# 消費者委員會
# 就《私營醫療機構規管》諮詢文件
# 呈交立法會衞生事務委員會的意見書

2015 年 2 月 17 日

## 引言

1. 消費者委員會（"消委會"）樂於向立法會衞生事務委員會就《私營醫療機構規管》諮詢文件提出意見。

2. 目前規管私營醫療機構的制度和法例，包括《醫院、護養院及留產院註冊條例》（第 165 章）和《診療所條例》（第 343 章）分別早於 30 年代和 60 年代制訂，至今已不合時而，未能有效地保障消費者的健康及權益。近年發生在非住院情況下施行高風險醫療程序時造成傷亡的多宗醫療事故，也突顯規管制度的不足之處。故此，消委會歡迎政府制定新的私營醫療機構規管制度，並原則上支持《諮詢文件》中的建議。

## 擬受規管的三類私營醫療機構及其定義

3. 消委會知悉政府擬以風險為本的方法，擬訂新規管制度的規管範圍包括「醫院」、「進行高風險醫療程序的日間醫療機構」和「在法團組織管理下提供醫療服務的機構」，並知悉《諮詢文件》中對上述醫療機構的定義。另外，《諮詢文件》建議設立機制檢討和更新對高風險醫療程序實施的規管範圍和標準。消委會認為除此之外，規管當局亦應設立機制定期（例如每五年進行一次檢討）審視受規管的醫療機構的定義及規管範圍，確保規管制度可因應醫療技術和醫療機構服務形式的發展與時並進。

## 擬在新規管制度下推出的 19 個規管範疇及其適用範圍

*委任負責人*

4. 消委會支持《諮詢文件》第 5.7 段及 5.8 段的建議，強制規定每間受規管的私營醫療機構都必須委任一名負責人，如私營醫療機構的違法或違規行為嚴重影響醫療服務的安全或可靠程度，而負責人於適當地行使其責任時應能合理地控制該等醫療服務，有關負責人須為此等違法或違規行為承擔責任（如所涉罪行證明屬實，則應受懲處）。然而，消委會關注上述「違法」或「違規」行為是否只針對違反擬議的規管範疇的行為，倘若私營醫療機構發生導致傷

亡的醫療事故或有醫生在該處所提供的服務被醫務委員會裁定為專業失德時，所委任的負責人是否須要同時承擔責任。鑑於近年不時發生有進行高風險療程的機構在提供服務時導致傷亡的事故，消委會認為私營醫療機構所委任的負責人須同時承擔醫療事故的責任，包括有關在使用或管理醫療設施和僱用不適合或不合法的人士管理上的責任，而此規定必須於新法例中列明。

*設立投訴管理制度*

5. 消委會同意《諮詢文件》第 5.19 段建議的兩層投訴管理機制，同時關注有關的私家醫院投訴獨立委員會的組成。消委會認為該獨立委員會須包括有平衡數目的非醫護界別的代表，以避免可能發生的偏頗於涉事醫護人員及醫院的判決。

6. 《諮詢文件》第 5.20 段建議，非醫院性質的私營醫療機構不須跟從建議規管的私家醫院的兩層投訴管理機制，而是採用簡化機制，由有關私營醫療機構的指定人員處理投訴。消委會認為，由於新規管制度下非醫院性質的私營醫療機構有機會進行高風險的醫療程序或小型手術，而消費者對這些醫療服務在安全、完整性和質素方面的要求，未必比醫院醫療服務的要求低。故此，消委會建議上述兩層投訴管理機制的規定應擴展至非醫院性質的私營醫療機構，並且，參照對醫院的規定，要求非醫院性質的私營醫療機構須每月向衞生署呈報投訴摘要。

*醫療風險警示事件管理*

7. 消委會對於《諮詢文件》以涉及大量成本和資源為由，建議擬議的醫療風險警示事件管理機制及呈報系統暫不應用於非醫院性質的私營醫療機構的安排有所保留。為了改善醫療風險警示事件的資訊披露及加強服務質素保證，消委會認為應規定非醫院性質的私營醫療機構，尤其是進行高風險醫療程序的日間醫療機構，須向規管當局適時呈報醫療風險警示事件。

*提供收費表*

8. 消委會支持在提高收費透明度的範疇下，要求私營醫療機構提供收費表、提供報價、提供認可服務套餐和披露實際收費的統計數據。提高收費透明度固然對保障消費者權益十分重要，但消委會認為同樣重要的是需要設立措施監察及檢討私營醫療機構收費加價的情況，以避免私營醫療服務因為自願醫保計劃的實施而可能出現大幅加價的傾向。

