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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.

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(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;

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(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 oneyear 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.

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(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 nonidentifiable 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).

## **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.