香港美容醫療協會
Hong Kong Association of Cosmetic Practice

中華人民共和國
香港特別行政區
食物及衛生局
醫療規劃及發展統籌處

電郵函件

高永文局長：

有關《私營醫療機構規管諮詢文件》之意見書

茲悉 政府當前正就《私營醫療機構規管諮詢文件》收集公眾及業內人士意見， 故本會特此來函。香港美容醫療協會是由從事醫學美容療程研究多年的註冊醫生組成之非牟利合法社團組織，現謹代表全體醫生會員就是次諮詢文件表達意見如下:

一) 對於政府考慮加強立法以保障大眾市民的權益， 香港美容醫療協會表示歡迎和同意，並承諾願意積極參與配合，提出參考意見，為香港市民健康福祉和醫療體系持續發展出一分力。

二) 基於醫生專業操守評核和醫療程序多樣化的複雜性，多年來香港執業醫生除了要通過專業資格的考核和每年持續進修審核要求外，同時嚴格受香港醫務委員會的專業守則和《醫生註冊條例》(第 161 章) 所規管。

三) 有見於早前發生在非住院情況下而造成傷亡的數宗醫療事故，令社會上出現以機構為本的規管聲音，以類似 “一刀切” 形式限制部份被界定為 “高風險醫療程序/行為” 只可在醫院內進行，本會提出以下幾點考慮:

i. 於《私營醫療機構規管諮詢文件》附件 B《由工作小組二提出，並獲督導委員會通過的建議》第(6)項，有關受規管的日間醫療中心應符合的主要設施和規定的涵蓋範疇，其列出的 5 項要點並 沒有清晰明確的指引。 “設施管理” “環境設備” 等涵蓋範疇定義廣泛，本會成員難以就此作出客觀分析表達意見。

ii. 同上文附件 B (1)《高風險程序及只可在醫院進行的程序的建議涵蓋範圍》A)部**醫療程序的風險**第 3 點 "高風險外科程序包括下列程序"，3(b) 指出 "抽取超過 500 毫升的組織及/ 或體液[恥骨上的穿刺抽液除外]"均被歸納為高風險外科程序。及有關 B)部**高風險麻醉程序的涵蓋範圍** [6] 第 7 點(h) 指出 "腫脹麻醉"均視為高風險的麻醉程序。

iii. 上述 2 點有關高風險醫療程序和高風險麻醉程序的定義和闡釋，本會曾作出相關醫學文獻及外國醫學指引的研究考證，得出與諮詢文件不盡相同的參考指引和結論。由於有關醫學文獻、案例及外國醫學指引均為英文版本，本會因此摘錄撮要其相關重點、建議、條件，並詳情列明有關文獻和指引的來源出處於附件一 APPENDIX A 內，請 局長予以參考細閱。

iv. 至於被界定為 "高風險醫療程序/行為"的部分醫學美容療程，過去十年間在香港需求量一直上升。到目前為止雖則我們沒有過去曾接受醫學美容療程的具體統計數字，但就現時以私營機構和私人執業醫生提供醫學美容療程的比例和上升趨勢來評估，我們相信現時公眾對此的需求非常龐大，而且將會因為社會潮流而有持續上升的趨勢。

v. 倘若該部分醫療程序/行為被規管只可在醫院進行，換句話說由於公營醫院對於病人病情的嚴重性、緩急次序、需求等因素考慮，公眾只能選擇於私家醫院內進行此類沒有迫切性的醫療程序/行為。

vi. 按目前香港私家醫院的供應數量來說，這無疑是大幅度削減市場服務提供者的選擇，使公眾社會對該部分醫療程序/行為的需求和市場供應出現嚴重落差。

vii. 供不應求的情況會對社會帶來幾個嚴重衝擊的可能性：

1) 造成私家醫院以提高價格來舒緩短期內配套不足等等突如其來的需求和工作壓力，變相不但削減了公眾的選擇外，使公眾不能夠以現時的消費指標選擇醫療服務，更要付出額外的金錢和等待時間來換取現有的醫療服務；
2) 以私家醫院的價格層面來說，部分公眾人士或有可能因此再負擔不起，且失去現時享有接受醫療程序的平等機會。以醫學美容醫療程序為例，由於我們難以一個緩急的優先輪後準則衡量，這會否造成院方在有限的配套上，較傾向於選擇大金額消費的客户群為優先? 假如有類似情況發生，公眾的選擇權和接受醫療療程的公開平等機會均有可能受損；
3) 按現時大市場的消費模式，部分公眾很有可能因為香港的供求不足、選擇局限和價格高昂等因素，而考慮到香港鄰近地區如中國內地、台灣、韓國等地進行有關醫療程序/行為；

