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

Our Ref. : *FHB/H/53/6*
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20 June 2018

Ms Maisie LAM
Clerk to Bills Committee
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms LAM,

Bills Committee on Private Healthcare Facilities Bill
Letter from Dr Hon Pierre CHAN

I refer to your letter dated 8 June 2018 requesting the Government to give a response to Dr Hon Pierre CHAN's letter of the same date. Our reply is set out in the ensuing paragraphs.

Medical Laboratory

2. At present, apart from persons who are exempted from the Supplementary Medical Professions Ordinance (Cap. 359) (such as registered medical practitioners while practising medicine), any person who practises the profession of medical laboratory technologist (MLT) must be registered under Cap. 359, and must comply with the Code of Practice for Registered Medical Laboratory Technologists promulgated by the Medical Laboratory Technologists Board (the Board), so as to maintain the quality in medical laboratory work. Any company carrying

on the business of practising the profession of MLT must have at least one director who is a registered Part I MLT. Directors of incorporated laboratories being MLTs, as well as registered Part I MLTs who are the supervisors of unincorporated laboratories, should take the overall responsibility for the operation of the laboratories concerned. Moreover, the Board, being a statutory body established under Cap. 359, is responsible for handling the registration, as well as promoting adequate standards of professional practice and professional conduct, of all registered MLTs in Hong Kong. Any MLT who breaches a condition of his / her registration may be subject to inquiries, and may be liable to disciplinary actions. Cap. 359 also prohibits an MLT practising his / her profession in premises which are considered by the Board to be unsuitable for such practice.

Pathology Services in Private Hospitals

3. At present, hospitals registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) are providing pathology services in order to support their clinical services (e.g. surgical services). These supporting services are regulated under Cap. 165 as part of the services provided in the hospital. Regulatory standards for pathology services are stipulated under Chapter 13 of the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (at **Annex**). For example, in terms of staffing, a specialist in pathology should be appointed by the hospital to take charge of the service. Alternatively, a specialist in pathology should be appointed as an advisor. The hospital should also assign a registered Part I MLT to take charge of the day-to-day operation of the laboratory. That Chapter has also stipulated other relevant requirements, such as the requirement for a hospital to formulate relevant policies and procedures in respect of the laboratory, as well as to stipulate requirements in respect of the operation of a blood bank and the management of an organ bank.

Scope of the Private Healthcare Facilities Bill

4. The Private Healthcare Facilities Bill (the Bill) does not cover premises where no practice of registered medical practitioners or registered dentists takes place. Under the new regulatory regime, the services provided by other healthcare professionals (such as Chinese medicine practitioners, MLTs, physiotherapists and optometrists) in the premises of licensed PHFs will be regulated as part of the facility service and subject to relevant codes of practice. For example, the pathology services provided in a hospital will be considered as clinical support services, and will continue to be covered and regulated under the hospital licence concerned. Healthcare professionals practising in premises other than those regulated under the Bill will continue to be regulated under the relevant laws and codes of practice.

5. The Bill seeks to introduce a new licensing system for different types of PHFs. Different PHFs will each be subject to a set of regulatory standards commensurate with the risk of the services it provides. On the other hand, the Bill enhances the enforcement power of the regulatory authority, with an aim to ensuring effectiveness of the new regulatory regime. The Department of Health will formulate suitable regulatory standards for private hospitals based on the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes currently in force. Under the new regime, the regulatory standards in respect of pathology services will be largely the same as those set out in the aforementioned Code of Practice. For day procedure centres and clinics, the licensees and chief medical executives concerned have to ensure the facilities have suitable equipment and mechanism in place to cope with the service needs. For example, the facilities concerned have to set up procedures for obtaining laboratory services, and to set up mechanisms for handling specimens properly.

6. As stated in our letter dated 7 May 2018, under the revamped regulatory framework, we focus on regulating premises where registered medical practitioners and registered dentists practise. The Bill provides for a new regulatory regime for four types of PHFs (namely, hospitals, day procedure centres, clinics and health services establishments), replacing

Cap. 165 and the Medical Clinics Ordinance (Cap. 343) currently in force. For premises where other healthcare professionals practise, they will continue to be regulated under the laws in respect of the relevant professions and the corresponding statutory bodies. Therefore, we do not see a need to regulate medical laboratories under the Bill at the moment. In the event that we consider it necessary to enhance regulation in respect of a certain type of PHF in future, we will thoroughly consult the relevant professions and stakeholders, and will take their views into consideration.

Yours sincerely,

(Bill LI)
for Secretary for Food and Health

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Chapter 13 Pathology

13.1 General Requirements

Hospitals providing acute care should provide an adequate range of pathology services to meet the needs of the services.

13.2 Staffing

13.2.1 A specialist in pathology is appointed to take charge of the service. Alternatively, a specialist in pathology should be appointed as an advisor to review regularly the facilities, equipment and staff training of the service.

13.2.2 A medical laboratory technologist I is assigned to take charge of the day-to-day operation of the laboratory. He should ensure that the procedures and tests performed by technical staff are within the scope of their professional training and experience.

13.2.3 At least one medical laboratory technologist is put on duty during the operating hours of the service.

13.3 Other Requirements

13.3.1 Where special pathology services are not available, appropriate arrangements can be made for the collection and transportation of pathology specimens to be performed in another institution by registered medical laboratory technologists.

13.3.2 There should be policies and procedures on the following areas –

(i) safety aspect of the laboratory
(ii) maintenance of performance standards including quality control
(iii) recording of all specimens received and processed by the laboratory
(iv) arrangements for notification of urgent test results
(v) collection, labelling, transportation and storage of pathology specimen

(vi) protection of staff handling pathology specimens
(vii) procurement of reagents
(viii) checking on the expiry dates of reagents
(ix) disposal of specimens and reagents
(x) contingency plans for various emergencies including chemical spillage

13.3.3 Records should be kept for calibration and quality control programmes.

13.3.4 Records should be kept for drills on various emergencies.

13.3.5 There is a clinical laboratory quality assurance programme.

13.4 Blood Bank

13.4.1 The operation of the blood bank should be in line with the recommendations of the Hong Kong Red Cross Blood Transfusion Service.

13.4.2 Contingency plan exists to meet demands for a large amount of blood for transfusion.

13.4.3 There is proper documentation of use and disposal of all blood products maintained in the bank.

13.5 Organ Bank

13.5.1 Where the establishment operates eye bank and bone bank, the procedures should comply with the Human Organ Transplant Ordinance (Cap 465).