Bills Committee on Private Healthcare Facilities Bill

Government's response to the follow-up issues raised at the Bills Committee meeting on 7 November 2017

Purpose

This paper sets out the Government's response to the follow-up issues raised at the meeting of the Bills Committee on Private Healthcare Facilities Bill (the Bill) held on 7 November 2017.

Exclusion for the Two Universities

2. The Bill aims at regulating private healthcare facilities (PHFs) providing medical services to the public. The legislative intent is to revamp the current framework to broaden the regulatory scope amid the evolving landscape of healthcare services, such as the emerging market of ambulatory day procedure centres and clinics. On the other hand, whilst The University of Hong Kong (HKU) and The Chinese University of Hong Kong (CUHK) have set up certain PHFs, it is noted that the primary purpose of such facilities is for teaching and research rather than service provision.

3. At the Bills Committee meeting on 9 October, representatives from the Faculties of Medicine of HKU and CUHK expressed the views that facilities managed or controlled by the Faculties should not be regulated under the Bill. The provision of medical services at these facilities forms an integral part of the teaching and research process. The patient flow and care model in these facilities are different from those in ordinary PHFs. In particular, with teaching and research being the primary objective, the care model in such facilities tends to be more enhanced and comprehensive, so as to allow more interaction and contact between patients and the university staff and students.

4. Given the above, the regulatory regime for ordinary PHFs may not sit well with the operational models of these facilities. Moreover, the two universities are independent and autonomous statutory bodies, each with its own ordinance and governing council and enjoy academic freedom and

institutional autonomy. They have already put in place a robust governance structure that is fit-for-purpose with due regard to the nature of these facilities and their unique cohort of stakeholders[1].

Governance

5. In HKU, a two-layer governance structure, with reference to that of the Hospital Authority (HA), has been established for each facility. At the facility level, each facility has an overarching Board/management committee, comprising key stakeholders, to steer and control the direction and operations of the facility. These stakeholders may include, as appropriate, HA representatives and community representatives, forming a mix of both professional and lay members. Additionally, each facility has a designated responsible officer, who is a senior clinical professoriate staff, to be responsible for the day-to-day administration of the facility, including the implementation of policies and procedures to safeguard and improve the quality of care and to ensure compliance. These policies and procedures include the highest standards of clinical leadership, supervision requirements, practice standards, clinical risk management, infection control and emergency preparedness. Reference had been made to HA in the development and implementation of these measures.

6. At the Faculty level, the HKU Health System has been established under the Li Ka Shing Faculty of Medicine, so as to exercise effective oversight of the Faculty's clinical services and to assure robust clinical governance. The HKU Health System ensures oversight and compliance assurance through -

(a) participating in relevant clinical governance structures/committees;
(b) establishing clinical guidelines, monitoring and review (including clinical audits);
(c) conducting audits in accordance with the established frameworks; and
(d) spearheading investigations into relevant incidents, so as to identify their root causes, as well as to ensure learning and improvement take place.

[1] Such stakeholders include but are not limited to the universities management, patients, teaching and research staff, students, the Government and the academia.

7. Similar arrangement is in place for the Faculty of Dentistry of HKU. At the Faculty level, the Faculty Board maintains a central overseeing and monitoring role of the activities of the Institute for Advanced Dentistry, including the operation of its Multi-Specialty Clinic.

8. In CUHK, a two-layer governance structure at the university level and Faculty level is in place for the facilities concerned. A healthcare facility needs to fulfill all the regulations made by CUHK and its Faculty of Medicine. Currently, endorsement and approval from CUHK's relevant committees and Faculty of Medicine are required before setting up a facility.

9. For clinical governance, CUHK adheres strictly to the standard and practice of HA, including but not limited to –

(a) the qualifications of healthcare professionals for providing services in the facility and delineation of their clinical responsibilities;
(b) all matters concerning medical diagnosis, treatment and care given, or to be given, in the facility; and
(c) all matters concerning the quality of care for, and the safety of, patients in the facility.

Complaints and Medical Incidents Handling

10. An established complaints management system, comprising three tiers, is in place for the relevant facilities in the two universities. The first-tier is at the service delivery level where the facilities should manage complaints at source. At the second-tier, a mechanism is in place at the Faculty level, so as to look into complaints unresolved at service delivery level by the facilities concerned. If a complaint remains unsettled, it will be escalated to the university level for further review. The complainant will also be informed of other sources for lodging complaints. In formulating the complaints management system, the two Faculties of Medicine have made reference to that of HA while the Faculty of Dentistry of HKU to that of The Prince Philip Dental Hospital (PPDH).

11. Regarding medical incidents, reporting and handling systems are established with reference to those of HA and PPDH accordingly. Under the systems, investigations will be carried out to identify possible causes of the incidents, and to encourage learning and improvement. For complaints involving alleged misconduct by medical practitioners and dentists, they will

also be subject to the jurisdiction of the Medical Council of Hong Kong and the Dental Council of Hong Kong respectively.

