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Legislative Council Panel on Health Services

Legislative Proposals for Regulation of Private Healthcare Facilities

PURPOSE

This paper briefs Members on the legislative proposals for strengthening regulation of private healthcare facilities (PHFs).

BACKGROUND

2. While PHFs in Hong Kong comprise a wide range of privately-owned facilities providing medical diagnosis and treatment, the current scope of regulation is limited to a narrow set of premises drawn up in 1960s mainly covering private hospitals and non-profit-sharing medical clinics. The existing regulatory frameworks are outdated. Moreover, over the past few years, a number of medical incidents involving PHFs have attracted public attention on the service quality of PHFs.

3. With a view to better regulating private healthcare services amid the evolving landscape of healthcare services, a Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) was established in October 2012 to conduct a root-and-branch review on the regulation of PHFs. Based on the recommendation of the Steering Committee, we rolled out in December 2014 a three-month public consultation on the proposal to revamp the existing regulatory regime for PHFs. We adopted a risk-based approach and identified three categories of PHFs (i.e. private hospitals, day procedure centres and clinics under the management of incorporated bodies) to be regulated. We also proposed various regulatory aspects, grouped under five broad categories of control[1], as the essential

[1] The five broad categories of control included corporate governance, standard of facilities, clinical quality, price transparency and sanctions.

regulatory requirements. In addition, we proposed that the regulatory authority be vested with certain types of powers[2] to facilitate its enforcement.

4. The community expressed broad support for the proposals we put up during the public consultation in general. We published the consultation report in April 2016 which summarised the consultation outcomes and set out the way forward for putting in place a new regulatory regime.

LEGISLATIVE PROPOSALS

5. The new regulatory regime will be implemented by a new piece of legislation, namely the Private Healthcare Facilities Bill (the Bill), which will replace the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) currently in force. Some key legislative proposals under the Bill are set out in the ensuing paragraphs.

(i) Types of PHFs to be Regulated

6. Under the new regime, there will be four types of PHFs subject to regulation, namely, (a) hospitals, (b) day procedure centres, (c) clinics and (d) health services establishments.

7. Of these four types of PHFs, day procedure centres and health services establishments are newly created categories, while hospitals and clinics are already in existence under current legislation. A distinguishing factor between day procedures centres and clinics is that certain "high-risk" medical procedures[3] can be performed in day procedure centres, but not in clinics. A

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[2] Under our proposal, the regulatory authority/the Government should be empowered to –
(a) issue and amend regulations/codes of practice;
(b) inspect, collect and publish relevant information;
(c) suspend a facility/service/use of equipment; and
(d) appoint advisory committees, devise, review and update the scope and standards of regulation for facilities providing "high-risk" medical procedures.

[3] Medical procedures in ambulatory settings are defined as "high-risk" by three factors, namely (a) risk of procedure, (b) risk of anaesthesia involved and (c) patient's condition.

list of "high-risk" medical procedures proposed by the Administration can be found at **Annex A**.

8. The term, health services establishment, is meant to encompass new modes of operation or delivery of medical services that entail a significant level of risk, such as facilities used for the purpose of medical research. The Secretary for Food and Health will be empowered to declare new categories of health services establishments in the future, so as to cater for possible regulatory needs in response to the evolving medical technology and changing needs of our society.

9. As regards clinics, as stated in the consultation document and report, our focus would be on those under the management of incorporated bodies since these clinics have more complex structure of operations. We propose that those clinics which involve only solo or small group practice (called "small practice clinics") should be exempted under the new regime. A small practice clinic refers to a clinic that is operated by not more than a certain number of registered medical practitioners or registered dentists, who are all – and also the only ones – responsible for the management of the clinic as well as practising in the clinic. We are conducting a survey on private clinics and day procedure centres in the market and also seeking views from the medical profession on the exemption arrangement. Without prejudice to the survey findings and the discussion outcomes, our initial view is that setting the exemption threshold between three to five registered medical practitioners/registered dentists would be appropriate. In recognition of the nature of small practice clinics, a person will be allowed to concurrently operate up to two or three small practice clinics.