4) 對於鄰近地區的醫療素質和規管制度，我們心裡都沒有底。假如因為上述原因直接/間接促使香港市民接受到外地良莠不齊或比香港私家醫院收費水平為低的醫療服務，造成不必要的金錢損失和身體上的傷害；我們是否更需要周詳的考量現時香港市場的供求需要、使公眾和業內各方的醫療服務提供者取得平衡? 我們必須確保政策改革是盡可能將市民接受有關醫療服務而受傷害的機會減少，而並不是將有可能受傷害的機會移至海外發生。

viii. 香港醫療體系的持續發展、及香港執業醫生的專業水平長久以來均有良好的規管監督和極高的認受性，倘若因為市場供求失衡而造就市民需要到鄰近地區就醫，這無疑對香港的醫療體系的聲望及競爭力都帶來影響。

ix. 就機構為本的規管建議，有關高風險醫療程序和高風險麻醉程序的闡釋定義，和以施行醫療程序/行為的地點只能為醫院內進行的諮詢提案，很有可能帶來上述的潛在狀況。最後因此而得益的，恐怕不是原先本義上我們希望保障的公眾市民及社會上各階層人士。

x. 最後，作為一群處於最前線的醫生，我們至誠希望能夠得到一個積極參與醫療政策諮詢委員會成為一份子的機會。本會明白醫療政策之檢討、改革和諮詢必須以保障市民的健康安全，促進醫療體系長遠均衡發展為最终目的，應當摒除個人或個別界別的利益，慎重考慮政策改革諮詢的迫切性、完備性和平衡性。懇請 當局及有關醫療政策諮詢委員會讓本會代表出席有關政策檢討及制定的會議，讓一群走在最前線的醫生能夠有一個直接溝通的渠道，同心協力為香港醫療體系和病人安全把關，積極防範於未然。

謹此 希望食物及衛生局予以考慮本會所表達的意見，如對上述意見書有任何問題或查詢, 請電郵予 info@hkacp.org.hk 與本會聯絡。謝謝!

附 件

一. APPENDIX A
二. 香港美容醫療協會簡介
三. 會員名單

香港美容醫療協會
2015 年 3 月 11 日

香 港 美 容 醫 療 協 會
Hong Kong Association of Cosmetic Practice

附件一

APPENDIX A

HKACP would like to express our views and suggest to the Document, so together we may draw up the best policy to protect the safety of the general public undergoing medical procedures.

In view of ambulatory surgical facilities, level of risk for ambulatory surgeries and specialty demarcation, our group has performed a literature search, and would like to present what we have found in the next few pages.

We hereby express our concern, as the Document has a few points that do not tally with the current evidence-based medicine.

1) The removal of tissue volume more than 500ml being categorized as high risk medical procedure, in the case of liposuction.
2) Tumescent anaesthesia is regarded as high risk anaesthetic procedure.

We would also like to know the exact criteria to what make up an ambulatory centre.

香港美容醫療協會
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Liposuction, Cosmetic surgery procedure review with respect to facility and level of risk

In view of "recommended scope of high risk and hospital-only procedures, section A risk of procedures, part 3b, the removal of tissue volume more than 500ml being high risk procedure should be revised. In general <5000ml of total aspiratory is suggested in ambulatory setting from different sources. But those are for Caucasian populations. One study in Brazil suggested correlation of the aspirate limit to 5% of the total body weight. While for Asian people, for a normal BMI to slightly overweighed patient, their weights are from 60 – 80kg, the total aspirate is limit is around or not more than 3000ml to 4000ml.

Also, the liposuction technique should also be standardized, the use of tumescent solution lignocaine dose should be not more than 35mg/kg, but in high risk patients including low protein levels, the limit should be lower. Adrenaline use is less than 0.07mg/kg.