*提供認可服務套餐*

9. 消委會知悉《諮詢文件》建議私營醫療機構可自願提供認可服務套餐。消委會認同《諮詢文件》第 8.29 段及 8.30 段所述，私營醫療機構提供認可服務套餐，有助提高透明度和保障病人的權益。為了加強對消費者的保障，讓消費者可就醫療服務支出作更有把握的預算及方便比較，消委會認為若私營醫療機構就常見手術/程序提供服務（例如白內障切除手術、盲腸切除手術、腹腔鏡膽囊切除手術、胃鏡檢查和結腸鏡檢查等），便應強制規定該機構須就有關手術/程序提供認可服務套餐。為更有效推動受規管的私營醫療機構向病人提供認可服務套餐，消委會認為應就推行認可服務套餐訂立時間表。另外，消委會認為有關認可服務套餐的資料或收費更新，應適時通知規管當局及備存於當局設立的電子平台。

*罰則*

10. 《諮詢文件》建議，對非醫院的私營醫療機構就未經註冊而營運而施加的最高罰則為罰款 10 萬元及監禁三個月，而就違反法例中的其他條文而施加的最高罰則為罰款 25,000 元，如持續違反規定，則每日罰款 2,000 元。鑑於部分在上述機構進行的程序亦涉及高風險，對生命同樣會構成重大影響，消委會認為建議的罰則太輕，與所可能涉及的風險程度不相稱。故此，消委會認為應考慮醫療服務和程序的風險等級不同而有相應罰則。

**擬賦予規管當局的權力**

11. 消委會同意《諮詢文件》建議規管當局/行政當局應獲授予的權力。另外，消委會認為規管當局應採取積極行動，管理及監督受規管的私營醫療機構，確保其遵從相關法例。

12. 除了獲授予的權力，消委會認為規管當局的職能應包括就私營醫療機構的規管制度進行公眾教育和宣傳。

**其他意見**

13. 消委會知悉《諮詢文件》附件 B（1）的高風險程序及只可在醫院進行的程序的建議涵蓋範圍，該附件以醫學術語列出。消委會認為在建議的涵蓋範圍落實後，應以普及易明的用語及實際例子，提供公眾參考。鑑於部分有意購買高風險醫療程序的消費者，未必清楚了解及獲告知當中涉及的風險，消委會建議新法例規定提供涉及高風險醫療程序的機構，必須在消費者同意購買有

關服務前，向其詳細解釋當中涉及的程序和風險。

14. 為避免私營醫療機構因自願醫保計劃的實施而可能出現濫用醫療程序的情況，消委會建議規管當局設立機制，與醫務委員會定期研究、調查和檢討私營醫療機構進行的醫療程序是否必需及合理。另外，規管當局亦要主動及定時向公眾滙報和披露相關訊息。

## 結語

15. 消委會認同有確切需要檢討及改革現行的私營醫療機構規管制度，以更有效地保障消費者健康及權益。故此，無論自願醫保計劃是否落實或落實的時間表為何，消委會認為政府都應盡快訂立新制度規管私營醫療機構。消委會冀望擬議的規管制度及新法例得以早日制訂及落實。

消費者委員會
2015 年 2 月

消費者委員會 CONSUMER COUNCIL
香港 · HONG KONG

國際消費者聯會
執委會及理事會成員
EXECUTIVE AND
COUNCIL MEMBER OF
CONSUMERS
INTERNATIONAL

來函檔號 YOUR REF.
本函檔號 OUR REF. CC 1/257/PTPD

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16 March 2015

Healthcare Planning and Development Office
Food and Health Bureau
19/F, East Wing
Central Government Offices
2 Tim Mei Avenue, Tamar
Hong Kong

Dear Sir/Madam,

Re: Public Consultation
Regulation of Private Healthcare Facilities

In response to the captioned public consultation, the Council is pleased to submit its views for consideration of the Food and Health Bureau.

Should you have any queries, please feel free to contact Ms. Vera TAM, Chief Planning and Trade Practices Officer at .

Yours faithfully,

Gilly WONG
Chief Executive
Consumer Council

Encl.

**Consumer Council**

**Submission to the Food and Health Bureau on**
**Regulation of Private Healthcare Facilities**

1. The Consumer Council (the Council) is pleased to submit its views concerning a consultation document issued by the Food and Health Bureau (FHB) on Regulation of Private Healthcare Facilities (PHFs).

