescribed healthcare providers (HCP) will be conducive to the improvement of healthcare. In the long run, the Electronic Health Record Sharing System (the System) would help reduce the length of stay of healthcare recipients (HCR), unplanned re-admissions, medication/prescription errors and duplicated laboratory and radiology tests, thereby achieving more efficient use of the society's limited healthcare resources. The System will also provide a rich database for research and statistics, which should facilitate the overall management and quality of healthcare.

Sustainability Implications

2. The System is a territory-wide patient-oriented information infrastructure that would contribute to the sustainable development of healthcare services. It would facilitate integration of different healthcare services, thereby enhancing the efficiency, quality and continuity of care of HCRs. It will also facilitate public health policy formulation and enhance disease surveillance. We anticipate that gradually each year there will be newborns and school kids joining the System. With legislative framework in place, both public and private HCPs and HCRs could benefit from legal protection. It is in line with the sustainability principle of pursuing policies to promote and protect the health of the people of Hong Kong.

Financial Implications

3. The ten-year eHR programme is estimated to incur a total non-recurrent expenditure of \$1,124 million. In July 2009, the Finance Committee of the Legislative Council approved a new commitment of \$702 million for the first stage of the eHR programme (from 2009-10 to 2013-14)¹. The non-recurrent funding required for developing the System will be met from within that commitment.

4. A recurrent funding of \$259 million in 2014-15 and \$266 million in a full year has been earmarked for the operation and maintenance of the first stage of the System. For the second stage development under planning, we will justify and seek additional recurrent resource, where necessary, in accordance with the established mechanism.

¹ Further top-up of \$442 million for taking forward the second stage implementation has been earmarked and is subject to Finance Committee's approval in due course.

Civil Service Implications

5. Resources have been given in previous Resource Allocation Exercises for the setting up of a dedicated eHR Office in the Food and Health Bureau to steer and oversee the eHR programme, with the Hospital Authority (HA) as the technical agency for developing the System. HA will also be the technical agency to provide support to the operation of Stage 1 eHR programme, including systems maintenance, IT operations, engagement, participation, standards and business support services as well as implementing the publicity, promotional and enrolment activities for the eHR programme. The institutional arrangements for the office of the eHR Commissioner are under deliberation. Should new resources for the establishment of the office of the eHR Commissioner be required at a later stage, we will bid resources according to the established resource allocation mechanism.