In view of non-maleficence, good and standard but not exaggerated resuscitation skill and facilities are required. Procedural physician should bear standard resuscitation skills e.g. ACLS and basic instruments should be present. Also, since safe simple sedation could be made by qualified practitioners and being fellowship should not be the pre-requisite for performing sedation in clinic according to various evidences.

Topics	Recommendation	Source	Level of evidence	Remarks
Large volumes (>5000 cc of total aspirate)	Large volume liposuction should be performed in an acute care hospital or in a facility that is either accredited or licensed, regardless of the anesthetic method.	Expert opinion	D	Not in Ambulatory setting
	Should be monitored overnight in an appropriate facility by qualified and competent staff members who are familiar with liposuction perioperative care.	Rohrich et al., 2006	D	
	The best interest of the patient to perform large volume procedures as separate serial procedures and to avoid combining them with additional procedures	Hunstad, 1996	D	
Ambulatory centre Liposuction (<5000 cc of total aspirate)	5000 mL in a single operative session	Mysore V. Tumescent liposuction: standard guidelines of care.Indian J Dermatol Venereol Leprol. 2008 Jan;74 Suppl:S54-60.		Actually for both ambulatory and hospital setting
	<5000ml in ambulatory setting For liposuction as an adjunct to other procedures, it is suggested that there should be a maximum of 2000 cc's total aspirate volume.	NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES PROGRAM, College of Physicians and Surgeons of British Columbia, August 2007	D	
	The recommended volume of fat removed is in proportion to the fat content and/or size and/or weight of the patient being treated, and the recommended volume of fat removed generally does not exceed 4500 mL in a single operative session.	ACADEMY GUIDELINES, American Academy of Dermatology Dec 10, 2000.	D	
	a volume of aspiration not superior to 5% of body weight is proposed as a safe limit Around 3kg (3000ml) fo a 60kg adult	Cantarelli J, Godoy MF. Safe limits for aspirate volume under wet liposuction. Obes Surg. 2009 Dec;19(12):1642-5.	C, Case series, 30 patients	
Conclusion: In general <5000ml of total aspirate is suggested in ambulatory setting from different sources. One study in Brazil suggested correlation of the aspirate limit to 5% of the total body weight. While for Asian people, for a normal BMI to slightly overweighed patient, their weights are from 60 – 80kg, the total aspirate limit is around 3000ml to 4000ml.				

Topics	Recommendation	Source	Level of evidence	Remarks
Tumescent Anaesthesia	35-45 mg/kg lidocaine and doses should not exceed 55 mg/kg	Mysore V. Tumescent liposuction: standard guidelines of care.Indian J Dermatol Venereol Leprol. 2008 Jan;74 Suppl:S54-60.	D	
	Maximum safe dose of tumescent liposuction performed in non-hospital accredited facilities is Lidocaine 35 mg/kg.	NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES PROGRAM, College of Physicians and Surgeons of British Columbia, August 2007	D	
	Limit the lidocaine dose to 35 mg/kg. This level may not be safe in patients with low protein levels and other medical conditions where the metabolic byproducts of lidocaine breakdown may reach problematic levels.	Klein, 1993; Pitman, Aker, & Tripp, 1996; Samdal, Amland, & Bugge, 1994; Burk, Guzman-Stein, & Vasconez, 1996; Hanke et al., 2004; Nordstrom & Stange, 2005; Rubin et al., 2005	B	
	Limit the lidocaine dose to 35 mg/kg. This level may not be safe in patients with low protein levels and other medical conditions where the metabolic byproducts of lidocaine breakdown may reach problematic levels.	American Society of Plastic Surgeons' Patient Safety Committee. Evidence-Based Patient Safety Advisory: Liposuction	B	
	Epinephrine dosage utilized in infiltrate solutions varies and may range from 1:100,000 to 1:1,000,000. Recommended that epinephrine doses not exceed 0.07 mg/kg.	NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES PROGRAM, College of Physicians and Surgeons of British Columbia, August 2007	D	
	Epinephrine use should be avoided in patients who present with pheochromocytoma, hyperthyroidism, severe hypertension, cardiac disease, or peripheral vascular disease. In addition, cardiac arrhythmias can occur in predisposed individuals or when epinephrine is used with halothane anesthesia. The surgeon must carefully evaluate these types of patients before performing liposuction.	Matarasso, "Lidocaine," 1999; Kenkel et al., 2004; Brown et al., 2004	D	

Conclusion: there is not much controversy in lignocaine dose of 35mg/kg, but in high risk patients including low protein levels, the limit should be lower. Adrenaline use is less than 0.07mg/kg.

