DEPARTMENT OF HEALTH

Report of the Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting

for submission to the Steering Committee on Review of Regulation of Private Healthcare Facilities

2014

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Executive Summary

1. The Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting (the Working Group) was one of four working groups set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities in November 2012. It was tasked to define the range of high-risk medical procedures/practices that are conducted in ambulatory setting, and to recommend appropriate regulatory approaches for Hong Kong.

2. Taking reference from overseas regulatory regimes and adopting a risk-based approach, the Working Group set up five expert groups to deliberate the scope of regulations and regulatory approach for five priority areas which were potentially performed in ambulatory facilities and carrying significant risks.

Regulation of private health facilities in overseas jurisdictions

3. Regulation of private ambulatory health facilities in overseas jurisdictions varies in extent but the adoption of a risk-based approach is a common feature. Heightened regulatory control through registration or licensing is commonly imposed on facilities providing invasive procedures such as surgical operations under anaesthesia, endoscopy, renal dialysis and chemotherapy.

4. Basic licensing requirements in overseas jurisdictions usually include responsibility of licensee, staffing requirements, physical environment, equipment, medical records, risk management such as infection control and contingency plan,

and quality assurance. Additional licensing requirements or standards may be imposed to facilities providing specific classes of procedures so as to address the specific risk these procedures entail.

5. Ambulatory or day facility typically does not provide overnight accommodation. Some jurisdictions also limit the duration of procedures or stay in an ambulatory facility in order to restrict those complicated procedures with long operating and recovery time to hospitals.

The regulatory gap

6. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) are the existing ordinances that regulate private healthcare facilities in Hong Kong. Registered healthcare professionals working in licensed healthcare facilities are bound by the respective licensing conditions for the facilities as well as the relevant professional codes of practice and conduct.

7. The set-up and operation of all healthcare facilities are also subject to requirements under ordinances such as building structure, fire safety, radiation safety, drugs, waste disposal, occupation health and safety, personal data privacy and advertisement. However, these ordinances are not designed to regulate healthcare facilities in particular and do not address the specific risks associated with high-risk procedures.

8. Many surgical and interventional procedures that were previously performed in hospital only can now be conducted in outpatient setting, which is largely unregulated. There is a need to introduce more stringent regulation to bring the regime in line with modern-day standards and to protect patient safety.

Consultation on the draft recommendations

9. Upon the advice of the expert groups, the Working Group had worked out a list of draft recommendations in late 2013. It was proposed that ambulatory facilities where high-risk medical procedures were performed should be regulated. A procedure is high-risk if it is so classified by ANY of following three factors –

- the procedure is classified to be high-risk; or
- the anaesthesia involved is classified to be high-risk; or
- the patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation)) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

10. The Working Group consulted 45 professional organisations of the medical sector on the draft recommendations between December 2013 and February 2014. Thirty-five organisations responded and were generally in support of the draft recommendations, including the principles adopted for defining high-risk procedures, proposed scope of high-risk and hospital-only procedures, regulatory framework and advisory role of Hong Kong Academy of Medicine. Specific comments and views included special consideration for paediatric patients, concerns about cost

implications of compliance, credentialing of practitioners, etc.

Recommendations

11. Taking reference from overseas regulatory regimes and feedbacks collected in the consultation, the Working Group puts forward eight recommendations for the consideration of the Steering Committee.

Recommendation (1)

High-risk procedures/practices should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals.

Recommendation (2)

A procedure is high-risk if it is so classified by ANY of the following three factors --

(a) the procedures is classified to be high-risk; or

(b) the anaesthesia involved is classified to be high-risk; or

(c) patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

When deciding whether a procedure is high-risk and whether a patient should undergo the procedure in ambulatory- or hospital-setting, medical practitioners and dentists should take into account the age, body size and other physical conditions of

the patient, in addition to the criteria for defining high-risk and hospital-only procedures.

