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Report of the Bills Committee on Private Healthcare Facilities Bill

Purpose

This paper reports on the deliberations of the Bills Committee on Private Healthcare Facilities Bill ("the Bills Committee").

Background

2. At present, private hospitals, nursing homes and maternity homes are regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), whereas non-profit-sharing medical clinics are regulated under the Medical Clinics Ordinance (Cap. 343)¹. These private healthcare facilities are required to register with the Department of Health ("DH"). DH has issued a Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes and a Code of Practice for Clinics Registered under the Medical Clinics Ordinance to set out the respective standards of good practice. Compliance with the relevant requirements is a condition for registration and renewal of registration of these private healthcare facilities.

3. The above two Ordinances were enacted in 1936 and 1963 respectively, to which no substantive amendments have been introduced since 1966 albeit changing landscape of the healthcare market. Separately, the Audit Commission has conducted a review of DH's regulatory control of private hospitals in 2012 and made a number of recommendations in Report No. 59 of the Director of Audit. In the light of the above and to address the increasing public concern over the

¹ Under section 2 of the Medical Clinics Ordinance, clinics do not include, among others, facilities that are managed, maintained or controlled by any department of the Government or the Hospital Authority, or used exclusively by certain healthcare professionals who have duly registered under other legislation.

regulation of high-risk medical procedures performed in ambulatory setting, the Administration established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee")² in October 2012 to conduct a holistic review of the regulation of private healthcare facilities.³ The Administration launched in December 2014 a three-month public consultation exercise to gauge the public's views on the proposals put forth in the Consultation Document on Regulation of Private Healthcare Facilities to revamp the existing regulatory regime for private healthcare facilities. In April 2016, the Administration published the Consultation Report on Regulation of Private Healthcare Facilities which set out the consultation outcomes and the way forward for putting in place a new regulatory regime.

The Bill

4. The Private Healthcare Facilities Bill ("the Bill") was published in the Gazette on 16 June 2017 and received its First Reading at the Legislative Council ("LegCo") meeting on 21 June 2017. The Bill seeks to provide for a new regulatory regime for four types of private healthcare facilities, namely hospitals, day procedure centres, clinics and health services establishments, which will replace the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance, and the Medical Clinics Ordinance and its subsidiary legislation currently in force. The Bill covers, among others, the licensing scheme; exemption arrangement for small practice clinics; regulatory requirements; mechanism on managing complaints against private healthcare facilities; and incidental and related matters. The key features of the Bill are set out in paragraphs 5 to 23 of the LegCo Brief issued by the Food and Health Bureau on 14 June 2017 (File Ref: FH CR 3/3231/16).

The Bills Committee

5. At the House Committee meeting on 23 June 2017, Members agreed to form a Bills Committee to study the Bill. The membership list of the Bills Committee is in **Appendix I**.

² The Steering Committee is underpinned by four working groups, namely (a) Working Group on Differentiation between Medical Procedures and Beauty Services; (b) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting; (c) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies; and (d) Working Group on Regulation of Private Hospitals.

³ Two adverse incidents took place in October 2012 and June 2014 causing casualties resulting from the performance of high-risk invasive procedures offered by a beauty service company and a surgical procedure called liposuction provided by a hair transplant centre respectively.

6. Under the chairmanship of Mr CHAN Han-pan, the Bills Committee has held 12 meetings with the Administration. The Bills Committee has also received oral representation from 31 organizations and three individuals at one of these meetings. A list of organizations and individual which/who have given views to the Bills Committee is in **Appendix II**.

Deliberations of the Bills Committee

Types of private healthcare facilities subject to regulation

Proposals in the Bill

7. Under the Bill, a private healthcare facility is a hospital, a day procedure centre, a clinic or a health services establishment not managed or controlled by the Government, the Hong Kong Garrison, the Hospital Authority ("HA") or the Board of Governors of The Prince Philip Dental Hospital, and does not include premises that are temporarily used for emergency or rescue purposes. Clauses 4, 5, 6 and 7 of the Bill provide for the specific meanings of the expressions "hospital", ⁴ "day procedure centre", ⁵ "clinic" ⁶ and "health services establishment"⁷ respectively under the Bill. The Administration has advised the Bills Committee that the meanings of these private healthcare facilities as presently drafted have the effect that premises where no practice of registered medical practitioners or registered dentists takes place will not be subject to the new regulatory regime.

⁴ Under the Bill, a "hospital" is any premises that are used, or intended to be used, for providing medical services to patients, with lodging; carrying out medical procedures on patients, with lodging; or receiving a pregnant woman for childbirth or a woman immediately after she gives birth to a child, but does not include the premises specified in Schedule 1 to the Bill.

⁵ Under the Bill, a "day procedure centre" is any premises that do not form part of the premises of a hospital; and that are used, or intended to be used, for carrying out scheduled medical procedures that are described in Schedule 2 to the Bill on patients, without lodging, whether or not the premises are also used, or intended to be used, for providing medical services to patients, without lodging; or carrying out minor medical procedures on patients, without lodging.

⁶ Under the Bill, a "clinic" is any premises that do not form part of the premises of a hospital, a day procedure centre or an outreach facility; and that are used, or intended to be used, for providing medical services to patients, without lodging; or carrying out minor medical procedures on patients, without lodging.

⁷ Please refer to paragraphs 15 to 17 below for deliberations on this type of private healthcare facility.

Scope of "medical procedure" and "medical service"

8. The Legal Adviser to the Bills Committee has noted that while the four types of private healthcare facilities proposed to be regulated are mainly distinguished from each other in terms of "medical services" or "medical procedures" to be provided at the relevant premises, the term "medical procedure" is not defined in the Bill. In the absence of a defined scope of "medical procedure", it is not clear as to whether the terms "medical service" and "medical procedure", the former of which is defined in clause 2 of the Bill to mean "in relation to a patient, a medical diagnosis, treatment (other than first aid treatment) or care for the patient given by a registered medical practitioner; or a registered dentist",⁸ are mutually exclusive or not.

9. The Administration has explained that "medical procedure" is a broad term that describes an act or a course of actions directed at or performed on an individual with the object of improving health, treating disease or injury, or making a diagnosis. Given the varying degree of complexity of medical practice and the advancement in medical technology, it may not be feasible to define "medical procedure" with precision. In the context of the Bill, a medical procedure can be performed by or on the direction of a registered medical practitioner or a registered dentist for diagnosis, treatment, improving health or other health-related purposes. To make clear the scope of medical procedures covered by the different types of licence for operating a private healthcare facility, the terms "scheduled medical procedure"⁹ and "minor medical procedure"¹⁰ are defined in the Bill. The Administration has further advised that the terms "medical service" or "medical procedure" are not mutually exclusive. Medical service includes but does not necessarily involve medical procedures. For instance, medical service provided in the form of medical observation is usually not regarded as a medical procedure.

⁸ As advised by the Administration, a medical treatment or care may be given directly by or on the direction or prescription of a registered medical practitioner or a registered dentist for the patient.

⁹ Under clause 2 of the Bill, "scheduled medical procedure" means a medical procedure that is described in column 2 of Schedule 2 to the Bill; that is not a medical procedure described in column 3 of Schedule 2 to the Bill; and that is carried out in an ambulatory setting. The carrying out of such medical procedure in a facility will require, subject to specifications by the Director of Health in a code of practice as provided for under clause 103 of the Bill, a day procedure centre licence.

¹⁰ Under clause 2 of the Bill, "minor medical procedure" means a medical procedure that is not a scheduled medical procedure; and that is carried out in an ambulatory setting. As advised by the Administration, it includes medical procedures described in column 3 of Schedule 2 to the Bill and many other medical procedures of a minor nature.

10. Members have enquired whether the following premises would be regarded as a private healthcare facility under the Bill: (a) a beauty centre providing medical beauty services to its customers, with the services provided by (i) a part-time registered medical practitioner or registered dentist employed by the centre, or (ii) a registered medical practitioner or a registered dentist not under the employment of the centre; and (b) a temporary setting for registered dentists and anaesthetists to provide dental care for persons with intellectual disabilities under monitored anaesthesia care. The Administration has advised that these premises will fall within the meaning of "day procedure centre" or "clinic", as the case may be. Clause 92 of the Bill prohibits except with the prior approval in writing of the Director of Health ("the Director"), or except as provided or permitted by any other law, the use by any premises (other than a permitted facility which is defined as a private healthcare facility for which a licence is in force or an exempted clinic) of titles or descriptions that include an expression specified in Schedule 7 to the Bill (such as day procedure centre, clinic, medical and treatment); and that suggest that the services provided in the premises are medical services provided in a private healthcare facility.