10. Any person operating a small practice clinic may give the Director of Health a notification of his intention to apply for the exemption. The Director of Health may grant the exemption which will be in force as long as the status of the clinic (to which the notification relates) as a small practice clinic remains unchanged. After the exemption is granted and there is any change of status and particulars of the clinic (e.g. the clinic is no longer eligible to be a small practice clinic), the operator has to inform the Director of Health.

(ii) Licensee and Chief Medical Executive

11. The Bill will set out explicitly the requirements, authorities and responsibilities of two important persons in managing licensed PHFs (i.e. not for small practice clinics being exempted), namely, (a) the licensee and (b) the chief medical executive.

12. The licensee[4] of a PHF assumes the full authority and responsibility for the operation of the facility. The licensee's responsibilities include ensuring the facility's compliance with licence conditions, codes of practice, etc.; and setting up and enforcing rules, policies and procedures relating to the quality of care for, and the safety of, patients in the facility as well as for the operation of the facility.

13. The licensee must appoint a chief medical executive to take charge of the day-to-day administration of the facility. The chief medical executive of a PHF is, at all times when the facility is in operation, responsible for the adoption and implementation of rules, policies and procedures concerning the healthcare services provided in the facility. For hospitals, day procedure centres and clinics, the chief medical executive must be a registered medical practitioner or a registered dentist, possessing the experience and qualifications that are necessary for administering the PHF. He must also be of integrity and good character, and is physically and mentally fit, to operate the PHF.

14. For different types of PHFs, we propose that the chief medical executive must have a certain specified length of post-registration experience in Hong Kong. Depending on the risk, scope and modus operandi of different settings, there will be further, different requirements imposed on persons serving as chief medical executives. Our initial proposal, which is still subject to refinement having regard to the latest consultation with stakeholders, is at **Annex B**.

[4] A licensee must be a legal person for hospitals, but could be either a legal or natural person for other PHFs.

(iii) Complaints Management System

15. When we published the consultation report, we proposed establishing a two-tier complaints management system to handle complaints against the PHFs to be regulated under the new regime[5]. In particular, we suggested exploring the feasibility of establishing an independent Committee on Complaints against Private Healthcare Facilities (Complaints Committee), which would be empowered to look into complaints unresolved at service delivery level by the PHFs concerned.

16. In this regard, we will stipulate in the Bill details of the two-level complaints management system. Insofar as the Complaints Committee is concerned, the Bill will set out its formation, functions and investigation powers. Details of the proposed Complaints Committee can be found at **Annex C**.

(iv) Price Transparency

17. Price transparency is one of the key elements in our revamped regulatory regime for PHFs. During the public consultation, we have received strong public support for enhancing price transparency of PHFs. We propose stipulating in the Bill that the licensee of a PHF must make available to the public the prices of any chargeable items and services provided in the PHF. For hospitals, the licensees will also be required to put in place a budget estimate system, and to publish historical statistics on fees and charges in respect of the treatments and procedures specified by the Director of Health.

18. In October 2016, the Government together with the Hong Kong Private Hospitals Association rolled out a pilot programme for enhancing price transparency for private hospitals. The Government has been monitoring the feedback of the pilot programme, and will assess the experience thus gained in finalising details of the Bill in respect of price transparency.

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[5] Under our proposal, the first-tier should be at the service delivery level at which PHFs should manage complaints at source as required in the codes of practice prescribed by the regulatory authority. The second-tier should handle unresolved cases according to a centralised and independent mechanism.

(v) Regulatory Measures and Sanctions

19. As mentioned in the consultation report, the Bill will stipulate regulatory measures to tackle with breaches of the law and licensing requirements including the codes of practice. These regulatory tools, such as powers for suspension of service or even cancellation of licence, would enable the Department of Health to better regulate different aspects of operation of PHFs.