2. Currently, regulation of PHFs in Hong Kong is limited to a narrow set of facilities drawn up decades ago mainly covered private hospitals and non-profit sharing medical clinics. As stated in the consultation document, the existing regulatory regime for PHFs in Hong Kong is outdated and has outlived its usefulness in protecting patients' safety and consumers' rights, as well as the sustainable development of Hong Kong's healthcare system. There have been urgent calls for a major revamp to substantially strengthen the regulation of private healthcare services amid the evolving landscape of healthcare services.

3. The urgency has been further intensified by the unfortunate happenings of various fatal medical incidents resulting from high-risk medical procedures performed in ambulatory setting in recent years.

4. The Council appreciates FHB's effort in putting forward a proposed regulatory regime of PHFs for public to comment. As a whole, the Council supports the proposals as set out in the consultation document in principle and provides views on some specific proposals for consideration of the FHB.

5. This submission comprises of: (I) the Council's responses to specific proposals; and (II) the concerns that consumers may have in relation to the proposed regulatory regime.

## (I) RESPONSES TO SPECIFIC PROPOSALS

### Classes of PHFs and their respective definitions

6. The Council has no objection to the proposed three classes of PHFs to be regulated. While understanding that a mechanism would be introduced to regularly review and update the list of high-risk procedures (paragraph 3.10 of the consultation document), the Council considers that there should also be mechanism in place to review on a regular basis (e.g. every 3 years or when new issues emerged) the definitions of PHFs and the scope of regulation so that the regulation could be appropriately adapted in light of the advancement of medical technology, rapid changes in medical practice and the mode of service provision of PHFs.

**Regulatory aspects and their applicability**

*Appointment of person-in-charge (PIC)*

7. The Council supports the proposal of the appointment of a PIC for each regulated PHF be required mandatorily. Besides, the Council considers it important that the qualification needed, capacity and the responsibilities of the PIC be specified in details.

8. According to the consultation document, the PIC will be held accountable (and liable to penalty if the offence is substantiated) for breaches or non-compliance of the PHF concerned as noted at paragraph 5.8 of the consultation document. However, the Council is concerned with the responsibility of the PIC in case of the occurrence of medical malpractices and sentinel events. In view of the fatal incidents resulting from procedures/treatments conducted in beauty centres in recent years, the Council considers it important that the PICs, especially for facilities providing high-risk medical procedures in ambulatory setting, should also be held accountable for medical malpractices and sentinel events as occurred in the PHF concerned, in particular the responsibility on the management of the operation of medical devices and employment of unprofessional medical practitioners, and that this requirement should be clearly specified in the new legislation.

*Complaints management system*

9. While agreeing that a two-tier complaints handling mechanism be introduced under the new legislation and an Independent Committee on Complaints against Private Hospitals be established to handle complaints at the second-tier as noted in paragraph 5.19 of the consultation document, the Council considers it important as to the composition of the Independent Committee. The Council opines that the Independent Committee, as its name called, should be chaired by an independent person, have the majority of its members be independent persons and include a balanced mix of representatives from medical and non-medical sector so as to avoid potential biased decisions that might be made in favour of the medical professionals and the private hospitals involved in the complaints.

10. The Council notes that in paragraph 5.20 of the consultation document, it is proposed that the two-tier complaints handling mechanism will not be adopted in non-hospital PHFs. In view of non-hospital PHFs will conduct high-risk procedures/ treatments or small-scale operations which could also pose fatal risk to consumers, the Council considers the requirement of safety and integrity of these procedures/treatments and operations should not be substandard to the hospitals. To enable proper consumer redress, the Council opines that the two-tier complaints handling mechanism should be extended to non-hospital PHFs. Besides, the Council recommends that a complaint digest be provided to the Department of Health by non-hospital PHFs regularly possibly every month as required in hospitals.

*Sentinel events management*

11. As regards the proposed sentinel events management, the Council has reservation that reporting of sentinel events is not required for non-hospital PHFs for reasons of compliance cost and resource implications to the PHF concerned. For improving disclosure of information in connection with a sentinel event and guarding against unsafe care, the Council is of the view that non-hospital PHFs, especially for ambulatory facilities providing high-risk medical procedures, should also be mandated to timely report to the regulatory authority upon the occurrence of a sentinel event.

*Provision of fee schedule*

12. The Council supports that under the module of price transparency, provision of fee schedule, provision of quotation, provision of recognized service packages and disclosure of historical bill sizes statistics be required. Though enhancing price transparency is important for consumer protection, the Council considers that there should be measures in place to review and oversee the increment of service fees of PHFs in order to prevent a predisposition towards drastic increase of service fees upon the implementation of Voluntary Health Insurance Scheme (VHIS) or any other new policies imposed that would have significant impact on price setting.