Recommendation (3)

Certain high-risk procedures should only be performed in hospital in view of its risk. Overall, high-risk procedures may be performed in ambulatory setting only if -

(a) the patient is discharged in the same calendar day of admission;

(b) the total duration of procedure and recovery does not exceed 12 hours; and

(c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologists (ASA) Physical Status Classification System.

Recommendation (4)

It is recommended to adopt the scope of high-risk and hospital-only procedures as set out in the **Annex I**.

Recommendation (5)

A statutory registration system should be introduced for ambulatory facilities where high-risk procedures are performed. An administrative listing system may be implemented before the mandatory registration system takes effect.

Recommendation (6)

Regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover –

(a) management of the facility;

(b) physical conditions;

(c) service delivery and care process;

(d) infection control; and

(e) resuscitation and contingency.

Regulated facilities should also be imposed further facility standards that are specific to the procedures being performed in the facilities, e.g. haemodialysis, cytotoxic chemotherapy and anaesthesia.

Recommendation (7)

It is recommended that the regulatory authority will have a mechanism to devise, and review and update as required, the scope of regulation and standards with regard to the expert advice of the Hong Kong Academy of Medicine on -

(a) the range of high-risk procedures; and

(b) the relevant procedure-specific facility standards.

Recommendation (8)

Regulated ambulatory facilities should be subject to general requirements that are applicable to other comparable regulated healthcare facilities.

1 BACKGROUND

1.1 The Administration announced in October 2012 the establishment of the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) to conduct a review on the regulatory regime for private healthcare facilities in Hong Kong. The aim of the review is to strengthen regulatory control of private healthcare facilities in order to safeguard public health.

1.2 At its first meeting on 2 November 2012, the Steering Committee set up four working groups to carry out focused study on four priority areas of concern regarding the provision of private healthcare facilities and to work out options on the way forward. One of the priority areas of concern was to address the health risk brought by high-risk medical procedures/practices performed in ambulatory facilities through regulatory control.

1.3 The Working Group on Defining High-Risk Medical Procedures/Practices Performed in Ambulatory Setting (Working Group) was thus formed and tasked to define the range of high-risk medical procedures/practices that are conducted in ambulatory setting, to make reference to the regulatory regimes in overseas jurisdictions while taking into account local circumstances and the demands and expectations of the public at large, and to recommend appropriate regulatory approaches for Hong Kong.

2 THE WORKING GROUP

Membership

2.1 The Working Group, chaired by Professor Raymond LIANG, comprised 10 members from the Steering Committee and 12 co-opted members from the Hong Kong Academy of Medicine and its member Colleges, the Provisional Hong Kong Academy of Nursing, medical practitioners' associations and patient group. Membership list of the Working Group is at **Appendix I**.

Terms of Reference

2.2 The Working Group endorsed the following terms of reference –

(a) to define the range of high-risk procedures/practices that should be performed in regulated ambulatory facilities only; and

(b) to recommend appropriate regulatory approaches to the Steering Committee.

Work Approach

2.3 The Working Group reviewed the regulatory regimes for ambulatory health facilities in England of the United Kingdom (UK), Singapore, and selected states or territories of Australia, Canada and the United States . Taking reference from these regimes and adopting a risk-based approach, the Working Group identified several classes of specialised procedures that were potentially performed in ambulatory

facilities and carrying significant risks. They were determined to be the priority areas for enhanced regulatory control.

2.4 Five Expert Groups were set up under the Working Group to deliberate on the scope of regulation and regulatory approach for each priority area (Table 1). Membership lists are at **Appendix 2**.

Table 1 Expert Groups set up under the Working Group

Expert Group	Priority Areas	Convenor
1	Surgical procedures	Dr Samuel KWOK
2	Endoscopic procedures	Dr Andrew YIP
3	Dental and maxillofacial procedures	Dr Sigmund LEUNG
4	Chemotherapy, diagnostic/ interventional radiological procedures	Dr LAW Chun-key
5	Renal dialysis, cardiac catheterisation, lithotripsy	Professor LAU Chak-sing

Discussion of the Working Group and its Expert Groups

2.5 The Working Group held a total of four meetings between April 2013 and March 2014. During the period, the five Expert Groups held ten meetings between June and November 2013 to work out the scope and approach of regulation, and the

medical sector was consulted on the draft recommendations between December 2013 and February 2014.