20. Moreover, we will stipulate in the Bill offences to deter serious and intentional non-compliance under the new regime. Licensees and chief medical executives, who play significant roles in managing PHFs, could be subject to sanctions for certain contraventions. In drawing up the scope and level of penalties of the proposed offences in the Bill, we have sought to protect public interests without placing unduly onerous responsibilities on relevant personnel in PHFs. For instance, it will be an offence for operating a PHF that is not licensed or exempted, with a maximum penalty of a fine of $5 million and imprisonment for five years. Another example is the offence for failing to comply with an order from the Director of Health to suspend the operation or provision of services in a PHF, with a maximum penalty of a fine of $1 million and imprisonment for two years. A list of offences under our latest proposal is at **Annex D**.

(vi) Regulatory Standards for PHFs

21. Under the new regime, different types of PHFs will each be subject to a set of regulatory standards commensurate with the risk of the services they provide. As regulatory standards will evolve in keeping with scientific advancement, international best practices and changing local circumstances, the Bill will empower the Director of Health to issue, revise or revoke various forms of codes of practice.

22. Regulatory standards for private hospitals, which will be the most stringent among all types of PHFs, will be formulated based on the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes currently in force. To draw up standards for day procedure centres and to give advice on

the standards for clinics, a Project Steering Committee on Standards for Ambulatory Facilities was set up by the Department of Health and the Hong Kong Academy of Medicine (HKAM) in mid-2015.

23. The standards for day procedure centres comprise the Core Standards, which apply to all day procedure centres, and Procedure-specific Standards, which apply to day procedure centres providing the specific class of procedures to which the standards relate (e.g. surgery, endoscopy and haemodialysis). The Core Standards have been promulgated by HKAM in late 2016, and the Procedure-specific Standards are under preparation. For clinics, we are consulting stakeholders on the Standards for Medical Clinics, which have been drafted with reference to the existing Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343) and relevant standards in overseas jurisdictions. Before the introduction of the statutory licensing system under the new regime, these Standards will serve as professional guidance for operators and the medical/dental professions.

(vii) Nursing Homes for the Elderly

24. There are a number of institutions registered as nursing homes under Cap. 165, which will be repealed under the new regime. These institutions are currently providing a diverse range of services. The majority of them provide care for elderly persons, whilst others provide services such as haemodialysis, day surgeries and drug dependence treatment[6].

25. For the aforementioned institutions which are registered as nursing homes for providing care for the elderly, they either provide purely nursing home places, or provide both nursing home and care and attention home places. Unlike hospital in-patients who are admitted primarily for medical treatment, residents of nursing homes do not require continuous and round-the-clock medical care. The great majority of these residents receive treatment from visiting medical practitioners and/or dentists when needed. These nursing

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[6] Depending on their nature and readiness to meet the relevant licensing requirements, these premises may be registered or will continue to be registered under the Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance (Cap. 566) or the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613). Some others will be regulated as PHFs under the new regulatory regime.

homes for the elderly are not medical facilities and should not be regulated as such under the new regime.

26. Consequential amendments will be made under the Bill for nursing homes to be regulated under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459) and its Regulation(s). We will introduce a new type of residential care homes under the Residential Care Homes (Elderly Persons) Regulation (Cap. 459A), namely nursing homes, in addition to the three existing types of residential care homes thereunder, namely, (a) care and attention home, (b) aged home and (c) self-care hostel. The amendments are technical in nature for the sole purpose of introducing a new type of residential care homes for the elderly (i.e. nursing homes), without any substantial changes to the existing level of regulatory requirements for the nursing homes to be regulated under Cap. 459. The existing level of regulatory requirements for the three existing types of residential care homes under Cap. 459 will remain unchanged.