11. Clause 12 of the Bill makes it an offence for a person who is not a healthcare professional specified in Schedule 6 to the Bill to purportedly perform, on premises other than certain excepted premises¹¹, a medical treatment¹² or medical procedure for another person who is (or may be) suffering from a disease, injury or disability of mind or body; and to cause personal injury to the other person during the treatment or procedure. Some members including Mr Tommy CHEUNG, Dr Elizabeth QUAT, Dr Junius HO and Mr SHIU Ka-fai consider that care should be taken to prevent the net from being cast unduly wide that beauty practitioners performing cosmetic procedures, such as body tattooing and eyebrow tattooing, would be unnecessarily caught. They are particularly concerned about whether the administration of local anaesthetic containing lignocaine, which has been registered with the Pharmacy and Poisons Board of Hong Kong and is legally obtained, at a beauty centre to a person for preventing pain during tattooing would constitute a medical procedure. From another perspective, Dr Pierre CHAN has expressed concern about whether those beauty service

¹¹ Under clause 12 of the Bill, "excepted premises" is defined to mean a private healthcare facility for which a licence is in force or an exempted clinic; any premises specified in Schedule 1 to the Bill; any premises exempted under clause 127 of the Bill; any premises managed or controlled by a specified authority; or any premises that are temporarily used for emergency or rescue purposes.

¹² "Medical treatment" is defined in clause 12 of the Bill to mean, in relation to an individual, a treatment (including any diagnosis and prescription for giving the treatment) of any description performed on the individual for treating of disease, injury or disability of mind or body other than certain specified treatments (e.g. dispensation of medicine). As advised by the Administration, it includes acts that may not be a medical procedure but is given for treating of disease, injury or disability of mind or body.

providers which refer the medical procedures performed by them as cosmetic procedures could be caught by clause 12.

12. The Administration has advised that to be caught by the proposed offence, the person concerned has to purportedly perform, on the premises concerned, a medical treatment or medical procedure for a person who is or may be suffering from a disease, injury or disability of mind or body, and cause personal injury to that person during the treatment or procedure. In coming up with the above offence, reference has been made to the offence of similar nature provided for under section 14(1A)(a) of the Medical Clinics Ordinance. The Administration has further advised that the Working Group on Differentiation between Medical Procedures and Beauty Services set up under the Steering Committee has identified the procedures, irrespective of whether they are for cosmetic or medical purposes, that should only be performed by registered medical practitioners or registered dentists because of their inherent risks. Traditional body tattooing and piercing are exempted from being considered as a medical procedure, whereas 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. Separately, the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156) have respectively made it an offence for a person to practise medicine or surgery without registration; and for a person, who is not a registered dentist, to practise dentistry within Hong Kong, irrespective of whether the act has caused personal injury. In view of the concern of members and stakeholders from the beauty sector on the administration of local anaesthetic for preventing pain during cosmetic tattooing, the Administration has undertaken to relay the issue to the Pharmacy and Poisons Board of Hong Kong, which is responsible for, among others, the registration and classification of pharmaceutical products, for consideration.

13. Under clauses 29 and 38(1)(c) of the Bill, the Director may by order suspend a facility service in a private healthcare facility for a period as he or she considers appropriate on the ground that he or she is satisfied that a medical procedure belonging to a class of specialized service other than that specified in the licence is or has been provided in the private healthcare facility concerned. Given that the term "facility service" is defined in clause 2(1) of the Bill to mean, in relation to a private healthcare facility, among others, the provision of a diagnostic or therapeutic procedure and that the term "medical procedure" appears to be wide enough to include a "diagnostic or therapeutic procedure", the Legal Adviser to the Bills Committee has enquired about the reason why "diagnostic or therapeutic procedure" instead of "medical procedure" is used in the definition of "facility service".

14. The Administration has advised that some diagnostic or therapeutic procedures carried out in a private healthcare facility may not be covered by the

term "medical procedure". A case in point is that electrical stimulation or traction by physiotherapists that serves a purpose reasonably incidental to a private healthcare facility can be carried out in the facility. Hence, the use of the more general term "diagnostic or therapeutic procedure" in the definition of "facility service" can better reflect the legislative intent, for the purpose of clause 29 of the Bill, to empower the Director to suspend the provision of any such procedures in a private healthcare facility.

Health services establishment

15. Health services establishment is defined in the Bill to mean any premises that fall within a category specified by the Secretary for Food and Health ("the Secretary"), by notice published in the Gazette, in Schedule 8 to the Bill; that do not form part of the premises of a hospital, a day procedure centre or a clinic; and that are used, or intended to be used, in relation to assessing, maintaining or improving the health of patients; or diagnosing or treating illnesses or disabilities, or suspected illnesses or disabilities, of patients. The one and only one category currently specified in Schedule 8 is premises of an education or scientific (or both) research institution in which medical services with lodging are provided to patients for the purpose of conducting clinical trials. As advised by the Administration, subjecting this type of private healthcare facility to regulation is meant to encompass new modes of operation or delivery of healthcare services that entail a significant level of risk.

16. The Legal Adviser to the Bills Committee has pointed out that the services to be provided by a health services establishment in relation to assessing, maintaining or improving the health of patients, or diagnosing or treating illnesses or disabilities, or suspected illness or disabilities, of patients as set out in clause 7(a) and (c) of the Bill could overlap with certain medical services to be provided by other types of private healthcare facilities.

17. The Administration has affirmed that it is possible that some hospitals, day procedure centres and clinics may comprise premises satisfying the descriptions for health service establishments under clause 7(a) and (c) of the Bill. For instance, a private hospital may contain premises of an education and/or scientific research institution in which medical services with lodging are provided to patients for the purpose of conducting clinical trials. It is for this reason that a health services establishment should not form part of the premises of a hospital, a day procedure centre or a clinic, as stipulated in clause 7(b) of the Bill. At present, The University of Hong Kong ("HKU") and The Chinese University of Hong

Kong ("CUHK") have each set up a phase 1 clinical trial centre in the Queen Mary Hospital and the Prince of Wales Hospital respectively.¹³

Exclusion for certain private healthcare facilities set up by two universities

18. The representatives from the Faculties of Medicine of HKU and CUHK have respectively requested, at the meeting of the Bills Committee for receiving views from deputations on the Bill, that those private healthcare facilities managed or controlled by HKU or CUHK for the primary purpose of teaching or research rather than service provision should be excluded from the application of the Bill in order not to stifle their teaching or research activities. Noting that the relevant facilities are primarily used for teaching or research purposes, and that a robust governance structure that is fit-for-purpose with due regard to the nature and the unique cohort of stakeholders of these facilities has already been put in place in HKU and CUHK respectively, the Administration has agreed to move amendments to amend clauses 2, 3, 12(3), 92(6) and 123 of the Bill, and add a new Schedule 1A to the Bill to the effect that a day procedure centre, clinic or health services establishment primarily used for teaching or research relating to medicine or dentistry and that is managed or controlled by a scheduled university which, as proposed, includes HKU and CUHK, will not fall within the meaning of a private healthcare facility and will not be regulated under the Bill ("the exclusion proposal"). The Administration has listed out 14 existing private healthcare facilities of HKU or CUHK which, based on the information provided by HKU and CUHK, would meet the above proposed criteria for exclusion ("the 14 facilities") for reference of the Bills Committee.

19. Some members including Mr CHAN Chi-chuen, Dr KWOK Ka-ki, Dr Fernando CHEUNG and Dr Pierre CHAN have queried about the need for excluding certain facilities managed or controlled by the two universities from regulatory control. They do not subscribe to the Administration's view that the putting in place by HKU and CUHK of a robust governance structure that is fit-for-purpose with due regard to the nature of their facilities and their unique cohort of stakeholders could justify the proposal. They have pointed out that some of the 14 facilities may at the same time be providing medical services to members of the public that fall outside the scope of teaching or research activities or requiring payment by patients for the medical services provided. There might be cases that some other private healthcare facilities which would be subject to regulation under the Bill, such as clinics operated under medical groups, are also governed by a robust mechanism on clinical risk management and standards of

¹³ The Administration has proposed to move certain amendments to the Bill to exclude from regulation under the Bill facilities fulfilling the specified criteria (paragraphs 18 to 21 below refer). These two clinical trial centres are included in the 14 facilities referred to in paragraph 18.

facilities. The proposal, if implemented, would set a bad precedent in regulatory control on the one hand, and on the other hand run contrary to patients' interest, which should be of prime concern in formulating the new regulatory regime. Dr Pierre CHAN is of particular concern that there will be no quantification by the Administration of the activities of the facilities of the scheduled universities to assess their meeting of the criterion of being "primarily used for teaching or research relating to medicine or dentistry".

