

中華人民共和國香港特別行政區政府總部食物及衞生局

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The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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8 January 2018

Ms Clara TAM
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Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
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Dear Ms TAM,

Private Healthcare Facilities Bill

I refer to your letter dated 1 December 2017. Our reply to your request for clarification in relation to the Private Healthcare Facilities Bill (the Bill) is set out below.

Meaning of "Medical Procedure"

2. Broadly speaking, "medical procedure" is a term to describe 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. For example, a medical procedure can be a simple act of needle injection, a laryngeal examination with endoscope, or a surgical operation comprising multiple steps and involving various personnel. 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. The term is therefore commonly left undefined in the relevant legislation of other jurisdictions, such as the Commonwealth of Pennsylvania of the United States¹ and New South Wales of Australia².

- 3. Against the above background, we do not seek to define "medical procedure" under the Bill. Our detailed response to your observations on "medical procedure" under the Bill is as follows –
- (a) and (c) as mentioned in paragraph 2 above, "medical procedure" is a broad term which is not to be defined. 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. Certain terms relating to medical procedures are defined under the Bill to describe the scope covered by different types of licence. "Scheduled medical procedure" is a medical procedure that should not be carried out in clinics, and carrying out such procedure in a facility will require, subject to specifications by the Director of Health under clause 103, a day procedure centre licence. On the other hand, "minor medical procedure" is a medical procedure that can be carried out on an outpatient (i.e. ambulatory) basis in a hospital, a day procedure centre or a clinic. It includes procedures described in column 3 of Schedule 2 and many other procedures of a minor nature. Examples of such procedures are wound dressing, tooth extraction and excision of sebaceous cyst.

Other than medical procedures that are "scheduled medical procedures" and "minor medical procedures", there are also procedures that may be performed in hospitals only. Clause 103(1) of the Bill empowers the Director of Health to specify, in a code of practice, a procedure falling into the description of a scheduled medical procedure (i.e. the description in column 2 of Schedule 2, but not in column 3 of Schedule 2) but may only be carried out in a hospital. Examples of such procedures are bronchoscopy and therapeutic gastrointestinal endoscopy on children. In addition, surgical operations that may require the

The term "medical or surgical procedures" is used in section 4 of Private Health Facilities Act 2007 No. 9.

The term "surgical or medical procedures" is used in Title 28, Pennsylvania Code, Section 912.3.

patient's continuous confinement within the facility for more than 12 hours, such as colectomy and total knee replacement, may only be carried out in a hospital. In view of the vast and rapidly evolving scope of medical practice, it is impossible to list them all;

- (b) medical service, in relation to a patient, is defined under clause 2 of the Bill as a medical diagnosis, treatment (other than first aid treatment) or care for the patient given by a registered medical practitioner or a registered dentist. It includes but does not necessarily involve medical procedures. For example, giving medical advice to a patient by a registered medical practitioner is a medical service, but is usually not regarded as performance of a medical procedure. Also, medical service provided in the form of medical observation is usually not regarded as a medical procedure. Given the above, the terms "medical service" and "medical procedure" are not mutually exclusive; and
- (d) some diagnostic or therapeutic procedures conducted in a private healthcare facility may not be covered by the term "medical procedure". For example, electrical stimulation or traction by physiotherapists that serves a purpose reasonably incidental to a private healthcare facility can be carried out in the facility. Such kind of procedures can be considered as diagnostic and therapeutic procedures, but are not necessarily medical procedures. For the purpose of clause 29 of the Bill, we consider that using the more general term "diagnostic or therapeutic procedure" in the definition of "facility service" better reflects our intention to empower the Director of Health to suspend the provision of any such procedures in a private healthcare facility.

Offence under Clause 12

4. Under clause 12 of the Bill, it is an offence for a person not being a healthcare professional, on any premises other than an excepted premises, to purportedly perform a medical treatment 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. Medical treatment, in relation to an individual, is defined under clause 12 as 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, subject to certain exceptions set out under that clause. It includes acts that may not be a medical procedure but is given for treating of disease, injury or disability of mind or body. An example is the prescription of an agent purportedly to have therapeutic effect to treat a cancer patient.

- 5. Clause 12 seeks to deter persons who are not healthcare professionals as defined under the Bill from offering, on premises other than excepted premises, medical treatments or medical procedures that may potentially cause injuries to persons who are (or may be) suffering from diseases, injuries or disabilities of mind or body. Such treatments and procedures should be sought from properly trained and qualified healthcare professionals.
- 6. In coming up with the offence under clause 12, reference was made to the offence under Section 14(1A)(a) of the Medical Clinics Ordinance (Cap. 343), which will be replaced by the Bill when enacted and implemented. Under that offence, any person who in a clinic which is not registered does any medical diagnosis, prescribes any medical treatment or performs any medical treatment in relation to a person which results in personal injury to that person commits an offence. Under section 2 of Cap. 343, "clinic" is defined as any premises used or intended to be used for the medical diagnosis or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body, subject to certain exceptions as set out under that provision; while "medical treatment" is defined under that provision as medical treatment of any description subject to certain exceptions.
- 7. The offence under clause 12 is carefully crafted to ensure that the criminal net is not cast unduly wide. It does not affect other offence provisions that already exist in other legislation. For instance, the performance of a surgical operation by a person who is not a registered medical practitioner or a registered dentist will constitute illegal medical or dental practice under the Medical Registration Ordinance (Cap. 161) or the Dentists Registration Ordinance (Cap. 156), whether or not it causes personal injury.

Health Services Establishments

- 8. A health services establishment (HSE) refers to premises 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. Under clause 101 of the Bill, the Secretary for Food and Health may specify a category of HSE in Schedule 8 to the Bill. Our detailed response to your questions on HSE under the Bill is as follows –
- HSE serves to encompass new modes of operation or delivery (a) of healthcare services that entail a significant level of risk. Clause 7(c) of the Bill has been crafted broad enough to cater for possible regulatory needs in response to the evolving medical technology and changing needs of our society. Therefore, it is possible that some hospitals, day procedure centres and clinics may comprise premises satisfying the descriptions for HSEs under clauses 7(a) and 7(c) of the Bill. For example, 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 an HSE 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;
- (b) when, in future, a new mode of operation or delivery of healthcare services emerges and the existing types of private healthcare facilities under the prevailing regime cannot best regulate the premises concerned, the Secretary for Food and Health may specify a new category of HSE, so as to cater for this new regulatory need; and
- currently, The University of Hong Kong and The Chinese University of Hong Kong have set up two Phase 1 Clinical Trial Centres respectively. We have proposed to introduce an amendment to exclude from regulation under the Bill facilities fulfilling certain criteria³, including the two aforementioned

We propose that facilities fulfilling the following criteria should not be regulated under the Bill –

⁽a) being managed or controlled by HKU or CUHK;

⁽b) being a day procedure centre, clinic or HSE; and

⁽c) being primarily used for teaching or research relating to medicine or dentistry.

clinical trial facilities. Similar clinical trial facilities to be set up in the future will be regulated as category 1 of HSEs.

Yours sincerely,

(Michael LI) for Secretary for Food and Health

c.c. DoJ (Attn: Ms Rayne CHAI and Miss Elaine NG)
Clerk to Bills Committee