CONSULTATION WITH STAKEHOLDERS

27. We have been engaging various stakeholders on our legislative proposals. These include professional councils/authorities (including Hong Kong Academy of Medicine, the Medical Council of Hong Kong, the Dental Council of Hong Kong and Supplementary Medical Professions Council), professional associations (including the Hong Kong Medical Association, Hong Kong Dental Association Limited, the Hong Kong Private Hospitals Association, Hong Kong Doctors Union, Association of Private Medical Specialists of Hong Kong and the Federation of Medical Societies of Hong Kong), universities, existing licensees under Cap. 165 and Cap. 343, existing PHF operators as well as patient organisations, etc. So far, we have attended over 60 briefings, seminars, visits and meetings to explain the legislative proposals and to seek feedback from stakeholders.

28. To sustain our efforts in building consensus on the new regulatory regime, we have issued a letter to all doctors and dentists in Hong Kong in early February 2017, informing them of our legislative proposals and inviting them to briefing sessions in February and March respectively.

LEGISLATIVE TIMETABLE

29. We are finalising details of the new regulatory regime for PHFs, taking into account the views received from stakeholders. We aim to introduce the Bill to the Legislative Council in the first half of this year.

ADVICE SOUGHT

30. Members' views are invited on the proposals above.

Food and Health Bureau
Department of Health
February 2017

Annex A

List of "High-risk" Medical Procedures which can be performed in Day Procedure Centres

Column 1 **Class of "High-risk" Medical Procedures**	**Column 2** **Details of "High-risk" Medical Procedures (Note 1)**	**Column 3** **Exceptions to "High-risk" Medical Procedures in Column 2 (i.e. These Procedures may also be Carried out in Clinics)**
1. Surgical Procedure	(a) Creation of surgical wound to allow access to major body cavity or viscus (including access to central large joints)	(i) Creation of surgical wound to allow access to peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below) (ii) Needle injection into joint cavity (iii) Intraocular injection with fine needle by ophthalmologists (iv) Injection of botox
	(b) Removal of tissue or fluid, or both, of a total volume of 500ml or above	Suprapubic tap
	(c) Removal of tissue or fluid, or both, of any volume from deep seated organ in children aged under 12 years old	
	(d) Removal of any volume of fluid or tissue, or both, from thoracic cavity	Diagnostic pleural tapping
	(e) Insertion of prosthesis	(i) Prosthesis in ear, nose and throat cavity (ii) Dental prosthesis and implant (iii) Facial implant (iv) Extra-ocular prosthesis and

		implant (v) Intrauterine or vaginal prosthesis (vi) Bulking agent of urethra (vii) Prostatic urethral stent (viii) Urethral sling (ix) Testicular prosthesis
	(f) Core biopsy	(i) Core biopsy of superficial tissue (such as skin, prostate, breast and uterus) but not including thyroid or salivary glands (ii) Core biopsy of superficial muscle (iii) Core biopsy of peripheral muscle
	(g) Biopsy of organ or tissue requiring image guidance	(i) Biopsy of breast tissue (ii) Biopsy of superficial lymph node
	(h) Fine needle biopsy of deep-seated organ	
	(i) Lumbar puncture	
	(j) Transplant of any cell, tissue and organ (including autograft, allograft, xenograft, processed tissue or blood products[1]), skin flap (including face lift)	(i) Skin graft less than 1% of total body surface area (ii) Conjunctival autograft (iii) Transplant procedures which primarily involve dental-alveolar region
	(k) Termination of pregnancy	

[1] Includes platelet-rich plasma (PRP).