20. The Administration takes the view that duplicating relevant efforts on governance, clinical management and complaints handling, etc. simply to ensure that the day procedure centres, clinics or health services establishments primarily used for teaching or research relating to medicine or dentistry and are managed or controlled by HKU and CUHK also comply with another set of regulatory requirements under the Bill might not be an optimal use of resources by the two universities, which are independent and autonomous statutory bodies, each with its own ordinance and governing council and enjoys academic freedom and institutional autonomy. In addition, the regulatory regime for ordinary private healthcare facilities may not sit well with the operational models of these private healthcare facilities as their patient flow and care model are different from those in ordinary private healthcare facilities. Similar exclusion is in place in the Medical Clinics Ordinance in that relevant premises maintained or controlled by HKU and CUHK are excluded from the definition of "clinic". Upon the passage of the Bill, if it comes to the knowledge of DH that an excluded facility no longer meets the criteria for exclusion, DH will request the operator of the facility concerned to apply for a licence. In respect of the services provided by registered medical practitioners or registered dentists in the 14 facilities, it should be noted that the great majority of their patients (if not all of them) are involved in teaching or research,¹⁴ and only those registered medical practitioners and registered dentists who are staff and students of the two universities are allowed to practise in these facilities.¹⁵ At present, 11 out of the 14 facilities have fee-charging services. In setting the fees and charges of services requiring payment by patients, HKU and CUHK would give due regard to factors including the cost of services, prevailing market rates and affordability of patients, with an aim of ensuring that sufficient patients are available for the purposes of teaching or research.

21. These members in general remain concerned about the rationale for the exclusion proposal, in particular that, according to the Administration, it would not actively inspect the premises of the private healthcare facilities of the

¹⁴ According to the Administration, these patients are requested to complete a consent form for the purpose of teaching or research.

¹⁵ According to the Administration, in cases of top-notch non-local experts practise in these facilities for the purpose of teaching or research, the two universities will respectively ensure that relevant laws and regulations are complied with.

scheduled universities being excluded from regulation of the Bill to assess if they still meet the criterion of being "primarily used for teaching or research relating to medicine or dentistry" but would do so only upon receipt of complaints and intelligence. They have requested the Administration to fully consult the stakeholders, including patient organizations and service users of the relevant facilities, on the proposal. The Administration has advised that the key patient organizations it has consulted on the proposal are of the view that the existence of a robust mechanism on clinical risk management as well as complaints and medical incidents handling are the key factors for determining whether the relevant facilities managed or controlled by the two universities should be excluded from regulation.

Medical laboratory

22. The Bill as currently drafted will render the services provided by healthcare professionals¹⁶ other than registered medical practitioners and registered dentists, such as medical laboratory technologists, physiotherapists and optometrists, in a licensed hospital, day procedure centre, clinic or health services establishment be regulated as part of the facility service and subject to relevant code(s) of practice ("CoP") to be issued by the Director under clause 102 of the Bill. Separately, these healthcare professionals, while practising in premises other than those licensed under the Bill, will continue to be regulated under the relevant laws and codes of professional conduct. Dr Pierre CHAN has expressed particular concern about the rationale for not subjecting private medical laboratories to the new regulatory regime in order to keep pace with other advanced places but requiring, upon the enactment of the Bill, the practice of medical laboratory technologists to be subjected to two sets of regulatory control depending on the premises where their practice takes place. Referring to the blood product incident in October 2012 causing one death and serious sickness of three other patients resulting from, among others, inappropriate processing of cells and their derived products for advanced therapies for human application, he takes the view that premises-based regulation of medical laboratories should be introduced under the Bill so as to better safeguard patient safety and public health.

23. The Administration has advised that the object of the Bill is to regulate, through a new licensing system, premises where registered medical practitioners and registered dentists practise. Hence, the Bill does not cover premises where only healthcare professionals who are neither registered medical practitioners nor registered dentists practise. The proposed arrangement is in line with the existing arrangement that supporting services (including laboratory services) available in private hospitals registered under the Hospitals, Nursing Homes and Maternity

¹⁶ Under the Bill, "healthcare professional" means a person specified in Schedule 6 to the Bill.

Homes Registration Ordinance are being regulated under the Ordinance as part of the hospital services. Separately, a Task Force on Regulation of Advanced Therapeutic Products in Hong Kong was set up in December 2017 to look into the need to formulate a regulatory framework for cell and tissue-based therapy and health products for advanced therapies. The Administration has further pointed out that at present, any company carrying on the business of practising the profession of medical laboratory technologist must have at least one director who is a registered Part I medical laboratory technologist under the Supplementary Medical Professions Ordinance (Cap. 359). Directors of incorporated laboratories being medical laboratory technologists, as well as registered Part I medical laboratory technologists who are the supervisors of unincorporated laboratories, should take the overall responsibility for the operation of the laboratories concerned. The Administration does not consider it appropriate to regulate medical laboratories under the Bill at this stage.

Premises in relation to a private healthcare facility

Scope of the premises of a licenced facility

24. Under clause 2 of the Bill, "premises" includes any place and, in particular, includes any land or building; any vehicle or vessel (other than a sea-going ship as defined in the Merchant Shipping (Seafarers) Ordinance (Cap. 478)); and any part of any land or building or of any above-mentioned vehicle or vessel. Clause 8 of the Bill provides that premises, in relation to a private healthcare facility, comprise the places that are physically connected by internal access among themselves; or physically attached or in close proximity to, or adjoining, one another; and that form a distinct whole for the facility to function as a single entity. In the case of a private hospital already registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance, a transitional arrangement is provided for in clause 125 such that for an application for a hospital licence during the specified period for premises covered by the existing certificate of registration of a hospital, the new hospital licence is to cover the main premises of a registered hospital as well as certain associated premises of the hospital, which are not in close proximity to the main premises, but which were covered by the existing certificate of registration so as to constitute one single private healthcare facility. The associated premises that may be included in the application are those that do not form part of the premises of a day procedure centre or an outreach facility; and are used, or intended to be used, for providing medical services to patients (without lodging); or carrying out minor medical procedures on patients (without lodging).

25. Dr Pierre CHAN has pointed out that there are cases that some services (e.g. medical laboratory services) provided on the premises of a private hospital

already registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance are managed by another entity but not the private hospital concerned, with the services provided therein not involving any practice of registered medical practitioners and registered dentists. He has enquired about whether and, if so, under what circumstances an existing private hospital could exclude certain part of its premises from the application for a hospital licence during the specified period under the new regulatory regime, with the effect of making the services provided therein not part of the facility service and thus not subjected to regulation under the Bill. Dr Pierre CHAN has also expressed concern on the respective liability of the private hospital and the service provider for incidents occurred on those premises.

26. According to the Administration, the person registered in respect of a private hospital under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance is held responsible for complying with the conditions of registration, including CoP, in the operation of all services in the registered premises. Such requirement should be complied with regardless of the mode of management, or any business arrangement made with third-party providers in respect of the services provided. Likewise, the licensee of a private hospital under the new regulatory regime is proposed to be wholly responsible for the operation of the facility, including all services provided in the premises covered by the licence. The licensee must ensure that all such services are provided in compliance with, among others, the conditions of the licence.

Requirement on separate entrance

27. Mr CHAN Han-pan and Mr SHIU Ka-fai have expressed concern that for various reasons such as the terms of the Deed of Mutual Covenant, some existing operators of a facility (which falls within the meaning of private healthcare facility under the Bill) which has an entrance that is shared with premises that serve a purpose that is not reasonably incidental to the facility concerned (e.g. medical services vis-à-vis beauty services) would have difficulties to comply with clause 67 of the Bill (if enacted). Under that clause, the operator of a private healthcare facility for which a licence is in force or an exempted clinic (or collectively named as "permitted facility" in the Bill) is required to, among others, 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 type of facility for which the licence is issued or the practice carried on in the exempted clinic as specified in the letter of exemption for the facility, as the case may be.

28. The Administration has explained that an aim of the above requirement is to separate premises where registered medical practitioners and/or registered

dentists provide services, which are subject to the regulatory measures stipulated in the Bill and the standards to be prescribed in CoP, from premises that are not subject to such regulation. Doing so will enable consumers to have a clearer idea about the proper authority or channel from which they may seek redress in case of dissatisfying services, and operators of a permitted facility to be clear about the premises and the services for which they and the chief medical executive of the facility (if applicable) would be held accountable. This apart, the requirement will obviate the need for the Director or an authorized officer to pass through other privately-owned premises in order to enter a permitted facility for inspection. To address the stakeholders' concern, the Administration has agreed to move an amendment to the Bill to add a new clause 136A to the effect that the requirement on separate entrance should not apply during the validity period of a provisional clinic licence issued by the Director under clause 135 of the Bill for clinics already in operation on a specified date, subject to certain conditions. This provides room for existing clinics to continue their operation on the premises whilst looking for ways (such as relocating to new premises after the expiry of the current leases) to meet the new requirement.