Exclusion

12. In response to the two universities' views set out in paragraph 3 above, we proposed to introduce an amendment to exclude facilities fulfilling certain criteria[2]. We consider that the 14 existing facilities set out in the Annex to LC Paper No. CB(2)196/17-18(02) meet the criteria of being primarily used for teaching or research relating to medicine or dentistry, as these facilities share the following common traits -

(a) in respect of the services provided by registered medical practitioners or registered dentists, the great majority of patients, if not all of them, are involved in teaching or research; and

(b) except the staff and students of the two universities, no other registered medical practitioners and registered dentists are allowed to practise in these facilities. In addition, in case top-notch non-local experts practise in these facilities for the purpose of teaching or research, the universities will ensure that relevant laws and regulations are complied with.

13. To sum up, we consider that a robust governance structure (including those pertaining to complaints and medical incidents handling) has already been in place in the two universities. Duplicating relevant efforts, simply to comply with another set of regulatory requirements under the Bill, might not be an optimal use of resources.

Patient Organizations' Views

14. Subsequent to the Bills Committee meeting on 7 November, we had a meeting with representatives of patient organizations to discuss matters related to the Bill. Regarding the proposal to exclude from the Bill relevant facilities managed or controlled by the universities, the representatives considered that the key factor that determined whether the facilities should be excluded was the existence of a robust mechanism on

[2] We proposed that facilities fulfilling the following criteria should not be regulated under the Bill –
(a) being managed or controlled by HKU or CUHK;
(b) being a day procedure centre, clinic or health services establishment; and
(c) being primarily used for teaching or research relating to medicine or dentistry.

clinical risk management as well as complaints and medical incidents handling in these facilities.

Letter of Exemption for Small Practice Clinics

15. Under clause 42 of the Bill, a person that operates, or intends to operate, a small practice clinic may ask the Director of Health (the Director) for a letter of exemption for the clinic. Such request must be made in the form and way specified by the Director.

16. The letter of exemption for a clinic may be issued if the Director is satisfied that the conditions set out in clause 43(1) of the Bill are met. The request form for letter of exemption serves to obtain the information necessary for proving the clinic's eligibility, supported by the operator(s)' declaration, as well as the particulars that would allow the public and the licensing authority to identify the exempted clinic (e.g. name, address and floor plan). A draft request form will be provided to the Bills Committee when available, so as to illustrate the information required to facilitate the clause-by-clause examination of the relevant provisions.

Two-year Period on Facility Complaints

17. HA has established a two-level complaints system to handle public complaints. At the first-tier, all complaints are handled by the respective hospitals/clinics. Unresolved complaints will be reviewed by the Public Complaints Committee (the Committee) established under the HA Board. The Committee does not normally handle a complaint relating to services provided by HA more than two years before the date of the lodging of the complaint.

18. The two-year period mentioned in paragraph 17 above was formulated with reference to the policies and practices of both overseas and local complaint redress organizations. In Hong Kong, similar arrangements are adopted by the Office of The Ombudsman, the Office of the Privacy Commissioner for Personal Data and the Independent Police Complaints Council.

19. We have taken into consideration the arrangements mentioned in paragraphs 17 and 18 above in formulating the complaints management system under the Bill.

Use of Local Anaesthetics in Cosmetic Tattooing

20. Local anaesthetics are pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). According to regulation 36 of the Pharmacy and Poisons Regulations (Cap. 138A), a pharmaceutical product must be registered with the Pharmacy and Poisons Board before it can be supplied legally in the market, subject to certain exceptions under that regulation. Local anaesthetics containing Part 1 poisons (such as lignocaine) can only be supplied by a registered medical practitioner for the purposes of medical treatment, or sold in a registered pharmacy by a registered pharmacist (or in his/her presence and under his/her supervision), etc. as required under section 21 of Cap. 138. The illegal sale and possession of Part 1 poisons and unregistered pharmaceutical products are criminal offences. The maximum penalty for each offence is a fine of $100,000 and two years' imprisonment.

21. Cap. 138 does not prohibit a person's administration of local anaesthetics containing lignocaine, so long as the local anaesthetic concerned is supplied by a registered medical practitioner or bought from a registered pharmacist in a registered pharmacy. Depending on the circumstances, the administration of local anaesthetics to a person for the purpose of pain control is an act of practising Western medicine. Moreover, the use of pharmaceutical products, such as local anaesthetics, may cause adverse effects and response that vary amongst individuals. Advice from healthcare professionals should be sought in using these products.