	(l) Dilation and curettage	
	(m) Circumcision with use of skin sutures in paediatric patients	
2. Endoscopic procedure	(a) Endoscopic procedure requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))	
	(b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) or gastrointestinal tract	Cystoscopy[2]
	(c) Therapeutic endoscopic procedure (such as endoscopic resection)	Minor therapeutic procedure (such as removal of foreign body)
3. Dental procedure	Maxillofacial surgical procedures that extend beyond dento-alveolar process, including but not limited to (a) Maxillary osteotomies and mandibular osteotomies including angle reduction (b) Open reduction and fixation of complex maxillofacial fracture (c) Surgical treatment of diagnosed malignancies (d) Surgical treatment of complex haemangioma (e) Surgery involving major salivary glands (f) Open surgery of temporomandibular joint	(i) Temporomandibular arthrocentesis (ii) Temporomandibular arthroscopy

[2] Cystoscopy does not include therapeutic cystoscopic procedures such as cystoscopic insertion or removal of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or foreign body or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy.

	(g) Harvesting of autogenous bone from outside the oral cavity (h) Primary cleft lip and palate surgery	
4. Chemotherapy	Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication	
5. Haemodialysis	Haemodialysis	
6. Interventional radiology and lithotripsy	Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance	
7. Anaesthetic procedure[3]	(a) General anaesthesia	
	(b) Neuroaxial blocks (spinal, epidural, caudal)	
	(c) Major plexus blocks (brachial, lumbar, sacral)	
	(d) Intravenous regional anaesthesia	
	(e) Intercostal nerve block	
	(f) Major nerve blocks: • Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves; • Sciatic and femoral nerves; or • Posterior tibial nerve, pudendal nerve or para-cervical block	

[3] The risks of anaesthesia considered include risk of gross, vital physiological derangement, risk of inadvertent systemic injection (such as neurovascular bundle and intra-dural injection), loss of protective reflexes, prolonged disturbance of mobility or body balance and disturbance/loss of major functions of vital organs.

	(g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation for a significant percentage of a group of patients[4]	
	(h) Tumescent anaesthesia	

[4] For definition of "deep sedation", please refer to the "Guidelines on Procedural Sedation" promulgated by HKAM.

Notes:

1. Procedures defined in Column 2 may be performed in a day procedure centre only if -
   (a) the patient is discharged in the same calendar day of admission;
   (b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and
   (c) the patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by the American Society of Anesthesiologists (ASA) Physical Status Classification System[5].

2. The following procedures should only be performed in a hospital -
   (a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ;
   (b) Image-guided core biopsy of deep-seated organ;
   (c) Transarterial catheterisation or deep venous catheterisation;
   (d) Continuous venous-venous haemofiltration or haemodiafiltration;
   (e) Organ transplant [except corneal transplant] or complicated transplant procedures;
   (f) Bronchoscopy or pleuroscopy;
   (g) Therapeutic gastrointestinal endoscopy on children aged under 12 years old; and
   (h) Injection of sclerosing or embolisation agents into vascular or lymphatic compartment of deep-seated head and neck region.

3. Medical practitioners and dentists should take into account, in addition to the procedures listed in the table above, the age, body size and other physical conditions of the patient when determining whether a procedure should be performed in a day procedure centre or in a hospital.

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[5] ASA Physical Status Classification System:
Class 1 – normal healthy patient
Class 2 – mild systemic disease
Class 3 – severe systemic disease – stable
Class 3 – severe systemic disease – unstable (acute exacerbation)
Class 4 – severe systemic disease that is a constant threat to life
Class 5 – moribund patient who is not expected to survive without the operation

