



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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Miss Carrie Wong
Assistant Legal Advisor
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Dear Miss Wong,

Bills Committee on Electronic Health Record Sharing System (eHRSS) Bill

Thank you for your letter dated 10 February 2015. Our responses to your enquiries are set out below.

Clauses 10, 11, 22 and 23 (Suspension / cancellation of healthcare recipient (HCR)'s / healthcare provider (HCP)'s registration)

2. Clauses 10(1) / 11(1) of the bill provide that the Commissioner for the Electronic Health Record (eHRC) may, under the circumstances specified, suspend / cancel the registration of an HCR if he/she reasonably suspects that / is satisfied that certain events have occurred. Clauses 22(1) / 23(1) are similar provisions in respect of the registration of an HCP. The rationale for not specifically providing for the “representations” by an HCR / HCP against suspension / cancellation of registration is set out below.

3. Firstly, the events or circumstances leading to suspension / cancellation of the registration of an HCR / HCP are generally technical / regulatory related. Examples include the contravention of a provision of the eHRSS Ordinance, the contravention of a condition for registration, the impairing of security / compromising of integrity of the eHRSS and (for an HCP only) the non-compliance with the requirements specified by the eHRC for connecting the HCP to the eHRSS. Prompt action of suspension / cancellation is necessary for certain special situations such as when an HCR has provided wrong personal particulars that identify him/her as another HCR and when an HCP whose local electronic medical record (eMR) system has found to be

infected by computer virus, which may potentially result in dire consequences on the integrity of health records shared with the eHRSS. The merits of prompt suspension / cancellation of registration should outweigh any potential loss (either financially or otherwise) that the concerned HCR / HCP may incur. The eHRSS is by nature a voluntary scheme to facilitate sharing of health records that exist in local eMR systems and the HCR / HCP can take into account the reasons of suspension / cancellation of registration and re-apply for registration. The context and underlying consideration of our bill are therefore different from those of the Betting Duty Ordinance (Cap. 108) and the Mandatory Provident Fund Schemes Ordinance (Cap. 485).

4. Secondly, we anticipate that before the eHRC exercises the power of suspension or cancellation of registration, he/she will likely take necessary administrative actions to seek information / clarification from the concerned HCR / HCP (for instance, fact finding, case establishment, negotiation or warning, request for remedy). He/she has to reasonably suspect that / is satisfied that the circumstances as stipulated in Clauses 10(1) / 11(1) / 22(1) / 23(1) occurred. In practice, it will be a two-way interactive process during which the concerned HCR / HCP will be timely informed of the potential suspension or cancellation, and they can provide information or clarification to the eHRC.

5. Clauses 10(2) / 11(2) of the bill provide that the eHRC must, after the suspension / cancellation of registration of an HCR, notify “the specified person”¹ in writing (i) the suspension / cancellation, (ii) the date on which the suspension / cancellation takes effect, and (iii) the reasons for suspension or cancellation. Clauses 22(2) / 23(2) are similar provisions concerning the registration of an HCP, providing that the eHRC must similarly notify the concerned HCP. According to Clause 55, if the HCR / HCP is aggrieved by the suspension / cancellation decision of eHRC, he may appeal to the Administrative Appeals Board. In addition, Clause 47 of the bill provides that the eHRC will be a public officer. Accordingly, he/she will have to act reasonably under the administrative law principle with respect to the aforementioned provisions of the bill. These arrangements in the bill are able to appropriately protect both the interests of the HCR / HCP and the system integrity and safety.

6. In particular, we wish to highlight that sub-clause (d) of Clauses 10(1) / 11(1) and sub-clause (e) of Clauses 22(1) and 23(1) are concerned with the event that the concerned registration may impair the security or compromise the integrity of the eHRSS. There are a variety of examples. For an HCR, it

¹ The “specified person” means either the HCR himself/herself or his/her substitute decision maker, depending on whether the HCR is a minor / incapable of giving a “joining consent” and who made the application for the registration of the HCR. See Clauses 10(5) and 11(4) for details.

could be the HCR using fraudulent identity document for registration, using multiple identity documents to register at different points in time, or not informing the eHRC on changes of personal particulars, among others. For an HCP, it could be the HCP not following security best practices and controls for its local eMR system (such as physical control and installation of active anti-virus or anti-malware software with up-to-date definitions) or not suitably following up on a suspected security incident that affects the use of / connection with eHRSS, among others.

7. Given that the bill is technology neutral and that new factors or risks relating to security or integrity of the eHRSS will emerge over time due to technological advancement, it is not desirable nor feasible to list out the factors exhaustively in the bill. We will instead suitably promulgate guidelines and conduct publicity to promote HCRs' and HCPs' understanding of the precautionary steps and security measures.