Requirement on Chief Medical Executive

22. Under clause 53(4) of the Bill, a person must not serve at the same time as the chief medical executive of more than two day procedure centres or clinics, except in the situation referred to in clause 53(5) where a person is appointed under clause 50 to serve as a chief medical executive of three or more clinics operated at the same time by the same licensee. Such

requirement was proposed such that the chief medical executive would be able to take charge of the day-to-day administration of the facilities under his/her responsibilities. Some Members opined that a registered medical practitioner should be allowed to serve at the same time as the chief medical executive of more than two day procedures centres or clinics operated by different licensees. With each chief medical executive being allowed to take charge of more PHFs, the proposal may cast doubt on the internal governance of the day procedure centres and clinics concerned, which is one of the important regulatory aspects to be enhanced under the new regime. We would need more time to fully assess the implications of this proposal in consultation with relevant stakeholders, before considering whether it is appropriate to relax this requirement via a Committee Stage Amendment.

Requirement on Separate Entrance

23. In respect of permitted facilities (i.e. licensed facilities and exempted clinics), clauses 66 and 67 of the Bill set out the requirements on having distinct and separate premises as well as separate entrance respectively. Such requirements are in place because of the following reasons.

24. Firstly, the requirements concerned serve to separate a healthcare facility, which is subject to the regulatory measures stipulated in the Bill and the standards to be prescribed in the code(s) of practice, from premises that are not subject to such regulation. Over the past few years, several medical incidents involving beauty parlours have attracted public attention on the safety of medical procedures performed in these premises. There are also views from the community that the qualifications of the persons providing services in a beauty parlour are often unclear. For example, people are often confused on whether the person performing a particular procedure is a registered medical practitioner or not. With the requirements set out in clauses 66 and 67, premises where registered medical practitioners provide services will be separated from other premises. With clear segregation of premises, consumers will have clearer idea about the proper authority/channel from which they may seek redress in case of dissatisfying services. The risk of causing confusion to consumers will therefore be reduced. From the perspective of the operator of a permitted facility, the

premises and the services for which the operator and chief medical executive (if applicable) would be held accountable will also become clearer.

25. In addition, the requirements in clauses 66 and 67 facilitate enforcement under the new regime. Under clause 67, the operator of a permitted facility must ensure that the facility has a direct and separate entrance not shared with, or involving passing through, any premises that serve a purpose not reasonably incidental to the practice or type of the facility. If we allow the facility to have an entrance sharing with, or involving passing through, other privately-owned premises, the Director (or his/her authorized officers) may need to pass through some privately-owned premises before reaching the facility. If the owner of such privately-owned premises does not allow relevant officers to pass through his/her premises, a warrant may need to be obtained. Considering that there will be hundreds or thousands of permitted facilities under the new regime, it would be highly undesirable, if not infeasible, for relevant officers to obtain warrants whenever entrance to a permitted facility is required.

26. Against the above, we consider that the requirements in clauses 66 and 67, particularly the requirement on separate entrance, are crucial to the Department of Health (DH)'s effective enforcement. Such requirement ensures that relevant officers are able to enter a permitted facility for routine inspection or investigation for urgent incidents without undue delay.

Codes of Practice for Day Procedure Centres and Clinics

27. Under the new regime, different types of PHFs will each be subject to a set of regulatory standards (promulgated in the form of codes of practice) commensurate with the risk of the services they provide. Clause 102 empowers the Director to issue a code of practice about the matters set out therein.

28. To draw up standards for day procedure centres and to give advice on the standards for clinics, a Project Steering Committee on Standards for Ambulatory Facilities was set up by DH and the Hong Kong Academy of Medicine (HKAM) in mid-2015. The Project Steering Committee and its Task Forces comprise, among others, experts nominated by HKAM as well as other medical practitioners and dentists from public and private sectors.

So far, a set of Core Standards (at http://www.dh.gov.hk/english/main/main_orphf/files/CS_DPC.pdf), which applies to all day procedure centres, was promulgated by HKAM and DH in late 2016. Moreover, a set of Procedure-specific Standards for day procedure centres providing surgery, anaesthesia and sedation (at http://www.dh.gov.hk/english/main/main_orphf/files/Procedure_Specific_Standards_for_Surgery_and_Anaesthesia.pdf) was promulgated by HKAM and DH in May 2017, whereas those for other specific classes of procedures (e.g. endoscopy and haemodialysis) are under preparation.

29. The Standards for Medical Clinics, now under preparation, are devised with reference to the existing Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343) and relevant standards in overseas jurisdictions. DH had consulted relevant stakeholders (including major professional organizations) on the Standards, the draft of which were also sent to all registered medical practitioners and dentists in February 2017 (at http://www.dh.gov.hk/english/main/main_orphf/files/Ltd_20170201.pdf). DH is now revising the latest draft taking into account feedback received from stakeholders.

30. Before the introduction of the statutory licensing system under the new regime, the abovementioned standards for day procedure centres and clinics are adopted as professional guidance for operators, as well as for the medical and dental professions. The standards will be adapted to become the codes of practice under the new regulatory regime when the Bill is enacted and comes into force.

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