Annex B

Initial Proposal on Requirements for Chief Medical Executives

	Hospital	**Day Procedure Centre**	**Clinic**	**Clinic (an alternative regulatory rule applicable to clinics which are managed centrally by the same licensee)**
General Requirements	• Must possess the necessary experience and qualifications • Must be of integrity and good character • Must be physically and mentally fit to operate a PHF			
Qualifications	Registered medical practitioner	• Medical practice: Registered medical practitioner • Dental practice: Registered dentist • Both medical and dental practices: Registered medical practitioner		• Medical practice: Registered medical practitioner • Dental practice: Registered dentist • Both medical and dental practices: Registered medical practitioner
Years of Registration in Hong Kong	≥ 15 years	≥ 6 years	≥ 4 years	≥ 10 years
Other Requirements	• Must be appointed full-time • Must not serve as the chief medical executive of another PHF concurrently	• A person must <u>not</u> serve as the chief medical executive of <u>more than two</u> day procedure centres or clinics concurrently, except for the case at the column on the right • In the case of day procedure centres/clinics with both medical and dental practices, a registered dentist must be appointed to assist the chief medical executive		• A person may serve as the chief medical executive of <u>more than two</u> clinics of the same licensee concurrently, provided that – ➢ A Medical Advisory Committee is established for the clinics; and ➢ For each clinic, a registered medical practitioner/registered dentist serving the clinic is appointed to assist the chief medical executive

Annex C

Details of the Proposed Committee on Complaints against Private Healthcare Facilities

Formation

- The Secretary of Food and Health will appoint a chairperson, as well as not less than 24 and not more than 48 other members.
- At least half of the members of the Complaints Committee will be lay persons.
- There will also be a secretary (who is a public officer) and a legal adviser serving the Complaints Committee.

Functions

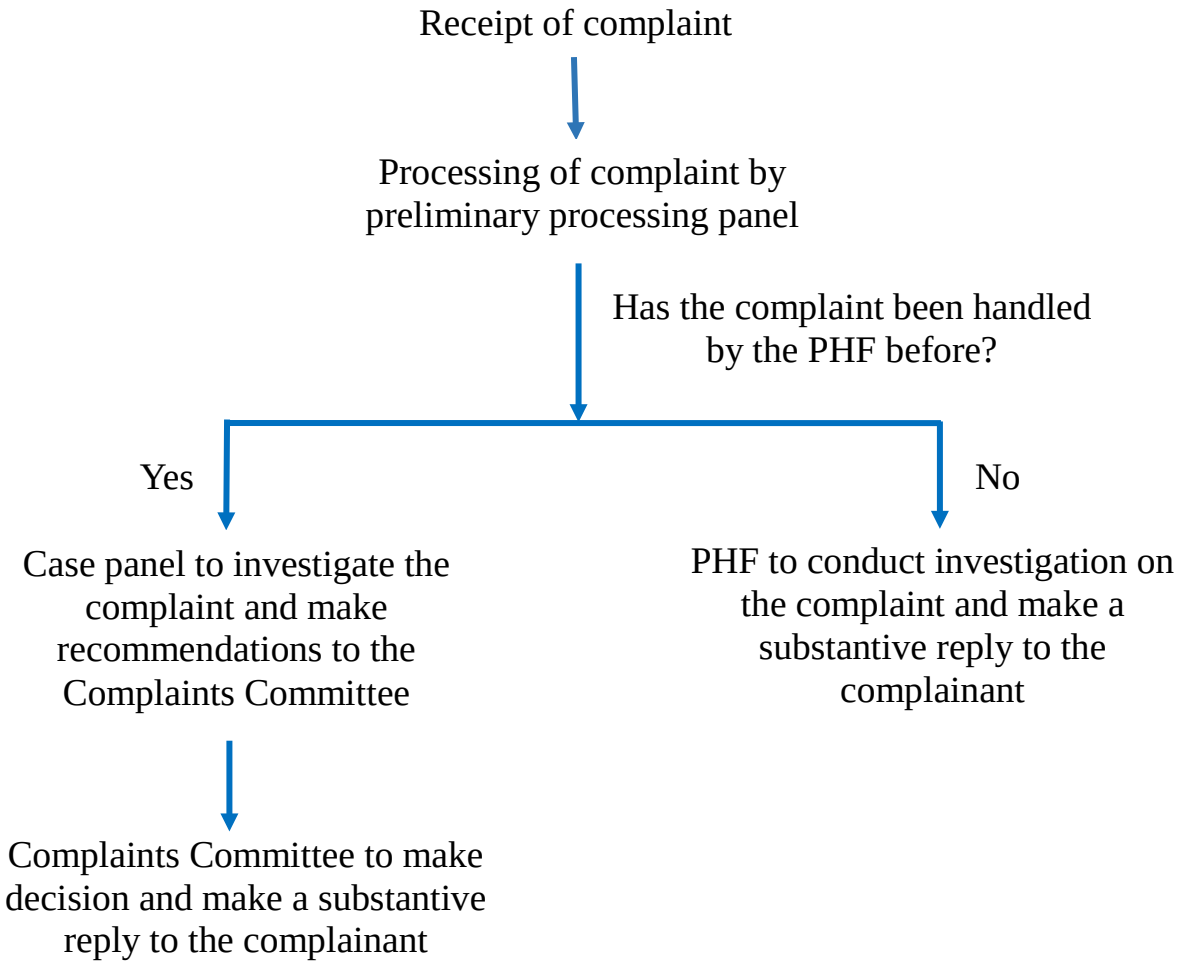
- The Complaints Committee has the following functions –
  - to advise the Director of Health on the policies on complaints management;
  - to receive and consider a complaint;
  - to make recommendations to the Director of Health on matters relating to a complaint (including whether to take any regulatory action against the PHF);
  - to refer, in appropriate cases, complaints to regulatory authorities for any follow up action;
  - to make recommendations to a PHF on any improvement measures;
  - to publish on a regular basis summary reports on the complaints handled and the recommendations made; and
  - to inform the public of complaint channels.