Clause 48 (Functions and powers of Commissioner)

8. Clause 48 of the bill provides for the functions and powers of the eHRC. The eHRC is empowered, among others, under Clause 48(1)(c), to "supervise" the compliance with the eHRSS Ordinance. As the ordinary / dictionary meaning of the word "supervise" could already cover that of the word "monitor", we do not consider it necessary or desirable to use the two words in parallel. This is in line with the guiding principle in legislative drafting that we should pursue clarity and avoid using more than one word when one word will do.

9. Indeed, the parallel use of the words "monitor" and "supervise" in a provision relating to the functions of an authority concerning compliance with the provisions of an ordinance is not common among existing ordinances. Examples that we can find are Section 8 of the Personal Data (Privacy) Ordinance (PDPO) (Cap. 486) and Section 5 of the Securities and Futures Ordinance (Cap. 571). In contrast, the use of the word "supervise" singly in such provision is very common, such as Section 4A of Insurance Companies Ordinance (Cap. 41), Section 6 of the Gas Safety Ordinance (Cap. 51), Section 7 of the Banking Ordinance (Cap. 155), Section 23 of the Aviation Security Ordinance (Cap. 494), Section 8 of the Land Titles Ordinance (Cap. 585) and Section 87 of the Residential Properties (First-hand Sales) Ordinance (Cap. 621).

10. HCPs are required to observe and follow the codes of practice and security guidelines published by the eHRC. The eHRC will also monitor the security compliance of local eMR systems of HCPs by means of HCPs' security assessments during their first registration to the eHRSS and subsequent periodic

assessment. Physical inspection of the eMR of HCP is not necessary. Correspondingly, it has already been provided in Clauses 22 and 23 of the bill that the eHRC may suspend / cancel the registration of an HCP for contravening a provision of a code of practice, contravening a condition for registration, or no longer complying with the requirements specified by the eHRC for connecting the HCP to the eHRSS / the system requirements on data sharing specified by the eHRC, among other events. In addition, as provided under Clause 50 of the bill, if it appears to the eHRC that there are circumstances suggesting the happening of the events that could lead to suspension / cancellation of registration of an HCP, the eHRC may in writing require the HCP to produce a record or document that is or may be relevant to the event and is in the HCP's possession.

11. The above explains that the eHRC is already empowered to require HCPs to comply with the technical requirements. We do not consider it necessary or sufficiently justified to empower the eHRC under the bill on forced inspection of HCPs' system. Such inspection would be intrusive and the power would be disproportionate to the objective, as previously explained to the Bills Committee². Meanwhile, individual HCPs are "data users" in respect of their local eMR systems in the context of the PDPO and accordingly need to ensure that the use of their eMR systems complies with the PDPO. The powers of the Privacy Commissioner for Personal Data (PCPD) over these HCPs, including the power to inspect their local eMR systems, are unaffected by our bill. As for suspected criminal offences under the bill, the Police will be the agency to investigate.

12. Clause 48(h) of the bill provides that the eHRC has the function to devise a mechanism for handling complaints relating to the operation of the eHRSS. The mechanism will be devised with reference to existing relevant guidelines of the Administration, and suitably promulgated to stakeholders when available. There is no need to stipulate detailed operational procedures of complaint handling in the bill.

Clause 50 (Commissioner to require production of records or documents in certain circumstances)

13. As provided under Clause 50 of the bill, if it appears to the eHRC that there are circumstances suggesting the happening of the events that could lead to suspension / cancellation of registration of an HCP, the eHRC may in

² As previously explained to the Bills Committee, the eMR systems of HCPs are not part of the eHRSS. The eHRC supervises connections of the eMR systems of HCPs to the eHRSS but not the eMR systems, while the eMR systems may be used by HCPs for other internal operational and business purposes outside the purview of the eHRC.

writing require the HCP to produce a record or document that is or may be relevant to the event and is in the HCP's possession.

14. Section 3 of the Interpretation and General Clauses Ordinance (Cap. 1) provides that "document" (文件) means "any publication and any matter written, expressed or described upon any substance by means of letters, characters, figures or marks, or by more than one of these means". Such definition does not preclude documents in the electronic format. In the absence of a specific definition in an ordinance, the interpretation of the term "document" will follow the definition of the term in Cap. 1. A specific definition of the term is necessary if it is considered that the meaning given by Cap. 1 cannot reflect the policy intent in a specific context. Having regard to the context of our bill, we do not consider it necessary to define "document" under our bill. The specific definition of the term in the Companies Ordinance (Cap. 622) can be differentiated. The term "document" is separately defined in various parts of that ordinance to help readers accurately interpret the meaning of the term used in different provisions of that ordinance. This is a specific and exceptional context not shared by our bill.

