



中華人民共和國香港特別行政區政府總部醫務衛生局
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28 April 2025

Ms Yvonne WONG
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Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
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Dear Ms Wong,

Electronic Health Record Sharing System (Amendment) Bill 2025

Thank you for your letter dated 16 April 2025. Our responses to the legal and drafting issues raised in your letter are set out at **Annex**.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Erica Lam".

(Erica LAM)
for Secretary for Health

Encl.

c.c. Department of Justice
(Attn: Mr Michael CHOI, Senior Government Counsel)
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Annex

**The Administration's Responses to the Legal and Drafting Issues on
Electronic Health Record Sharing System (Amendment) Bill 2025
(Appendix of Letter from Assistant Legal Advisor
of the Legislative Council dated 16 April 2025)**

Clause 1(2) – Commencement

The Electronic Health Record Sharing System (Amendment) Bill 2025 (“the Bill”) aims to refine the existing legal framework of the Electronic Health Record Sharing System (“eHealth”) to support its function enhancements under the eHealth+ five-year development plan, which has commenced since the approval of the capital funding of HK\$1.396 billion by the Finance Committee of the Legislative Council in July 2024.

2. The key legislative proposals in the Bill, among other things, seek to create an enabling legal framework to support the eHealth+ development. They include the proposals to empower the Secretary for Health to require specified healthcare providers (“HCPs”) to provide specified health data of registered healthcare recipients (“HCRs”) into the HCRs’ personal eHealth accounts, to empower the Commissioner for the Electronic Health Record (“eHRC”) to recognise non-Hong Kong HCPs and non-Hong Kong information infrastructures for the operation of eHealth, and to facilitate the use of electronic medical documents, etc. Other proposals are expected to take immediate practical effect upon commencement of the Electronic Health Record Sharing System (Amendment) Ordinance 2025 (“Amendment Ordinance”) and require corresponding changes be made to the existing eHealth system and operational workflows, such as the proposed streamlined consent mechanism for HCRs.

3. The Government is preparing the technical set-up, including the implementation arrangements for the streamlined consent mechanism. Subject to the passage of the Bill within this legislative session and technical readiness of the eHealth system, we plan to commence operation of the Amendment Ordinance by the end of 2025 at the earliest, so as to tie in with the implementation of the relevant eHealth+ development projects in a timely manner. We will assess the preparation progress and consider moving a committee stage amendment (“CSA”) to specify the commencement date of the Amendment Ordinance if appropriate.

Clauses 28 and 48 – Recognition of non-Hong Kong HCPs and non-Hong Kong information infrastructures, and right of appeal to the Administrative Appeals Board (“AAB”)

(a) Current regime for Hong Kong HCPs

4. eHealth is positioned as a territory-wide electronic platform that enables HCPs in the public and private sectors in Hong Kong to view and share HCRs’ electronic health records (“eHRs”) for healthcare purposes with their authorisation. Under section 19 of the Electronic Health Record Sharing System Ordinance (Cap. 625) (“Cap. 625”), specified categories of HCPs that provide healthcare at a service location in Hong Kong may apply to the eHRC to be registered as a HCP for eHealth. The HCPs’ registration process involves an application to be made by the interested HCP to the eHRC. Accordingly, section 20 of Cap. 625 requires the eHRC to notify, with reasons, the relevant HCP if the eHRC decides to refuse the application. Section 56 of Cap. 625 also provides the HCP with a right of appeal to the AAB, should the eHRC refuse the registration of the HCP concerned.

5. A set of Code of Practice (“CoP”) is issued by the eHRC under section 52 of Cap. 625 to provide practical, technical and operational recommendations and measures to safeguard the security and privacy of eHealth, thus facilitating interpretation and compliance with Cap. 625 by the registered HCPs. The CoP is administrative in nature. Depending on the fact and action committed in relation to such non-compliance with the CoP, the eHRC is empowered to carry out any disciplinary actions, including suspension and cancellation of registration of an HCP in eHealth.

(b) Proposed regime for non-Hong Kong HCPs and non-Hong Kong information infrastructures

Recognition process

6. With the increasing use of cross-boundary healthcare services among Hong Kong citizens, the legislative intent of clause 28 of the Bill is to empower the eHRC to recognise non-Hong Kong HCPs and non-Hong Kong information infrastructures for the operation of eHealth, thereby facilitating Hong Kong citizens to use their eHRs across the boundary in a more convenient and secure manner and enhancing the continuity of care. The Bill adopts a different approach by empowering the eHRC to actively recognise non-Hong Kong HCPs and non-Hong Kong information infrastructure vis-à-vis the current regime for Hong Kong HCPs as set out in paragraphs 4 to 5.