Licensing scheme

Licensee being a limited company

29. The Bill prohibits a person from operating a private healthcare facility without a licence except in the case of a small practice clinic for which an exemption is granted under clause 43 of the Bill¹⁷. It is proposed under clause 14 of the Bill that licensees of private hospitals have to be a company, or other body corporate, operated by a board of directors which has to include a person who is neither a registered medical practitioner nor a registered dentist and who is not an employee of the hospital concerned. For private healthcare facilities other than a hospital or a scheduled clinic listed in Schedule 5 to the Bill¹⁸, the applicant can be either a legal person or a natural person who is not necessarily a registered medical practitioner or a registered dentist. According to the Administration, such arrangement is aimed to ensure that the licensee of a hospital, for which the mode of operation tends to be more sophisticated and the scale of operation tends to be larger, would put in place a rigorous corporate governance mechanism overseen by a board of directors. For other types of private healthcare facilities,

¹⁷ Deliberations in respect of the exemption are detailed in paragraphs 38 to 42 below.

¹⁸ Under clause 14 of the Bill, the applicant for an application for a licence to be issued for a clinic that is a scheduled clinic must be a person who was registered under section 5(2) of the Medical Clinics Ordinance immediately before its repeal in respect of the scheduled clinic; or a registered medical practitioner who is currently practising in the scheduled clinic and whose name is not included in Part I of the General Register kept under section 6(1) of the Medical Registration Ordinance as at 1 April 2017.

the proposed arrangement to allow the applicant concerned to be either a legal person or a natural person would provide flexibility to cater for the varying scale and scope of services provided by these facilities.

30. Dr CHIANG Lai-wan has pointed out that if the licensee of a private healthcare facility is a limited company, its director(s) or officers will not be held liable for any negligence of the company which is a separate legal person. She is of the view that licensees of private healthcare facilities other than a hospital should better be a natural person rather than companies or other body corporates to deter serious non-compliance under the new regulatory regime as they would be held personally liable. Alternatively, reference should be made to the licensing requirements for banks as specified in the Banking Ordinance (Cap. 155) to require that the licensee of a private healthcare facility, if being a legal person, has to be subject to a minimum capital requirement so as to ensure that the facility would have enough capital base to cover civil claims by patients. She considers that this could avoid the risk that the licensee of a private healthcare facility, being a limited company with a small amount of share capital, may not be able to compensate the patients concerned in case of medical or dental incidents.

31. The Administration has advised that it is provided for under clause 94 of the Bill that if an offence under the Bill, such as failure to comply with the suspension order made by the Director, is committed by a body corporate, and it is proved that the offence has been committed with the consent or connivance of, or is attributable to the neglect or omission of a director, shadow director, company secretary, principal officer or manager, or any other person concerned in the management of the body corporate, that person commits the offence. In the Administration's view, the above provision is conducive to deterring serious non-compliance by licensed facilities under the new regulatory regime, even if the licensee concerned is a legal person. The Administration does not intend to impose under the new regulatory regime a capital requirement on licensees that are legal persons as such a requirement is disproportionate and may hamper the provision of healthcare services by those private healthcare facilities which are of smaller sizes. The Administration has advised that there are no such requirements in similar premises-based statutory licensing schemes for certain welfare and education institutions, such as the licensing schemes for residential care homes for the elderly, residential care homes for persons with disabilities and schools.

32. Dr CHIANG Lai-wan has further suggested that those private healthcare facilities the licensee of which is a limited company should be required to take out a liability insurance for its chief medical executive who is responsible for the day to day administration of the facility. She considers that this serves as another means to ensure that their patients would be provided with adequate compensation in negligence claim arising from medical or dental incidents occurred in the

facilities. She has also expressed concern that some private healthcare facilities require their patients to sign a consent form with exemption of liability clause to exclude or restrict the facility's liability in the case of a medical or dental incident caused by negligence of the facility and she has called for appropriate regulation under the Bill to protect the interests of patients.

33. The Administration takes the view that it is not necessary or justified to impose a statutory obligation on the part of licensees to take out a liability insurance. It should be noted that depending on individual circumstances, negligence claim arising from medical or dental incidents occurred in a private healthcare facility may in many cases be brought against the attending registered medical practitioner(s) or registered dentist(s) who owes a duty of care to his or her patients but has breached such duty and caused damages. As a common practice, registered medical practitioners and registered dentists should have been covered by professional indemnity insurance. A civil action may also be brought against the licensee if the incident occurred in a private healthcare facility was caused due to a negligence in the operation of the facility. The Administration has further advised that the exemption of liability clause in a signed consent form would be of no effect in so far as liability for death or personal injury is concerned as such liability resulting from negligence could not be excluded or restricted according to section 7 of the Control of Exemption Clauses Ordinance (Cap. 71).

Conditions of licence

34. Dr Helena WONG is of the strong view that all private healthcare facilities, or at the very least private hospitals, should be required, as a condition of a licence to be imposed by the Director under clause 17(3) for the issuance of a licence for a private healthcare facility, to register as a healthcare provider for the Electronic Health Record Sharing System. This will help foster public-private collaboration in healthcare delivery for the benefits of patients through two-way sharing of the patients' electronic health records between public and private healthcare providers. While the 12 private hospitals currently in operation are all registered healthcare providers, she has doubts as to whether private hospitals newly set up in the future would register as a healthcare provider for the System as the Bill imposes no obligation on them in this regard.

35. The Administration has stressed that participation of healthcare providers in the Electronic Health Record Sharing System is voluntary. It is envisaged that the new private hospitals, if any, would register as a healthcare provider in order to enjoy the benefits of viewing and sharing the health records of their patients on the System. That said, in view of the concerns raised by members in this regard, the Administration has undertaken to specify in the relevant CoP under the new

regulatory regime that all private hospitals should register as a healthcare provider under the System.

Hospitals providing palliative hospice services

36. Members note that at present, there are 11 institutions registered as nursing homes under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance providing residential care for elders or persons with disabilities but are not concurrently licensed under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459) or the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613). These nursing homes are listed in Schedule 9 to the Bill as scheduled nursing homes. Depending on the nature of the scheduled nursing homes and their readiness to meet the relevant licensing requirements, the registered persons in relation to these homes may choose to apply for, in relation to all, or a part, of the registered premises, a licence under the new regulatory regime; a licence under the Residential Care Homes (Elderly Persons) Ordinance; or a licence under the Residential Care Homes (Persons with Disabilities) Ordinance. Noting that some scheduled nursing homes aspire to become private hospitals in due course to provide palliative hospice services, Dr Helena WONG has expressed concern as to whether new hospitals of this nature, which are operated by non-governmental organizations ("NGOs") for the provision of palliative hospice services, have to pay the application fee for the issuance of licence for a hospital as set out in item 1 of Schedule 3 to the Bill (i.e. in the range of \$426,000 to \$755,900 depending on the number of beds). Dr KWOK Ka-ki takes the view that given the inadequacy of public palliative hospice services, non-profit-making hospitals established and operated by NGOs for the provision of palliative hospice services should be subject to a licence fee and a set of licensing requirements distinct from that for a hospital.

37. The Administration has advised that the fees in Schedule 3 payable in relation to applications for licences under the Bill apply to all facilities (including hospitals) established and operated by private sector and NGOs. Its intention is that if the applicant is a registered person in relation to a scheduled nursing home with the certificate of registration of the nursing home being valid at the time and the application for a hospital licence is made within the period to be specified by the Director, the application is only required to be accompanied by a lower fee tantamount to renewal of licence for a hospital as specified in item 12 of Schedule 3 (i.e. \$5,020). The Administration will move an amendment to the Bill to add a new clause 125A to make the above clear.