Clause 51 (Commissioner to issue code of practice)

15. The code of practice (CoP) under Clause 51(1) of the bill is an administrative instrument for providing guidelines on best practices relating to the use of eHRSS. It is of technical nature and in essence an operation manual. It will help users to better understand the working of the system and how to perform certain functions, e.g. procedures to handle application for registration. Breach of any provision in the CoP in itself will not directly impose on the person any civil or criminal liability. After all, we will accept alternative approaches / means that fulfil the underlying requirements on the level of care and standards of practice. For instance, various security measures other than those suggested in the CoP can be adopted to ensure physical and system security of the eMR system of an HCP. New options would also emerge over time due to technological advancement. That said, following the guidelines in the CoP will help minimise the risk of breaching the future eHRSS Ordinance.

16. Subject to the usual evidential rules, the CoP, like any other public document, is admissible in legal proceedings. Meanwhile, it is not our intention to follow Section 13 of the PDPO or Section 30 of the Unsolicited Electronic Messages Ordinance (Cap. 593) to provide that a failure to observe any provision of a CoP may be relied upon as tending to establish a particular matter in the proceedings or as taking such matter as proved.

Clause 53 (Establishment of Board)

17. Clause 54(2) of the bill stipulates that the Electronic Health Record Research 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 eHRC, or a person nominated by the eHRC as representative, as ex officio member; and
- (c) not more than 10 other members appointed by the Secretary for Food and Health.

18. With regard to members in (c), we have undertaken vide our written response to Bills Committee following 3rd meeting on 26 May 2014 (LC Paper No. CB(2)1775/13-14(03)) to propose a committee stage amendment to the bill to elaborate on the specific requirements for the members.

19. As regards the issues raised in para. 8 of your letter dated 10 February 2015, our original approach is to rely on the Interpretation and General Clauses Ordinance (Cap. 1), i.e. the Secretary for Food and Health, as the person being conferred with the powers to make appointment, would have the power to determine the term of appointment, re-appointment and removal of members. Nevertheless, we are prepared to make express provisions for these matters as suggested in your letter.

Clause 59 (Service of notice etc.)

20. In the absence of a specific definition in an ordinance nor in Cap. 1, the interpretation of a term will be based on its ordinary / dictionary meaning. The term “officer” generally refers to a person who holds an office of authority or trust in an organization, such as a corporation or government. The list of persons who may be an officer of a company is not exhaustive, depending on the functions actually performed by a particular person. It is desirable for an ordinance of general application (where the meaning of “officer” is not a focus of discussion) to allow flexibility in interpreting the term without a specific definition. We do not consider it necessary to depart from the norm of local legislation (including the PDPO), that is, not specifically defining the term “officer” in our bill. On the other hand, the definitions of “officer” in the Mandatory Provident Fund Schemes Ordinance (Cap. 485) and the Companies Ordinance (Cap. 622) are necessary in their own contexts. In Cap. 485, the definition of “officer” is necessary for finding out whom the relevant duties in relation to the Mandatory Provident Fund scheme are imposed on. In Cap. 622, the term “officer” is separately defined in different parts of that ordinance to

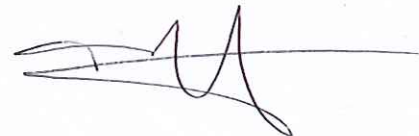
help readers accurately interpret the meaning of the term used in different provisions of that ordinance. These are specific and exceptional contexts not shared by our bill.

Drafting matters

21. There are some ordinances in which “personal particulars” are defined (such as in ordinances concerning electorate registers), but there are also various ordinances in which the term is not defined. In the latter case, the ordinary / dictionary meaning is relied upon for interpretation of the term. For instance, the Medical Practitioners (Registration and Disciplinary Procedure) Regulation (Cap. 161E) provides that an application for registration as a medical practitioner must contain, among others, the “personal particulars” of the applicant, without defining the term “personal particulars”. The same approach is necessary in our bill for preserving flexibility to meet changing operational needs of the eHRSS and technological advancement over time.

22. At the same time, we will give due regard to the privacy of the personal data of HCRs and comply with relevant requirements under the PDPO. For instance, Data Protection Principle 1 of the PDPO, which applies to data users including the eHRC, requires that collection of data has to be “for a lawful purpose”, “adequate but not excessive” and “by fair means”. In addition, HCRs will be informed of the purposes and implications of collection their personal data via a Patient Information Notice and a Personal Information Collection Statement before any personal data is collected, while the overall privacy policy and data protection measures of eHRSS will be listed out in a Privacy Policy Statement.

Yours sincerely,



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for Secretary for Food and Health

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