3 REGULATION OF PRIVATE HEALTH FACILITIES IN OVERSEAS JURISDICTIONS

3.1 Members of the Working Group and its Expert Groups were introduced to the regulatory regimes for ambulatory health facilities in selected states of Australia including New South Wales, Victoria, Queensland, and Western Australia, Ontario of Canada, Singapore, England of the United Kingdom, and Pennsylvania of the United States (US). Key features of these regimes are summarised at **Appendix III**.

Regulatory Framework

3.2 Private ambulatory health facilities are regulated to various extents in the jurisdictions reviewed, and the adoption of a risk-based approach is a common feature.

3.3 Members noted that in Singapore and England, essentially all private healthcare facilities or providers, ranging from hospitals to solo-practice of medical and dental practitioners, were regulated. Providers of specified classes of high-risk procedures/services (e.g. surgery, chemotherapy, haemodialysis) are required to obtain further approval from the health authority (Singapore), or to register under the respective class of procedures/services with the authority (England), and are subject to the regulatory requirements specific to that class of procedures/services.

3.4 In some states and territories of Australia, Canada and US, whether a health facility is regulated depends on the type of procedures/services performed therein. Registration, license, certification and/or accreditation are required for facilities

where specified high-risk medical procedures are performed, such as hospitals and ambulatory surgical centres. General medical and dental clinics are usually not regulated beyond registration of medical practitioners or dentists.

3.5 In the jurisdictions reviewed, heightened regulatory control through registration or licensing is commonly imposed on facilities providing the following classes of procedures/services: surgical operations under anaesthesia, endoscopy, renal dialysis, chemotherapy, cardiac catheterisation, and interventional radiology.

Regulatory Standards

3.6 Of the overseas regimes reviewed, the legislation mainly prescribes the scope of regulation, licensing procedures, basic requirements in relation to the facility and the operator, power of the regulatory authority to monitor compliance, and sanctions. Basic licensing requirements usually include responsibility of licensee, staffing requirements, physical environment, equipment, medical records, risk management such as infection control and contingency plan, and quality assurance.

3.7 Additional licensing requirements or standards may be imposed to facilities providing specific classes of procedures, so as to address the specific risks these procedures entail, e.g. endoscope processing/decontamination for endoscopy facilities, and resuscitation equipment and access to emergency care for surgical facilities. Licensing requirements may be imposed through separate guidelines or codes issued by regulatory authority or by a cognizant professional body empowered to do so, and compliance with these codes and guidelines is mandatory.

Ambulatory Facility vs. Hospital

3.8 An ambulatory or day facility typically does not provide overnight accommodation. In Queensland, for example, a day hospital is defined as a facility at which day hospital health services are provided to persons who are admitted to and discharged from the facility on the same day. In Pennsylvania, ambulatory surgical facility is a facility that is not located in hospital and providing outpatient surgical treatment to patients who do not require hospitalisation but constant medical supervision following the surgical procedure performed.

3.9 Some jurisdictions limit the duration of procedures or stay in an ambulatory facility, in order to restrict those complicated procedures with long operating and recovery time, and therefore of greater risks, to hospitals. In Singapore, the total duration of admission to an ambulatory surgery centre shall not exceed 12 hours. In Pennsylvania, procedures performed in an ambulatory surgical centre shall not exceed 4 hours in operating time or general anaesthesia and 4 hours in directly supervised recovery.

4 BRIDGING THE REGULATORY GAP

4.1 Members were briefed on the existing regulatory regimes for private healthcare facilities. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap.165) and the Medical Clinics Ordinance (Cap.343) are the two principal ordinances that regulate private healthcare facilities.

Hospitals, Nursing Homes and Maternity Homes Registration Ordinance

4.2 Under *Hospitals, Nursing Homes and Maternity Homes Registration Ordinance* (Cap. 165), all private hospitals and nursing homes are required to be registered with the Director of Health. A hospital/nursing home is defined as "any establishment for the care of the sick, injured or infirm or those who require medical treatment, including a nursing home...". Public hospitals maintained by the Hospital Authority are exempt from registration.