7. Under the proposed regime of the Bill, the recognition of a non-Hong

Kong HCP or the operator of a non-Hong Kong information infrastructure will not be processed through an application made by those non-Hong Kong entities to the eHRC. The eHRC will instead initiate the recognition process by identifying and selecting suitable non-Hong Kong HCPs and non-Hong Kong information infrastructures after considering relevant factors, including the demand of Hong Kong citizens in using the cross-boundary healthcare services provided and the technical feasibility of the systems involved. As there will not be any application made by non-Hong Kong HCPs or operators of non-Hong Kong information infrastructures in the recognition process, it is not necessary to require the eHRC to notify them the reasons for the refusal of recognition under the Bill.

Suspension and revocation of recognition

8. According to clause 28 of the Bill, the recognition of non-Hong Kong HCPs and non-Hong Kong information infrastructures is subject to meeting specified system requirements and conditions imposed by the eHRC, in order to safeguard data privacy and system security. For relevant matters that are governed by the CoP in relation to Hong Kong HCPs, we will consider including them in the conditions to be imposed by the eHRC for the recognition of a non-Hong Kong HCP or that of a non-Hong Kong information infrastructure as appropriate. Under the Bill, the eHRC will be empowered to suspend or revoke the recognition of a non-Hong Kong HCP or that of a non-Hong Kong information infrastructure, in case the eHRC reasonably suspects or is satisfied that the imposed conditions are contravened or the recognition may impair the security or compromise the integrity of eHealth.

9. The Government does not intend for the Bill to have extra-territorial effect. To ensure that there are sufficient leverages in place to enforce the imposed conditions, and regulatory compliance in the relevant jurisdictions, we envisage that the cross-boundary sharing and use of eHRs through eHealth will need to be backed by Government-to-Government arrangements and/or agreements to be entered into with the non-Hong Kong HCPs and the operators of the non-Hong Kong information infrastructures concerned. The specified requirements and conditions for the recognition as well as the suspension and revocation arrangements will be stipulated in these arrangements and/or agreements. In light of the above, it is considered not necessary to include the contravention of Cap. 625 and the CoP as grounds for the eHRC to suspend or revoke a recognition of a recognised non-Hong Kong HCP or a non-Hong Kong information infrastructure under the Bill.

Right of appeal

10. In line with the Government's legislative intent that the Bill will not have

extra-territorial effect, the Bill does not provide for the right of appeal to the AAB by a person who is aggrieved by a decision of the eHRC to suspend or revoke a recognition of a non-Hong Kong HCP under the proposed new section 26C(1) or 26D(1) of Cap. 625 or to suspend or revoke a recognition of a recognised non-Hong Kong information infrastructures under the proposed new section 26G(1) or 26(H) of Cap. 625.

Clauses 29 and 48 – Enforcement notice and right of appeal to the AAB

11. On similar consideration of the non-extraterritoriality of the Bill, the requirement under the proposed new section 26Q(2) of Cap. 625 is not applicable to recognised non-Hong Kong HCPs. To facilitate HCRs in building comprehensive personal eHR profiles, the Government would consider requiring a recognised non-Hong Kong HCP to provide specified health data through the conditions attached to the recognition, to be imposed by the eHRC under the proposed new section 26E(1)(b) of Cap. 625.

12. The enforcement notice arrangement is to provide the eHRC with the necessary powers to ensure compliance with the requirement for the specified HCPs to provide specified health data of registered HCRs into the HCRs' personal eHealth accounts. Under the proposed new section 26R(4) of Cap. 625, the eHRC may amend an enforcement notice issued to a specified HCP under the proposed new section 26R(1) of Cap. 625 by another notice in writing. This serves to offer greater flexibility for the eHRC to enforce the requirement and encourage collaborations with HCPs in building comprehensive personal eHR profiles for HCRs in support of their healthcare needs. For example, if the specified HCP, on reasonable grounds, requests for an extension of time for providing the specified health data to eHealth, the eHRC may, after due consideration, amend the enforcement notice concerned.

13. In the event that an enforcement notice is amended by the eHRC by another written notice pursuant to the proposed new section 26R(4) of Cap. 625, the original enforcement notice will be taken to have no effect. The 28-day time limit for appeal to the AAB against the decision of the eHRC under the proposed new section 56(2)(g) of Cap. 625 will begin from the day after the receipt of the amended enforcement notice by the relevant specified HCP. We will consider moving CSAs to provide greater clarity of the aforesaid arrangements and implications.