Small practice clinics

38. Clauses 41, 42 and 43 of the Bill provide that on the request of a person who operates or intends to operate a small practice clinic, the Director may issue a letter of exemption to permit the person to carry on the practice in the clinic concerned without a licence. A small practice clinic is defined in the Bill as a clinic operated by a registered medical practitioner or a registered dentist as a sole proprietor; a partnership of not more than five partners, each of whom is a registered medical practitioner or a registered dentist; or a company with not more than five directors, each of whom is a registered medical practitioner or a registered dentist. The registered medical practitioner(s) and/or registered dentist(s) concerned should be the only one(s) serving the clinic, and having (or in the case of a clinic operated by a company, through the company having) the exclusive right to use the premises forming the clinic. None of the individuals signing the request for a letter of exemption could be for the time being in any of the following capacities (in whatever combination) for three or more other exempted clinics: (a) the sole proprietor of an exempted clinic; (b) a partner of a partnership operating an exempted clinic; and (c) a director of a company operating an exempted clinic. The Administration has informed the Bills Committee that the policy intention for the proposed exemption is to focus the regulatory effort on clinics under the management of incorporated bodies. At the request of the Bills Committee, the Administration has provided the draft of the request form for a letter of exemption to illustrate the information required for proving a clinic's eligibility for the exemption.

39. Dr Pierre CHAN has enquired about the rationale for not extending the scope of the proposed exemption to include those clinics which are managed by medical groups but served by less than five registered medical practitioners or registered dentists. The Administration has explained that the registered medical practitioners or registered dentists employed to serve in these clinics would not have full control of the clinics to ensure their effective governance. Dr KWOK Ka-ki has enquired whether premises with five or more registered medical practitioners being co-tenants sharing the use of those premises but have no involvement in the practice of each other could also be exempted from regulation. The Administration has advised that in that case, the premises concerned do not fall within the meaning of small practice clinic.

40. Members note with concern that while the Bill has provided for an appeal against a decision of the Director in relation to, among others, refusing to issue a licence, suspending or cancelling a licence or refusal of renewal of a licence, to be made to the Administrative Appeals Board, no appeal mechanism is provided for in the Bill if a person making the request or the operator of an exempted clinic is aggrieved by the decision of the Director to refuse to issue a letter of exemption

pursuant to clause 43(4) or to revoke the exemption granted pursuant to clause 45. As advised by the Administration, in such cases, the person or the operator concerned may provide additional information (which has not been available to the Director) within the period specified for the Director's further consideration. In any case, the person or the operator concerned may apply for a licence to operate the clinic.

41. To allow stand-in arrangements for registered medical practitioners or registered dentists who serve a small practice clinic when they are on leave (commonly known as "locum" in the sector), the Bill provides for the maximum number of days for the taking up of duties by other registered medical practitioners or registered dentists. On the proposed arrangement for a clinic operated by a partnership or company as set out in clause 41(6) whereby the aggregate number of days for the taking up of duties by other registered medical practitioners or registered dentists for the partners or directors operating the clinic must not exceed 180 days in a calendar year, Dr Pierre CHAN has suggested that the aggregate number of days should be proportionate to the number of partners or directors of the clinic concerned who are registered medical practitioners or registered dentists. He has pointed out that such clinic may have at most five partners or directors who are registered medical practitioners or registered dentists, and the total number of days for which another registered medical practitioner or another registered dentist takes up the duties of a partner or director in the clinic because of the partner's or director's absence from the clinic, as provided for in clause 41(5), could at most be 60 days in a calendar year.

42. The Administration has explained that the expressions "another registered medical practitioner", "another registered dentist" and "other registered medical practitioner or registered dentist" in clause 41(5) and (6) do not include the other original partners or directors of the clinic. In other words, when a partner or a director is absent from the clinic, the number of days for which another partner or director serves the clinic because of that person's absence will not be counted in the number of days stipulated in clause 41(5) and (6). The Administration has advised that if the proposed 180-day requirement is further relaxed, a registered medical practitioner or a registered dentist not involved in management of a small practice clinic will be allowed to serve the clinic for more than half of a year. This may be against the original intention of the Administration of granting exemptions to eligible small practice clinics.

Cancellation of licence on death of individual licensee

43. Dr Pierre CHAN has expressed concern as to whether the proposed deferment period as specified under clause 36(3) whereby the Director may, if satisfied that the conditions specified in clause 36(4) are met, defer the cancellation

of a licence by order on the death of the licensee who operated a day procedure centre, clinic or health services establishment as a sole proprietor (i.e. six weeks after the date of death of the licensee) would be sufficient for a new operator to apply for a new licence for the facility, as well as for the Director to process the application and issue a new licence as appropriate such that the facility concerned could continue to operate before it is qualified for the new licence.

44. As a reference, the Administration has advised that at present, in respect of an application for registration as a clinic under the Medical Clinics Ordinance which should be submitted to DH at least one month before commencement of the clinic's operation, DH will issue a certificate of registration within 14 working days upon verification of compliance with the registration requirements. The Administration has, however, agreed to move amendments to amend clause 36(3) of the Bill to extend the proposed deferment period for cancelling a licence to 12 weeks after the date of death of the licensee.

Regulatory actions in relation to licence that the Director may take

45. In respect of regulatory actions in relation to licence that the Director may take, members note that the Director may, among others, on a ground specified in clause 38(1) of the Bill, (a) refuse (i) to renew the licence, (ii) the application for variation of scale or scope of services specified in the licence of a private healthcare facility, and (iii) the application for variation of class of specialized service specified in the licence of a day procedure centre; (b) by order (i) suspend a licence for a specified period, (ii) cancel a licence, and (iii) suspend a facility service for a specified period; and (c) amend the conditions of a licence. The Bill makes it an offence for a licensee of a private healthcare facility not to comply with a suspension order. One of the grounds for the taking of the above regulatory actions is that the licensee or chief medical executive of the facility concerned contravenes or has contravened the ordinance (if enacted); a condition of the licence; a CoP issued under clause 102 of the Bill; or a direction given under clause 104 of the Bill. Under clause 113 of the Bill, the Director or an authorized officer may, without a warrant issued by a magistrate, enter a private healthcare facility for which a licence is in force at any reasonable time and exercise a power specified in clause 116 of the Bill for ascertaining, among others, whether the above are complied with.

46. Members have raised particular concern about the circumstances under which a private healthcare facility would be regarded as being, or having been, used in a way not serving a purpose reasonably incidental to the type of facility for which the licence is issued, which is a ground for action in relation to licence as set out in clause 38(1)(d)(i) of the Bill. The Administration has advised that it is provided for under clause 23 of the Bill that the licensee of a private healthcare

facility may apply to the Director to vary the scope of services specified in the licence. Depending on circumstances, organization of health talks and provision of services (e.g. Chinese medicine service, optometric service and physiotherapeutic service) to support the medical services provided by the facility concerned would generally not be regarded as having used the facility in a way not serving a purpose reasonably incidental to the type of facility for which the licence is issued.

Regulatory standards of private healthcare facilities

47. According to the Administration, different private healthcare facilities will each be subject to a set of regulatory standards commensurate with the risk of the services it provides. Clause 102 of the Bill seeks to enable the Director to issue a CoP, which may include a standard and a specification, about the equipment, fittings and furnishings in private healthcare facilities; the management and staffing arrangement of private healthcare facilities; the quality of care for, and the safety of, patients in private healthcare facilities; and any other matters for protecting the health and interests of individuals receiving healthcare services in private healthcare facilities. If a CoP is issued, the Director must by notice published in the Gazette identify the CoP and specify the date on which the CoP is to take effect. Separately, the Secretary may, under clause 122 of the Bill, make regulations to provide for, among others, the standards of accommodation, staffing, equipment, delivery of care, and operation or provision of any services, in private healthcare facilities.

48. The Administration has informed the Bills Committee that the regulatory standards for private hospitals will be formulated based on the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes currently in force. As regards the regulatory standards for day procedure centres and clinics, a Project Steering Committee on Standards for Ambulatory Facilities was set up by DH and the Hong Kong Academy of Medicine in mid-2015 to draw up standards for day procedure centres which will comprise a set of core standards and sets of procedure-specific standards for the provision of relevant class(es) of services including anaesthesia and sedation; surgery; endoscopy; dental procedures; chemotherapy; haemodialysis; and interventional radiology and lithotripsy, and to give advice on the standards for clinics. As of April 2018, a set of Core Standards for Day Procedure Centres, a set of Procedure-specific Standards for Day Procedure Centres – Surgery and Anaesthesia & Sedation and a set of draft Standards for Medical Clinic have been developed. These sets of standards will be as adapted to become CoP for the relevant private healthcare facilities when the new regulatory regime comes into force. Members have requested the Administration to provide for reference of the Bills Committee the above documents.

49. Dr Pierre CHAN has enquired about whether, for the sake of patient safety, the regulatory standards for pathology services provided on the premises of private hospitals to support the clinical services, in particular those in respect of staffing, quality control and the collection and handling of pathology specimens, would be enhanced under the new regulatory regime to cater for the evolving medical technology and laboratory practice. The Administration has advised that regulatory standards for pathology services provided as part of the services of a private hospital will be largely the same as the prevailing requirements as set out in Chapter 13 of the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes. For instance, the hospital concerned must appoint a specialist in pathology to take charge of the service, or to serve as an advisor to review regularly the facilities, equipment and staff training of the service. In addition, it must assign a Part I medical laboratory technologist to take charge of the day to day operation of the laboratory. There should also be a clinical laboratory quality assurance programme in place. The hospital concerned is also required to establish policies and procedures on various areas of pathology services, including the collection, labelling, transportation and storage of pathology specimens.