4.3 A private hospital or nursing home is considered fit for registration if its conditions relating to accommodation, staffing and equipment are appropriate for the services to be provided. The Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (the Code) sets out requirements on governance structure, staffing, facility management, protection of the patients' rights, complaint handling, risk management, and so forth. The Code also includes specific requirements for certain clinical and support services.

4.4 Members noted that there were ambulatory facilities providing ambulatory

surgery, haemodialysis and chemotherapy that were registered under Cap. 165, either as satellite clinics of private hospitals or registered nursing homes.

Medical Clinics Ordinance

4.5 The Medical Clinics Ordinance (Cap.343) was enacted in 1963 to provide for registration of clinics that are operated on a non-profit-making basis. Registered clinics are required to comply with licensing conditions including adherence to the Code of Practice for Clinics Registered under the Medical Clinics Ordinance, which covers staffing, accommodation and equipment. Premises used exclusively by medical practitioners or dentists with full registration in the course of their practice on their own account and not bearing any title or description that includes the word "clinic" or "polyclinic" are not required to be registered.

Other legislation related to operation of healthcare facilities

4.6 Registered healthcare professionals working in licensed healthcare facilities are bound by the respective licensing conditions for the facilities as well as the professional codes of practice and conduct that are laid down by the relevant statutory councils and boards.

4.7 The set-up and operation of all healthcare facilities are also subject to requirements under a number of ordinances in respect of building structure, fire safety, radiation safety, drugs, waste disposal, occupation health and safety, personal data, advertisement, so on and so forth. Ordinances of particular relevance to the

operation of a health facility are listed in **Appendix IV**. These ordinances, however, are not designed to regulate health facility in particular and therefore do not address the specific risks associated with the conduct of high-risk activities therein.

Need for greater regulatory control

4.8 The advance in medical technology and growing demand for surgical services had driven many of the surgical and procedural services from hospital to outpatient setting. Members noted the wide range of invasive procedures being performed in office-based setting nowadays, and these facilities were largely unregulated.

4.9 Members noted that both Cap. 165 and Cap. 343 do not cover private practices of registered medical practitioners and dentists. The professional codes of conduct promulgated by the Medical Council and the Dental Council of Hong Kong govern the medical practitioners and dentists in professional respect, but they have not set out requirements for the facility in respect of physical set-up, equipment, preparedness for emergency, infection control, support services, etc., and therefore cannot provide sufficient safeguard when high-risk procedures are performed.

4.10 Having reviewed overseas regulatory frameworks and the local situation, Members generally agreed that there was a need to introduce more stringent regulation to bring the regime in line with modern-day standards and to protect patient safety.

5 DEFINING HIGH-RISK PROCEDURES IN AMBULATORY SETTING

Principles for defining high-risk procedures

5.1 On recommendations of the Expert Groups, the Working Group agreed that high-risk procedures could be defined by criteria set out in respect of - (a) risk of procedures, (b) risk of anaesthesia involved, and (c) patient's conditions. A procedure is high-risk if it is defined as high-risk by any of these three factors.

5.2 Five Experts Groups deliberated on the procedures under their respective purview and proposed the range of procedures that should come under regulation. Reference was drawn from the range and definition of procedures or practices being regulated in overseas legislation.

5.3 In considering the risk of procedures, the Expert Groups had taken into account the invasiveness risk of post-operative haemorrhage, airway compromise and post-operative uncontrollable pain by outpatient management; possibility of prolonged recovery to normal physiology; and risk of infection. Whether the safety of a procedure performed by medical practitioners could be enhanced by regulation of the facility was also considered. Specific criteria for defining high-risk procedures in surgery, endoscopy, maxillofacial surgery and other medical or interventional procedures were drawn up and recommended to the Working Group.