Clause 40 – Offences

14. A statutory offence is presumed to require proof of *mens rea* (i.e. the mental element or intention of wrongdoing) unless the presumption is displaced expressly or by necessary implication. The proposed new section 41A of

Cap. 625 is not intended to be a strict or absolute liability offence, and the *mens rea* is not to be replaced. The prosecution will need to prove the intention of the person to purport to hold out as eHealth in establishing the criminal liability.

15. Taking into account the nature and severity of the offence, we propose to set the penalty level of the offence at a fine of level 3 (HK\$10,000) for the proposed new sections 41A and 41B of Cap. 625. We have made reference to offences of similar nature in other legislations, namely, section 2(4) of The Chinese Medicine Hospital of Hong Kong Bill, section 24(2) of The University of Science and Technology Ordinance (Cap. 1141), section 23(2) of City University of Hong Kong Ordinance (Cap. 1132), section 29(2) of Hong Kong Baptist University Ordinance (Cap. 1126), and section 26(2) of The Hong Kong Academy for Performing Arts Ordinance (Cap. 1135).

Clauses 43, 52 and 56 – Enforcement arrangements in relation to an enforcement notice

Offence relating to enforcement notice

16. It is our legislative intent that the *mens rea* requirement of the proposed offence relating to an enforcement notice under the proposed new section 47A(1) of Cap. 625 is to be displaced. A defendant may rely on the relevant statutory defences provided under the proposed new section 47A(3) of Cap. 625, by establishing that (a) the person had, before the date of the enforcement notice, been given by the HCR a notice in the form specified by the eHRC stating that the HCR did not consent to the person's provision of the specified health data to eHealth; or (b) the person had otherwise exercised all due diligence to prevent the commission of the offence. Under the proposed new section 47A(4) of Cap. 625, the defendant will bear an evidential burden and the prosecution will need to prove the contrary beyond reasonable doubt. In our view, the statutory defences pertain to the defendant's state of mind and the common law defence of "honest and reasonable mistaken belief" are inconsistent with these statutory defences. The fourth alternative referred to in *Kulemesin v HKSAR (2013)* 16 HKCFAR 195 applies, and the defendant is confined to relying on the statutory defences provided for in the Bill.

17. Under section 26 of the Magistrates Ordinance (Cap. 227) ("Cap. 227"), for any offence other than an indictable offence, where no time limit is provided by any enactment, prosecution must be initiated within six months from the date of the offence. We propose to extend the prosecution time limit for initiating prosecution to a period of two years for the proposed offence under the proposed new section 47A(5) of Cap. 625. This will allow sufficient time for the eHRC to handle the complaints of HCRs and investigate cases of non-compliance, to offer opportunity for the HCPs to discharge the criminal liability by complying

with the penalty notice, and to reduce the chance of specified HCPs escaping from criminal liability upon the expiry of the prosecution time limit.

18. Generally speaking, in providing signposts or other factual information for readers, notes in legislation help them to understand the legislation more quickly and to get a clearer picture of it. A note that is used for giving information to readers would not affect the interpretation of the legislation. The note at the end of the proposed new section 47A(5) of Cap. 625 is commonly used in provisions providing for specific time limits for initiating prosecution of specific summary offences. Relevant examples include section 64B(1) of the Personal Data (Privacy) Ordinance (Cap. 486) (“Cap. 486”), section 47 of the Fire Safety (Industrial Buildings) Ordinance (Cap. 636) (“Cap. 636”) and section 65 of the Mercury Control Ordinance (Cap. 640) (“Cap. 640”). In the present case, the note is intended to draw to readers’ attention that the time limit for initiating prosecution provided under the proposed new section 47A(5) of Cap. 625 would replace the one under section 26 of Cap. 227. The purpose of the note as readers’ aid is clear from the present context and does not require further express clarification. We also observe that Cap. 486, Cap. 636 and Cap. 640 adopt the same practice as the Bill in respect of the notes concerned and make no further clarification in respect of such notes.