Managing the day to day administration of a private healthcare facility

50. The licensee of a private healthcare facility, as proposed under clause 47 of the Bill, will be wholly responsible for the operation of the facility. The licensee is further required under the Bill to appoint a chief medical executive to take charge of the day to day administration of the facility concerned. The chief medical executive, as required of under clause 51 of the Bill, must possess the qualifications and experience necessary for administering a facility of that type; be physically and mentally fit to administer a facility of that type; and be a person of integrity and good character. For a day procedure centre or a clinic, the chief medical executive must also (a) be a registered medical practitioner or a registered dentist¹⁹ who has been registered for not less than six years (in the case of a day procedure centre) or four years (in the case of a clinic) in Hong Kong; and (b) not serve at the same time as the chief medical executive of more than two day procedure centres or clinics²⁰. According to the Administration, the latter requirement is aimed to ensure that the chief medical executive will be able to take

¹⁹ Under clause 53(3) of the Bill, if the practice specified in the licence for a day procedure centre or clinic is a dental practice only, the chief medical executive for the centre or clinic must be a registered dentist. In any other case, the chief medical executive for the centre or clinic must be a registered medical practitioner.

²⁰ Save for the specified circumstances provided for under clause 53(5) of the Bill as detailed in paragraph 53 below.

charge of the day to day administration of the facilities under his or her responsibilities effectively.

51. Some members including Dr Elizabeth QUAT and Mr SHIU Ka-fai have shared the view of some stakeholders in the beauty sector that the additional requirement that the chief medical executive of a day procedure centre or a clinic could not serve at the same time as the chief medical executive of more than two day procedure centres or clinics should be relaxed in order not to stifle the development of the beauty industry given current medical manpower constraint. Some other members including Dr KWOK Ka-ki are of the view that in determining the number of day procedure centres or clinics a chief medical executive could serve at the same time, there is a need to give due consideration to factors including the risks of the medical procedures being carried out and the medical services being provided by these facilities in order to safeguard patient safety.

52. The Administration has stressed that any proposal to allow a chief medical executive to take charge of more private healthcare facilities has to be balanced against its impact on the adequacy and effectiveness of the chief medical executive's oversight of the day to day operation of the facilities concerned. After careful consideration of members and stakeholders' view, the Administration will move amendments to amend clause 53(4) of the Bill to the effect that a person must not serve at the same time as the chief medical executive of (a) if serving only day procedure centres—more than two day procedure centres; (b) if serving only clinics—more than three clinics; or (c) if serving both—more than one day procedure centre and one clinic.

53. It is originally proposed in clause 53(5) of the Bill that a person may, however, serve as a chief medical executive of three or more clinics if the appointment is for three or more clinics operated at the same time by the same licensee (i.e. group of clinics) and the licensee has established a Medical Advisory Committee for the group of clinics and appointed for each of the clinics a registered medical practitioner or a registered dentist who is serving the clinic to assist the chief medical executive in carrying out the day to day administration of the clinic; is a registered medical practitioner or a registered dentist who has been registered for not less than 10 years in Hong Kong; and does not serve at the same time as a chief medical executive of another private healthcare facility. Consequential to the amendments described in paragraph 52 above, the Administration will amend clauses 50, 53(5) and 56(2) to specify the circumstances under which a person may serve as a chief medical executive of four or more clinics, rather than three or more clinics as originally proposed. These apart, the Administration will move another amendment to subclause (b) under clause 53(5) to allow that a person may serve as a chief medical executive

of four or more clinics if the person is a registered medical practitioner or a registered dentist who has been registered for not less than eight years in Hong Kong, rather than a period of 10 years of registration as originally proposed.

54. Mr CHAN Han-pan considers that in the case where a Medical Advisory Committee has been established for group of clinics, the licensee concerned should be allowed to appoint a single chief medical executive for the clinics if he or she has appointed for each of the clinics an administrative personnel, rather than a registered medical practitioner or a registered dentist who is serving the clinic as proposed, to assist the chief medical executive to carry out the day to day administration of the clinic. In his view, the appointment of a chief medical executive as well as the establishment of a Medical Advisory Committee, the chairperson of which is required to be a registered dentist if the practice specified in the licence for the facility is a dental practice only or a registered medical practitioner in any other case; and half of its membership is required to be registered medical practitioners or registered dentists, for group of clinics have provided adequate safeguard to ensure the quality of care for, and the safety of, patients in the facility.

55. The Administration has explained to the Bills Committee there is a need to ensure that the person appointed to assist the chief medical executive of group of clinics will have the professional knowledge required (such as drug management, infection control and risk management) to oversee the day to day administration of the clinic for the sake of patient safety. The Bill is silent on the number of clinics that person could serve to provide flexibility in manpower deployment.

56. As a related matter, the Administration has agreed to take on the suggestion of the Legal Adviser to the Bills Committee to amend the Chinese rendition of the word "integrity" in clause 51(c), which sets out one of the general requirements for the chief medical executive of a private healthcare facility, from "行止端正" to "行事持正", a rendition adopted in the Professional Accountants Ordinance (Cap. 50) and the Hong Kong Academy of Medicine Ordinance (Cap. 419), to better reflect how the person concerned is expected to act in that capacity.

Proposed requirements on price transparency

57. Members in general are of the view that price transparency in respect of the services provided by private healthcare facilities, in particular that of private hospitals, needed to be enhanced. Under clauses 61, 62 and 63 of the Bill, the licensee of a private healthcare facility has to make available to the public information about the prices of chargeable items and services provided in the facility as specified by the Director. For private hospitals, the licensees of which have to, apart from the above, put in place a budget estimate system to provide

estimates of the hospital fees and charges and publish historical statistics on the fees and charges for the specified treatments and procedures in the ways specified by the Director. Some members including Mr Tommy CHEUNG and Dr Helena WONG are of the view that the above measures could not address the common pricing practice of private hospitals to impose different level of service charges (such as that for consumables, medicines, injections, investigations and in-house doctors' ward round fees, etc.) according to the class of ward a patient stays which, in their view, is not reasonable. Mr CHAN Chi-chuen has expressed concern that the list of treatments and procedures requiring provision of budget estimates and/or publication of historical statistics on fees and charges, as well as the types and the form of presentation of the requisite statistics are not provided for in the Bill and hence, not subject to scrutiny by LegCo. Mr CHAN Kin-por takes the view that the Administration should require private hospitals to introduce packaged charges for more operations or procedures so as to further enhance price transparency of the services provided by private hospitals.

58. The Administration has advised that a pilot programme for enhancing price transparency for private hospitals was rolled out in October 2016. All private hospitals have participated in the pilot programme voluntarily to provide patients with information in respect of their fee schedules, budget estimates and historical bill sizes statistics. At present, the statistics published by the private hospitals in relation to the historical bill sizes include the annual number of discharges for cases undergoing a single specified operation or procedure and the actual billing data for the 50th percentile and 90th percentile of each specified operation or procedure. The Administration will model on the pilot programme to implement the price transparency measures of private hospitals proposed in the Bill. The above apart, the Administration will continue to encourage private hospitals to provide more services at packaged charges to provide patients with a reasonable level of confidence on the total cost of hospital services they could expect. It will also relay to the private hospitals members' concern on the private hospitals' common practice of linking the levels of service charges to the types of ward and encourage them to explain to their patients clearly the various levels of service charges according to the types of ward. The Administration has, however, stressed that it has no intention to regulate the price level or structure of services provided by private hospitals as private medical service, by its very nature, should be no different from other business transactions between consenting parties where prices are determined by market force.

59. Mr Tommy CHEUNG took the view that clauses 61 and 62 as currently drafted could not provide adequate safeguard for patients of private hospitals. The Bills Committee has considered a set of amendments to the Bill put forward by Mr Tommy CHEUNG to empower the Director to make regulations specifying the price information to be provided by a private healthcare facility for the

purposes of clause 61 of the Bill, as well as the treatments and procedures for which estimates of fees and charges are to be provided by a hospital for the purposes of clause 62.