5.4 The Expert Groups had considered the risks of anaesthesia in terms of risk of gross and vital physiological derangement; risk of inadvertent systemic injection of anaesthetics; loss of protective reflexes; prolonged disturbance of mobility or body balance; and risk of disturbance or loss of major functions of vital organs. Scope of high-risk anaesthetic procedures was agreed among the Expert Groups as well as by the Working Group.

5.5 In respect of patient's condition, the Expert Groups proposed and the Working Group agreed to adopt the American Society of Anaesthesiologists (ASA) Physical Status Classification System in defining patient's conditions.[1] Patients classified as ASA Class 3-unstable or worse should undergo medical procedures only in regulated facilities:

Hospital-only procedures

5.6 Members agreed that certain procedures should only be performed in hospitals, which are better equipped with resuscitation and supporting facilities, taking into account the inherent risk and complexity of the procedures and patient's

[1] 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

condition. In general, a high-risk procedure may be performed in ambulatory facility only if –

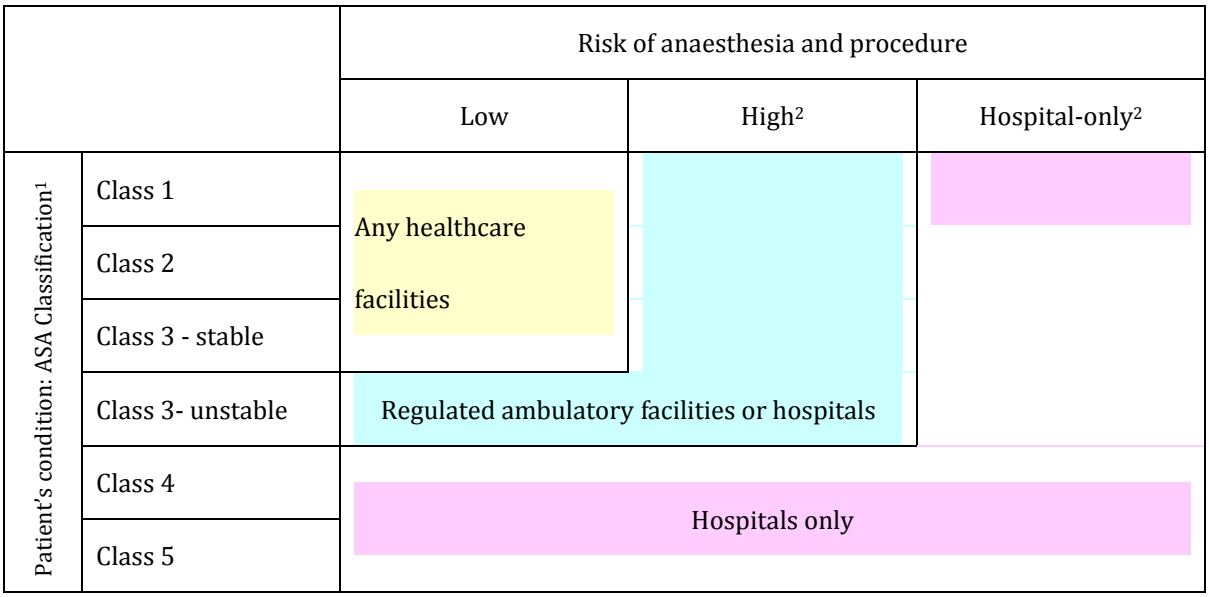
(a) the patient is discharged on the same calendar day of admission;

(b) the expected total duration of the procedure and the recovery does not exceed 12 hours; and

(c) the patient is not Class 4 or worse based on ASA Physical Status Classification System

Otherwise, the procedure should be performed in hospital. In addition, Members also endorsed a list of high-risk procedures that should be performed only in hospitals regardless of the above three criteria.

Figure 1. Principle of defining appropriate facilities for procedures



[1] Age, body size and other physical conditions of the patient should be also taken into account when deciding whether the procedure should undergo in ambulatory facility or in hospital.

[2] The scope of high-risk procedures, high-risk anaesthesia and hospital-only procedures are set out in Annex I.