Topics	Recommendation	Source	Level of evidence	Remarks
Resuscitation qualification	In addition to the anesthesiologist or physician with ACLS, all nursing staff shall have current certification in basic cardiopulmonary resuscitation.	NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES PROGRAM, College of Physicians and Surgeons of British Columbia, August 2007	D	
	Specialty fellow can perform sedation in clinic, but there is no statement saying that non-fellows are eligible to perform sedation in clinics.	HKAM guideline	E	
Conclusion: ACLS is not a must but it is advisable to have one. Sedation qualification is not well stated in guidelines, but being fellowship should not be the pre-requisite for performing sedation in clinic.				
Resuscitation Facilities	a) Stethoscope; b) A source of oxygen; c) A means of delivering positive pressure oxygen such as a self-inflating bag-mask device; d) An emergency resuscitation cart which includes: • A cardiac monitor with defibrillator • Endotracheal tubes, stylets, airways and face masks in a selection of sizes appropriate to the expected range of patient sizes and ages. • Two functioning laryngoscopes and a variety of sizes of laryngoscope blades • Magill forceps • IV supplies and accessory equipment such as syringes, needles, ECG leads, sponges, tape, etc. These shall be stored in an orderly manner and be easily accessible • Cricothyrotomy kit • A backboard for CPR if the surgical chair/table or recovery stretcher are not suitable • Emergency drugs	NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES PROGRAM, College of Physicians and Surgeons of British Columbia, August 2007	D	
	Pulse oximeter monitoring is essential in all cases	Mysore V. Tumescent liposuction: standard guidelines of care.Indian J Dermatol Venereol Leprol. 2008 Jan;74 Suppl:S54-60.	D	
Conclusion: Basic OT facilities have to be present as listed above.				

Evidence Rating Scale for Studies Reviewed

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or a systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or a systematic review of these studies
III	Retrospective comparative study; case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Scale for Grading Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preference.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V; little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

Specialty demarcation

Here are the conclusions of the review "Determining the Safety of Office-Based Surgery: What 10 Years of Florida Data and 6 Years of Alabama Data Reveal."

There are simple implications that Cosmetic procedures are popular and increasingly popular. And safety measure in the field is needed since more procedure means higher chances of complications. Among these procedures, GA procedures especially liposuction under GA are the black spots, solutions to it will be better guideline, use of LA/tumescent and presence of anesthetist. The use of tumescent is a safe procedure under standard guideline. Guidelines for post-operative care are also needed for possible complication and coherent care of patients. General measure is equally important with good cases selection. **Moreover, cosmetic procedure safety is not evidenced to be different among different specialties.** One shouldn't discriminate the other specialty for cosmetic procedures; the important point is to have relevant training and experience. And every specialty should work hand in hand for a better practice and safety. Accreditation is not a determinant of safety either, but health board and customers may be pleased to see centers are accredited.

Determining the Safety of Office-Based Surgery: What 10 Years of Florida Data and 6 Years of Alabama Data Reveal

Study: retrospective audit
Place: **Florida and Alabama**
Time period: 2000 – 2009 (**F**, 10 years) / 2003-2009(**A**,6 years)
Patient inclusion: Reported cases in AHCA domain and mandatory physician office adverse event reporting
Reported events:
Florida: 46 death/263 complications
Alabama: 0 death/49 complications