60. After consideration, the Administration has agreed to adopt, with certain modifications, the amendments proposed by Mr Tommy CHEUNG by moving a set of amendments to clauses 61, 62, 122 and 161 of the Bill to the effect that the Secretary may by regulation prescribe the price information to be provided, and the way it is to be provided, by the licensee of a private healthcare facility for the purposes of clause 61 and prescribe the treatments and procedures for which estimates of fees and charges are to be provided, and the way they are to be provided, by the licensee of a hospital for the purposes of section 62.

61. Mr CHAN Chi-chuen has expressed concern that the day procedure centres, clinics and health service establishments of the scheduled universities that meet the criteria of the exclusion proposal would have no obligation to make available to the public information about the prices of chargeable items and services provided in the facility. The Administration has assured members that it will encourage the scheduled universities to make such information available to the public.

Complaints against private healthcare facilities

Committee on Complaints against Private Healthcare Facilities

62. Members note that the licensee of a private healthcare facility is required under clause 64 of the Bill to put in place a complaints handling procedure for receiving, managing and responding to complaints that are received against the facility. On request of the Director, the chief medical executive of the facility concerned has to provide to the Director a summary of the complaints against the facility received by the facility, the findings of the investigations and the actions taken. In addition, a Committee on Complaints against Private Healthcare Facilities ("the Complaints Committee") is proposed to be established under clause 71 of the Bill to, among others, receive and consider facility complaints; make recommendations to the Director on matters relating to facility complaints which include whether to take regulatory action against the private healthcare facilities concerned; and refer, in appropriate cases, facility complaints to regulatory authorities for any follow-up action.²¹ Clauses 71(2), 71(4) and 74(1) of the Bill provide that the Complaints Committee is to consist of a chairperson; a deputy chairperson; as well as not less than 24, and not more than 48, other members appointed by the Secretary. At least half of the members of the

²¹ The various functions of the Complaints Committee are set out in clause 73 of the Bill.

Complaints Committee, including its chairperson and deputy chairperson, must be persons who are neither registered medical practitioners or registered dentists (i.e. lay persons). The proposed required quorum of a meeting of the Complaints Committee is to be 13 members.

63. Some members including Ms Alice MAK, Dr Helena WONG and Dr CHIANG Lai-wan are of the view that the chairperson of the Complaints Committee should be a lay person in order to ensure that facility complaints would be handled in an impartial manner. They have also expressed concern about how a balanced participation of those members being registered medical practitioners or registered dentists and those members being lay persons at a meeting of the Complaints Committee could be ensured under the proposed quorum requirement.

64. The Administration takes the view that the proposed composition of the Complaints Committee has on the one hand ensured a balanced participation by different stakeholders in order to increase the transparency, neutrality and credibility of the Committee, and on the other hand provided sufficient flexibility for the Secretary to appoint members of different backgrounds. It does not see the need to specify in the Bill that the chairperson of the Complaints Committee has to be a lay person as the current drafting would provide sufficient flexibility for the Secretary to appoint a lay person as the chairperson as he or she sees fit. The Administration has further assured the Bills Committee that the secretary of the Complaints Committee, who is a public officer, will, as in the case of any other statutory committees or boards, strive to ensure balanced participation of members at meetings of the Complaints Committee by notifying members of schedule of meetings in advance and accommodating members' schedules as far as practicable.

65. Members have requested the Administration to ensure that the drafting of the Bill could provide flexibility for the Secretary to, where necessary, appoint more than one legal advisers for the Complaints Committee. The Administration has advised that it is its intention to provide such flexibility. For the avoidance of doubt, it will move an amendment to clause 72(1)(b) of the Bill to the effect that the Secretary is to appoint one or more legal advisers for the Complaints Committee for a period and on the terms specified in the letter of appointment. Separately, the Administration has taken note of the view of members that there is a need to ensure that the remuneration offered could attract qualified solicitor or barrister to assume the role of legal adviser to the Complaints Committee.

Making and processing of a facility complaint

66. Under clause 82, a patient of a private healthcare facility; a substitute decision maker of the patient; a person authorized by the patient in writing to make a complaint; and the personal representative of the patient may make a complaint to the Complaints Committee against a private healthcare facility for which a licence is in force. The Administration has informed the Bills Committee that it will move an amendment to the clause to include a next of kin of the patient as persons who may make a facility complaint to the Complaints Committee.

67. Clauses 83 and 84 of the Bill require that if a facility complaint against a private healthcare facility is received, it must be processed by a preliminary processing panel. On receiving a report from the preliminary processing panel, the Complaints Committee must appoint a case panel to consider the facility complaint unless it has been withdrawn or there are grounds for the Complaints Committee not to do so. For the latter, one of the proposed grounds is that the event to which the complaint relates occurred more than two years before the day on which the complaint is made. Some members including Mr CHAN Chi-chuen and Ms Alice MAK are of the view that the two-year restriction may be too stringent. The Legal Adviser to the Bills Committee has drawn the attention of the Bills Committee that the Bill does not provide for the timeframe a private healthcare facility has to handle and complete the investigation of a complaint against the facility.

68. According to the Administration, the two-year period is proposed with reference to the complaints management system in HA, under which the Public Complaints Committee established under the HA Board for reviewing complaints unresolved at the first-tier 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. 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. The proposed arrangement under the Bill is appropriate. The Administration has further advised that private hospitals are currently required under the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes to set a timeframe, say, 10 working days, for providing an initial response to complaints it received. Similar requirements would be specified in the relevant CoP to be issued by the Director.

69. Members note that a case panel must, after considering a facility complaint, make one or more of the recommendations specified in clause 86(2) of the Bill to the Complaints Committee for consideration. The complaint case will be closed if the Complaints Committee approves the recommendation(s), or makes its own decision in relation to the complaint case or relevant issue. The complainant will

be informed in writing of the decision of the Complaint Committee and any action taken or to be taken in relation to the private healthcare facility concerned. Some members including Ms Alice MAK and Dr Helena WONG have expressed concern that no appeal mechanism is provided for under the Bill such that those complainants who are aggrieved by the decisions of the Complaints Committee could appeal for a review of the decisions. Dr Helena WONG is of the view that the Director or the Complaints Committee should make public those facility complaint cases which involved significant public interest.

70. The Administration has advised that given that there already exists a two-tier complaint handling mechanism involving the private healthcare facilities and the Complaints Committee, and that the Director may take any regulatory actions as he or she deems appropriate, it does not see a need to put in place another layer of appeal procedures for decisions of the Complaints Committee which will prolong the complaint handling process. The Administration has further advised that in the event that a facility complaint case constituted a significant public health risk, the details of which would be made public. Under clause 73(1)(g) of the Bill, the Complaints Committee would also publish on a regular basis summary reports on the facility complaints it has handled and its recommendations to the Director and the private healthcare facilities concerned. The Administration has advised the Bills Committee that a dedicated website would be set up for the purpose of, among others, publication of the information on how a facility complaint may be made and the above information.

Advisory committees relating to the regulation of private healthcare facilities

71. Clause 99 of the Bill enables the Director to appoint one or more advisory committees to advise on any matter relating to the regulation of private healthcare facilities. The Director may appoint the chairperson and other members, and determine the composition of an advisory committee. Some members including Mr SHIU Ka-fai are discontent with the Administration's failure to take into full account the evolving development of beauty sector and the operation of beauty service providers in formulating the proposed new regulatory regime for private healthcare facilities. In their view, the composition of the advisory committees should, where appropriate, include representatives from the beauty sector.

Service of notice or other document

72. Clause 121(1)(b) of the Bill provides that in the case of an individual, a notice or other document (however described) required to be given or sent under the Bill is, in the absence of evidence to the contrary, given or sent if it is addressed to the individual and delivered personally to the individual; or it is sent to the individual by post addressed to the individual at the individual's last known address. The Legal Adviser to the Bills Committee has noted that an electronic

mail transmission to the individual's last known electronic mail address and a text message at the individual's last known telephone number, which are provided for in the Electronic Record Sharing System Ordinance (Cap. 625) and the Private Columbaria Ordinance (Cap. 630), are not included as the means of service under the Bill.

73. The Administration takes the view that the notices or other documents to be given or sent to an individual under the Bill, which include, among others, notice of cancellation of licence and notice for giving a direction on how to comply with a CoP, can be of paramount importance to the operation of a private healthcare facility and serious consequences can result if they are not properly delivered to the individuals concerned. To ensure proper service of these notices, it considers it inappropriate to deliver them by means of electronic mail or text message.