19. Having considered the nature and severity of the offence, we propose to set the penalty level of the offence at a fine of level 5 (HK\$50,000), and a further daily fine of HK\$1,000 if the offence continues after the conviction. We have made reference to an offence of similar kind under section 50A(1) of the Cap. 486. The penalty therein is set, on a first conviction, at a fine at level 5 (HK\$ 50,000) and imprisonment for two years, and if the offence continues after the conviction, a daily penalty of HK\$1,000. We consider that a pecuniary penalty is sufficient deterrent to the specified HCPs from contravening the enforcement notice. Punishment by imprisonment is disproportionate to the gravity of the offence under the proposed new section 47A of Cap. 625 and is therefore not adopted in our case. We also note that healthcare professionals (“HCProfs”) charged with an offence punishable by imprisonment may be liable to disciplinary proceedings of the relevant regulatory bodies. The proposed penalty level is intended to avoid any direct consequence on the professional registration status of HCProfs arising from the offence.

Compliance of enforcement notice

20. The Government’s legislative intent is that for the purposes of the proposed new section 47B(2)(b) of Cap. 625, and sections 6(2) and 9(4)(b) of the proposed new Schedule 4 to Cap. 625, an enforcement notice would be taken to be complied with if the specified HCP has provided the specified health data to eHealth in the form and manner as stated in the enforcement notice,

notwithstanding the actual provision of the specified health data is made after the date specified in the enforcement notice. We will consider whether there is a need to move a CSA to provide greater clarity of our legislative intent.

Service of enforcement notice and penalty notice

21. Section 60 of Cap. 625 sets out how notices or documents required under Cap. 625 are to be properly delivered to relevant parties. We consider that the proposed amended section 60 of Cap. 625 would be appropriate for the service of an enforcement notice or a penalty notice.

Recovery order

22. As the recovery notice is to be issued by a magistrate, the Government's legislative intent is that the proposed amended section 60 of Cap. 625 would not apply to the service of the recovery notice. We will consider whether there is a need to move a CSA to provide greater clarity on the service arrangements of the recovery order, in consultation with the Judiciary.

Drafting issues

23. Whether it is necessary to use “任何” in the Chinese text of a provision when the English text of the provision uses “any” depends on the context of the provision. The proposed amended sections 7(3) and 12(3) of Cap. 625 concern the giving of a joining consent by a HCR and the giving of a sharing consent by a registered HCR respectively. The consents concern every single piece of sharable data of the HCR. In this context, we consider it appropriate to use “任何可互通資料” in the Chinese text to emphasise such a meaning.

24. In contrast, the proposed new sections 26T and 26U of Cap. 625 empower a registered HCR and a related person of the HCR to provide or obtain any sharable data of the HCR to or from eHealth. As the emphasis of the two proposed new sections is the provision and obtainment of sharable data respectively, there is no need to emphasise the meaning of “every single piece of sharable data”. In this context, we consider it unnecessary to add “任何” before “可互通資料” in the Chinese text of those sections.

25. Collocation is essential in legislative drafting. We consider that “暫時撤銷” collocates more naturally with “認可”. We note that section 86(1) of the Insurance Ordinance (Cap. 41) also uses “暫時撤銷” to collocate with “認可”. Thus, we consider that no amendments are necessary for the proposed new sections 26C and 26G of Cap. 625.

26. In relation to the proposed new section 53A of Cap. 625, we will consider moving a CSA to remove “在” from the Chinese text of the provision.

27. “.” and “。” are featured at the end of each of the proposed new items in the English and Chinese texts of the proposed renumbered Schedule 1 to Cap. 625 to achieve consistency with the existing items in that Schedule in respect of format. However, schedules added by legislation enacted in recent years generally do not feature “.” or “。” at the end of each of the items contained in them. An example is the new Schedule 3A to the Securities and Futures Ordinance (Cap. 571) that is to be added by section 28 of the Securities and Futures and Companies Legislation (Amendment) Ordinance 2021 (17 of 2021). As a new Schedule, the proposed new Schedule 5 to Cap. 625 adopts this format. The “.” and “。” at the end of the items in existing Schedules will be reviewed systematically at an appropriate juncture in the future and (if necessary) be removed by editorial amendments under the Legislation Publication Ordinance (Cap. 614). Thus, we consider that no amendments are necessary for the proposed new Schedule 5 at this stage.

CoP

28. Pursuant to section 52 of Cap. 625, a set of CoP has been issued by the eHRC to provide practical guidelines, good practices, and recommendations for the use of eHealth and to ensure secure and proper operation of the system. The Government will review and revise the CoP to reflect the substantial changes to the functions of eHealth as proposed under the Bill. We will revise the CoP in phases to tie in with the launch of the new functions when taking forward the eHealth+ development.