Setting up of Panels

- A preliminary processing panel, comprising members of the Complaints Committee, will be set up to process complaints and to advise the Complaints Committee accordingly.
- Case panels, comprising members of the Complaints Committee, will be set up to consider complaints, decide whether the allegations concerned are substantiated and make recommendations to the Complaints Committee.

Procedure

- A flowchart showing the procedure of complaints handling by the Complaints Committee (and its panels) is at below –



Complaints Committee's Decision

- The Complaints Committee's decision on a complaint (or a part of the complaint) may include –
  - not substantiated: closing of case;
  - substantiated:
    - referring to the Director of Health for possible regulatory actions;
    - referring to other regulatory authorities for possible further actions;
    - making recommendations to the PHF on improvement measures; and
    - advising the Secretary for Food and Health or the Director of Health regarding regulatory issues.
- The Complaints Committee may refuse to consider a complaint for reasons such as that the complaint received is frivolous or groundless.

Annex D

List of Offences under the Latest Legislative Proposal

1. Operating a PHF that is not licensed or exempted
2. Operating a PHF without appointing a chief medical executive
3. Failing to establish a Medical Advisory Committee
4. Failing to comply with the Director of Health's order to suspend a licence on the ground of operating a type of PHF other than that for which the licence is issued
5. Failing to comply with the Director of Heath's order to suspend a licence on the ground of carrying on in the PHF a practice other than that specified in the licence
6. Failing to comply with the Director of Health's order to suspend –
   (a) the operation of a section or unit in the facility;
   (b) the provision of a diagnostic or therapeutic procedure in the facility; or
   (c) the provision of the use of any medical equipment in the facility
7. Failing to display current certificate of licence
8. Failing to notify the Director of Health of the intention to cease operating a PHF
9. Failing to comply with any requirement imposed in ceasing operation of a PHF
10. Failing to notify the Director of Health of change of status or particulars of a small practice clinic
11. A person, being neither a registered medical practitioner nor a registered dentist in a premises other than a licensed PHF or certain exempted premises, purportedly performing a medical treatment or medical procedure for another person and causing personal injury to that other person
12. Using titles or descriptions for a premises not allowed under the Bill
13. Making false or misleading statements or representations
14. Refusing or failing to provide documents or information required by the Secretary for Food and Health/Director of Health
15. Wilfully obstructing or delaying the Director of Health or an authorised officer in performing functions under the Bill
16. Breach of confidentiality