Commencement of the Bill

74. Part 9 of the Bill provides for transitional arrangements for private hospitals and scheduled nursing homes covered by a valid certificate of registration and existing day procedure centres and clinics during the specified period, with the day of expiry of the transitional arrangements for scheduled nursing homes, existing day procedure centres and clinics to be appointed by the Secretary by notice published in the Gazette (which must be at least one year after the day on which the notice is published). According to the Administration, the regulatory regime will be commenced in phases based on the types of private healthcare facilities and their risk levels, with the regulatory regime of riskier types of private healthcare facility come into force earlier. Dr KWOK Ka-ki and Dr Pierre CHAN consider it necessary for the Administration to ensure that operators of private healthcare facilities and the medical and dental professions have been fully prepared before the new regulatory regime comes into force in full scale. Dr Pierre CHAN is particularly concerned that for the case of small practice clinics, which, according to the Administration, is estimated to be accounting for around 70% of the some 5 000 medical and/or dental clinics in Hong Kong, those operators who are not aware of the implementation of the new regulatory regime and the need for requesting for a letter of exemption for the clinics they operate may inadvertently commit an offence and be liable on conviction on indictment to a fine at level 6 and to imprisonment for three years.

75. The Administration has advised that it will commence registration for individual types of private healthcare facilities first; provisions prohibiting the operation of the types of private healthcare facilities concerned without a licence and prescribing other related offences will then be put in force, when the Administration considers that both members of the public and the stakeholders are ready for full-scale regulation of the types of private healthcare facilities

concerned (including, where appropriate, when they have obtained provisional licences or letters of exemption, as the case may be). Subject to the passing of the Bill in 2018 and the readiness of the stakeholders, the plan of the Administration is to commence registration of private hospitals in 2019, to be followed by day procedure centres and clinics²² in 2020 and 2021 respectively. The coming into operation of the relevant prohibition and offence provisions will be on a day to be appointed by the Secretary by notice published in the Gazette, which will be subject to negative vetting by LegCo.

76. The Administration has assured the Bills Committee that upon passage of the Bill, it will roll out a series of publicity activities and keep engaging stakeholders, including the professional councils or authorities, professional associations and patient groups concerned, on the commencement of various provisions of the Ordinance and the arrangements of the phased implementation to ensure that various parties are ready for the implementation of the new regulatory regime.

Amendments to the Bill

77. Apart from the amendments to be moved by the Administration to the Bill as elaborated in paragraphs 18, 28, 37, 44, 52, 53, 56, 60, 65 and 66 above, the Administration has proposed some textual, technical and consequential amendments to the Bill. The Bills Committee does not object to the amendments to be moved by the Administration to the Bill as set out in Appendix III to the report of the Bills Committee submitted to the House Committee (LC Paper No. CB(2)61/18-19)²³.

78. The Bills Committee will not propose any amendments to the Bill.

Follow-up actions by the Administration

79. The Administration has undertaken:

- (a) to relay issues relating to the concern of members and stakeholders from the beauty sector on the administration of local anaesthetic for

²² According to the Administration, when DH starts to receive applications for licences for clinics, it will also receive requests for letters of exemption in respect of small practice clinics.

²³ These amendments do not include an amendment to clause 146 of the Bill as set out in the amendments to the Bill to be moved by the Secretary if the Bill receives its Second Reading which were issued on 7 November 2018 under LC Paper No. CB(3)111/18-19.

preventing pain during cosmetic tattooing to the Pharmacy and Poisons Board of Hong Kong for consideration (paragraph 12 refers);

- (b) to specify in the relevant CoP to be issued by the Director under clause 102 of the Bill that all private hospitals should register as a healthcare provider for the Electronic Health Record Sharing System (paragraph 35 refers);
- (c) to encourage private hospitals to provide more services at packaged charges to provide patients with a reasonable level of confidence on the total cost of hospital services they could expect; and in respect of some members' concern on the private hospitals' common practice of linking the levels of service charges to the types of ward, to relay the concern to the private hospitals and encourage them to explain to their patients clearly the various levels of service charges according to the types of ward (paragraph 58 refers); and
- (d) to encourage the scheduled universities to make available to the public information about the prices of chargeable items and services provided in the day procedure centres, clinics and health service establishments under their aegis that will be excluded from the regulation of the Bill (paragraph 61 refers).

Resumption of Second Reading debate on the Bill

80. The Bills Committee raises no objection to the resumption of the Second Reading debate on the Bill, subject to the moving of the amendments to the Bill by the Administration as set out in Appendix III to the report of the Bills Committee submitted to the House Committee (LC Paper No. CB(2)61/18-19). The Administration has informed the Bills Committee of its intention to resume the Second Reading debate on the Bill at the Council meeting of 31 October 2018.

Consultation with the House Committee

81. The Bills Committee reported its deliberations to the House Committee on 19 October 2018.

Bills Committee on Private Healthcare Facilities Bill

Membership list*

Chairman Hon CHAN Han-pan, BBS, JP

Members Hon Tommy CHEUNG Yu-yan, GBS, JP
Prof Hon Joseph LEE Kok-long, SBS, JP
Hon WONG Ting-kwong, GBS, JP
Hon Starry LEE Wai-king, SBS, JP
Hon CHAN Kin-por, GBS, JP
Hon Paul TSE Wai-chun, JP
Hon Steven HO Chun-yin, BBS
Hon YIU Si-wing, BBS
Hon CHAN Chi-chuen
Hon Alice MAK Mei-kuen, BBS, JP
Dr Hon KWOK Ka-ki
Dr Hon Fernando CHEUNG Chiu-hung
Dr Hon Helena WONG Pik-wan
Dr Hon Elizabeth QUAT, BBS, JP
Dr Hon CHIANG Lai-wan, SBS, JP
Hon Andrew WAN Siu-kin
Dr Hon Junius HO Kwan-yiu, JP
Hon HO Kai-ming
Hon SHIU Ka-fai
Hon SHIU Ka-chun
Dr Hon Pierre CHAN

(Total : 22 members)

Clerk Ms Maisie LAM

Legal Adviser Ms Clara TAM

* Changes in membership are shown in Annex to Appendix I.

Annex to Appendix I

Bills Committee on Private Healthcare Facilities Bill

Changes in membership

Member	Relevant date
Dr Hon Elizabeth QUAT, BBS, JP	Since 7 November 2017

According to the Judgment of the Court of First Instance of the High Court on 14 July 2017, LEUNG Kwok-hung, Nathan LAW Kwun-chung, YIU Chung-yim and LAU Siu-lai have been disqualified from assuming the office of a member of the Legislative Council, and have vacated the same since 12 October 2016, and are not entitled to act as a member of the Legislative Council.

Bills Committee on Private Healthcare Facilities Bill

A. Organizations and individuals which/who have made oral representation to the Bills Committee

1. Association of Doctors in Aesthetic Medicine (HK) Limited
2. Association of Private Medical Specialists of Hong Kong
3. Consumer Council
4. Democratic Alliance for the Betterment and Progress of Hong Kong
5. Democratic Party
6. Faculty of Medicine, The Chinese University of Hong Kong
7. Federation of Beauty Industry (HK)
8. Haven of Hope Sister Annie Skau Holistic Care Centre
9. Hong Kong Academy of Medicine
10. Hong Kong Association of Medical Laboratories Limited
11. Hong Kong Beauty Management & Development Association
12. Hong Kong Beauty Press Limited
13. Hong Kong Dental Association
14. Hong Kong Doctors Union
15. Hong Kong Private Hospitals Association
16. Hong Kong Professionals And Senior Executives Association
17. International CICA Association of Esthetics
18. Knowledge Transfer and Consultancy Limited
19. Liberal Party
20. Patients' Alliance on Healthcare Reform
21. Project Steering Committee on Standards for Ambulatory Facilities
22. Society for Community Organization
23. Supplementary Medical Professions Council
24. The Dental Council of Hong Kong
25. The Federation of Medical Societies of Hong Kong
26. The Hong Kong Medical Association
27. The Hong Kong Nephrology Group
28. The Specialists Surgery and Endoscopy Centre Limited
29. The Society for the Promotion of Hospice Care
30. The University of Hong Kong

31. The Zubin Foundation
32. Mr CHAN Wai-kit
33. Prof Joanne CHUNG Wai-yee
34. Mrs Teresa TSOI

B. Organizations which have provided written submissions to the Bills Committee only

1. Beauty Industry Reform Research and Development Committee
2. Hong Kong Association of Community Oncologists
3. Human Health Holdings Limited
4. Pharmacists Connect
5. Quality HealthCare Medical Services Limited
6. Social Services Department, Po Leung Kuk
7. The Association of Licentiates of Medical Council of Hong Kong
8. The Hong Kong College of Pathologists
9. The Hong Kong Federation of Insurers
10. The Hong Kong Polytechnic University
11. The Society of Hospital Pharmacists of Hong Kong
12. Town Health International Medical Group Limited
13. Tung Wah Group of Hospitals
14. UMP Healthcare Holdings Limited