Points to note	Conclusion	Strategy
F: Cosmetic procedure accounted for 56.5% of deaths and 49.8% of complications A: Cosmetic procedure accounted for 42% of complications	Cosmetic surgery is common in day centre, Associates with higher Mortality and Morbidity due to its popularity	Better system and safety measures for cosmetic procedures
F: Liposuction under GA accounted for 22% of all cosmetic complications, 32% of death A: liposuction under GA accounts for 2 cases of hospital transfer (4.08%) F+A: no reported complication from tumescent liposuction	Liposuction is common procedure so that there is larger number of complications (top 5 invasive cosmetic procedure >200,000 cases in 2010) Liposuction safety needs to be improved Liposuction should be more cautious under GA	Liposuction guideline and safety drills needed under GA Tumescent liposuction safety is confirmed
A: 89% complication occurred in GA cases Two reported deaths were caused directly by GA – Malignant hyperthermia, allergic reaction	GA procedure safety needs to be improved	GA guideline and safety drills needed Anesthetist may be needed during the procedure
F+A: Liposuction complications documented are pulmonary emboli/fat emboli/respiratory failure/cardiorespiratory arrest/pulmonary oedema/ vasovagal attack (delayed by hours or days)	pulmonary emboli/fat emboli/respiratory failure/cardiorespiratory arrest/pulmonary oedema/ vasovagal attack are complications to be noted	Post Op care avoiding these complications are needed
F+A: Other procedure complications includes AF/ MRSA infection/seroma development	Only scattered case	Need general measure for general fitness for surgery and safety Good case selection needed, don't do procedure too liberally
F: Plastic surgeons accounts for 44.9% of complications A: Plastic surgeon accounts for 42.3% of complications	➢ Specialty is not a determinant factor for complications ➢ Plastic surgeons actually do more complicated cases, complication rate is therefore increased and may not be due to specialty per se	Specific training and practicing in cosmetic filed is the key to safety regardless of specialty
F: 38% of centres are accredited by independent organization A: 71% of centres are accredited by independent organization Both states health boards encourages 100% accreditation	No clear pattern to suggest accreditation is effective Health boards likes accreditation	Getting accreditation may not be a good suggestion. But standardizing the facilities in procedural suites are suggested.

香 港 美 容 醫 療 協 會

Hong Kong Association of Cosmetic Practice

附件二

香 港 美 容 醫 療 協 會

Hong Kong Association of Cosmetic Practice

簡介

香港美容醫療協會是非牟利為目的之合法社團組織, 由從事醫學美容和相關醫學美容療程研究多年的註冊醫生組成。

本會成立的宗旨為連繫業內醫生成員共同研究及分享有關醫學美容療程之學術專業及實際操作技術, 維護和進一步提升醫學美容的專業醫療技術水準, 為同業者提供具參考價值和指標的醫學美容療程專業守則及技術指引, 促進香港醫學美容業的發展使其更具競爭力和擁有前瞻性的國際視野。

同時, 本會希望透過分享正確、客觀、中肯的醫學美容知識予公眾, 令公眾更深入了解醫學美容的安全性、專業性和道德標準, 從而提高公眾對醫學美容方面的知識水平和選擇能力。

本會將團結從事醫學美容有關工作的醫生成員, 透過鼓勵持續專業進修、研究、分享, 多方面提升其學術領域及技術實踐水平, 為行業及尋求醫學美容療程之人士有效地創造最大的價值, 達到雙贏之局面。

香港美容醫療協會

Hong Kong Association of Cosmetic Practice

附件三

會員名單

President	Dr. Alan S L Wong
Vice-President	Dr. Ringo W K Lam
Secretary	Dr. David C H Wong
Scientific Committee Officer	Dr. Althy S L Au
	Dr. Sebestian T H Wong

Honorary Advisory Board	Prof. Andrew Burd 博昂志教授
	Dr. Yeung Chiu Fat Henry 楊超發醫生
	Dr. Leung Ka Ki 梁家騏醫生
	Dr. Fu Kam Fung Kenneth 傅錦峰醫生
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Dr. Lee Yip Chee Kevin
Dr. Ng Cheuk Him Raymond
Dr. Tsui Ka Chun Kenneth
Dr. Wang Chi Yuan Joseph
Dr. Wang I Sing Sandy
Dr. Wong Chit Sun
Dr. Wong Chuen Ho David
Dr. Wong Siu Lun Alan
Dr. Wong Tin Hau Sebestian
Dr. Wu Sheung Yung Raymond
Dr. Yao Ki Fu Joseph

(in alphabetical order)

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