*Provision of recognized service packages (RSPs)*

13. The Council notes that as proposed in the consultation document, provision of RSPs is voluntarily required among all regulated PHFs. Paragraphs 8.29 and 8.30 of the consultation document state that service packages should be encouraged to promote transparency and safeguard rights of patients, and that all regulated PHFs should be encouraged to offer RSPs to patients. The Council is of the view that, in order to better protect the rights of consumers for budget certainty and facilitate consumers to make comparison of medical services, PHFs should be mandatorily required to provide RSPs for common operations/procedures (e.g. cataract surgery for cataract, appendectomy for appendicitis, laparoscopic cholecystectomy for gallstones, endoscopies and colonoscopies) if the common operations/procedures are provided in the PHFs concerned.

14. The Council suggests that a timetable should be set by the Government for rolling out a specific number of RSPs within a certain time period. In addition, the Council suggests PHFs be required to notify the regulatory authority and make the information available at the common electronic platform provided by the regulatory authority in a timely manner any updates on the provision of RSPs and their prices.

*Sanctions*

15. Since the medical services provided in healthcare facilities are in nature life-concerned, the Council opines that the proposed maximum penalties for hospitals and other regulated PHFs in relation to unlawful operation and

non-compliance of other provisions of the legislation are too low to be commensurate with the risk involved. Therefore, the Council considers it necessary that the penalties of all regulated PHFs and all sanctions be increased.

16. Regarding the case of facilities providing high-risk medical procedures in ambulatory setting, in view of the fact that these facilities will perform high-risk procedures/treatments which may involve life-risk and that should not be compromised due to a different category in PHFs, the Council opines that the proposed maximum penalties for these facilities, which is lower than the proposed level for hospitals, is not well justified when taking into account the risk involved. For that reason, the Council suggests the maximum penalties be set with respect to the medical services provided and risk level involved.

**Powers of the regulatory authority**

17. The Council agrees with the powers to be conferred on the regulatory authority and considers that the regulatory authority should take proactive action in administer and supervising PHF's compliance with the provisions of the Ordinance. In addition to the proposed powers, the Council considers it important to specify that the regulatory authority should have the function of conducting public education and publicity programs on the regulation of PHFs, and the rights of consumers.

## (II) OTHER ISSUES OF CONCERN TO CONSUMERS

**High risk medical procedures**

18. The Council is aware that the consultation document has provided a list of recommended scope of high-risk and hospital-only procedures in technical and medical terms and definitions. The Council opines that this list should be made available to the public and be provided in layman terms with examples in practice for easy understanding of consumers. Since some of the consumers who plan to purchase high-risk medical procedures may not be well aware and informed of the risks involved, the Council recommends that service providers of high-risk medical procedures (including cosmetic/beauty services that fall into the scope of high-risk medical procedures/practices) be required to explain details of the procedures and risks involved to consumers before they agree to purchase the procedures/treatments under the new legislation.

**Qualification of practitioners and premises which practise and carry on the business of practising cosmetic/beauty services with risks involved**

19. The Council is concerned with the professional qualification of practitioners practising cosmetic/beauty services with risks involved. The Council understands that the review conducted early by the Working Group on Differentiation between Medical Procedures and Beauty Services considered that certain cosmetic services should be performed by registered medical practitioners because of the risks involved, Department of Health has subsequently issued advisory notes to the beauty

industry and medical profession to remind practitioners of this requirement when providing cosmetic services.

20. Moreover, the Council noted that under the proposed new regulatory regime, any medical procedure defined as high-risk should be performed only in regulated ambulatory facilities or hospitals by qualified healthcare professionals, and that facilities providing high-risk medical procedures in ambulatory setting should be regulated by a statutory registration system and subject to a set of core facility standards and requirements. It seems to the Council that there could be two situations, medical practitioners that perform cosmetic/beauty services that involve risks (but not high-risks) and medical practitioners that perform cosmetic/beauty services that involve high-risks.

21. However, the shortcoming is that in both cases, the proposed new regulatory regime, has not specified the professional qualification of the medical practitioners involved. In other words, currently there is no requirement on the professional qualification of medical practitioners who perform cosmetic/beauty services. For the sake of better protect the right and safety of consumers, the Council proposes that all medical practitioners who perform cosmetic/beauty services that involve risks or high-risks be required to acquire corresponding medical specialist training and qualification (e.g. on aesthetic medicine), and that the medical specialist training and qualification should be accredited by a professional body, for instance, the Hong Kong Academy of Medicine.

22. Regarding the premises carrying on the business of practising cosmetic/beauty services which involve risks but not high-risks, the Council is of the view that since a certain level of risks though not high-risks is involved, it is important that the good operation and maintenance of the facilities be regulated in order to safeguard consumer interests. The Council considers that a licensing regime be introduced to regulate this kind of premises.

**Review mechanism on the judicious use of medical services of PHFs**

23. In order to avoid a predisposition towards mis-use and abuse of medical treatments/operations by PHFs due to the implementation of VHIS or any other major Government policies, the Council suggests the regulatory body to establish a mechanism, with the contribution of The Medical Council of Hong Kong, to review on a regular basis whether the medical treatments/operations as performed by each regulated PHF are necessary and judicious. Also, the regulatory body should take a proactive role in reporting and disseminating the above information to the public.

**Regulation of medical laboratories**

24. Medical diagnoses and treatments have close relationship with medical examinations, tests and analyses, in other words, medical diagnoses/treatments are usually based on the results of medical tests/examinations/analyses. Some medical tests/examinations, for instance, blood tests for various parameters and purposes,

Pap test, biopsy, X-ray, CT Scan, MRI, ECG and ultrasound, etc., are provided by private medical laboratories nowadays and such services are becoming more common. On the other hand, the demand of private medical tests/examinations services may be further driven up by the implementation of VHIS. The Council, therefore, is concerned with the quality of services provided by medical laboratories, for instance, the professionalism, safety, accuracy of the tests/examinations, as well as the sales practices. As integrated services to consumers, the Council considers it important that regulatory regime with respect to the operation and quality management of medical laboratories or premises carrying on the business of performing medical tests/examinations be introduced.

*Companies/Premises carrying on the business of practising the medical laboratory technologist profession*

25. Current regulations on medical laboratories are solely person-oriented and there is no provision on the requirement of operation and quality management. According to Supplementary Medical Professions Ordinance (Cap 359)[1], a company carry on the business of practising the medical laboratory technologist profession should have at least one director thereof is a person who is registered in respect of medical laboratory technologist. All persons practising the medical laboratory technologist profession who are employed by the company are required to be registered in respect of that profession. The premises carry on the medical laboratory technologist profession should be considered by the board as specified in Cap 359 be suitable for such practice. However, the operation and quality management of medical laboratories is not regulated under Cap 359 or any other specific regulations in local.

26. According to the List of Companies Carrying on the Business of Practising the Medical Laboratory Technologist (MLT) Profession of the medical laboratory technologists board, there are 65 companies on the list as of January 2015, however, there are only 11 of them are accredited by HOKLAS based on ISO 15189 according to HOKLAS' record.

27. In order to better protect the consumers, the Council recommends that new regulation be introduced to regulate the operation, maintenance and quality management of medical laboratories. While understanding that there may be different scales of operation of laboratories in Hong Kong, the Council urges that the Government should consider benchmarking the regulatory approaches in overseas to enhance the quality and effective provision of laboratory services for betterment of Hong Kong consumers.

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[1] The regulations on medical laboratories include: Supplementary Medical Professions Ordinance (Cap 359), stipulated the definition of medical laboratory technologist profession, which refers to the practice of processing clinical, medical, legal, public health or veterinary specimens for the sole purpose of making and reporting on analysis or examination in vitro and the processing of all matters for human and animal consumption for the sole purpose of making and reporting on analysis or examination in vitro. Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulation (Cap 359A) stipulates the qualifications for registration of medical laboratory technologists.

*Companies/Premises performing medical tests/examinations which involve the use of medical devices*

28. The Council is aware that the regulatory framework for medical devices, for instance energy-emitting devices such as X-ray, is currently under review by the Department of Health. However, the Council is concerned that there may be possibility that some devices used for common medical examinations may not be classified as high risk and that may not be regulated under the regulatory framework under the above review exercise. In this case, the Council recommends that companies/premises performing medical test/examinations which involve the use of medical devices but not practising medical laboratory technologist profession (e.g. processing clinical and medical specimens for analysis or examination in vitro) should also be regulated for their good operation, maintenance and quality management, for instance, the presence of required accreditation to operate.

**CONCLUSION**

29. Overall, the Council considers it important that the existing regulatory regime for PHFs should be revamped by new legislation as soon as practically feasible, regardless of whether the VHIS is to be implemented.

**Consumer Council**
**March 2015**