6 PROPOSED REGULATORY FRAMEWORK

Regulatory measures

6.1 Members of the Working Group reached the consensus that ambulatory facilities where high-risk medical procedures were performed should be regulated by a statutory registration system. High-risk procedures should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals. Members also agreed that an administration listing system could be introduced before the statutory registration system came into effect.

Regulatory standards

6.2 Taking reference from overseas legislation, members agreed that a set of core regulatory requirements and standards should be imposed on all regulated ambulatory facilities, which could be broadly divided into the following five areas:

(a) governance of the facilities (e.g. person-in-charge, medical director);

(b) physical conditions (e.g. equipment, maintenance);

(c) service delivery and care process (e.g. staffing, medical record management, support services);

(d) infection control (e.g. sterile supply, infection control policy); and

(e) resuscitation and contingencies.

The regulatory standards to be imposed should be, in general, not more stringent than those imposed on private hospitals.

6.3 In addition, Members agreed that regulated facilities should be imposed further facility standards that were specific to the procedures being performed in the facilities (e.g. anaesthesia, surgical operations, chemotherapy, and haemodialysis).

6.4 Members agreed to adopt the Guidelines on Procedural Sedation promulgated by the Hong Kong Academy of Medicine (HKAM) as the regulatory standard for anaesthetic safety. Procedure-specific standards for facilities providing chemotherapy and haemodialysis were also drawn up by the relevant Expert Groups and agreed by the Working Group.

Mechanisms for reviewing scope of regulation and regulatory standards

6.5 In the view that new developments in technology and service delivery may change the risk profiles of individual procedures and hence the needs for regulation, Members agreed that the regulatory authority should have a mechanism to devise, and review and update as required, the scope of regulation and regulatory standards, and that HKAM and its member Colleges should be invited to provide expert advice, in professional respect, to the regulatory authority on (1) range of high-risk procedures for which ambulatory facilities should be regulated; and (2) facility standards specific to procedures.

7 CONSULTATION ON THE DRAFT RECOMMENDATIONS

7.1 The Working Group consulted the medical sector on the draft recommendations between December 2013 and February 2014. The consultation document was sent to 45 stakeholder organisations including the HKAM and its member Colleges, Provisional Hong Kong Academy of Nursing, Hospital Authority, academic institutions, Hong Kong Private Hospitals Association and practitioners' associations **(Appendix V)**.

7.2 Views from 35 organisations (77%) were received. The organisations that had responded were generally in support of the draft recommendations, including the principles adopted for defining high-risk procedures (i.e. risk of procedures, risk of anaesthesia and patient's condition), and the proposed scope of high-risk and hospital-only procedures, regulatory framework (i.e. statutory registration system, imposition of core and procedure-specific facility standards) and advisory role of HKAM.

7.3 Some stakeholders suggested that special consideration for paediatric patients should be given when defining the range of high-risk procedures and in setting standards. Having further consulted the relevant Colleges of the HKAM, the Working Group came to the view that medical practitioners should, as a general rule, take into account not only the criteria for defining high-risk and hospital-only procedures, but also the age, body size and other physical conditions of the patient when deciding whether the procedure is high-risk and can be performed in ambulatory setting.

7.4 Most organisations agreed with the proposed scope of high-risk and hospital-only procedures. Discrepant views mainly concerned the inclusion or exemption of specific procedures. The Working Group noted these views and the rationale put forth by the proponents. In formulating its final recommendations on the scope of high-risk procedures, the Working Group adopted the following principles:

(a) **Risk-based**: The inclusion or exclusion of a procedure should be risk-based and considered on par with other procedures of similar nature and comparable degree of risk.

(b) **Prudent approach**: For procedures on which consensus could not be reached, a prudent approach should be taken. A procedure should be classified as high-risk if it is so determined by relevant experts. Similar approach should be adopted for other issues where safety is a concern (e.g. classification of a procedure as hospital-only).

7.5 Stakeholders expressed divergent views on the classification of diagnostic gastrointestinal endoscopy. The Working Group advised the College of Surgeons of Hong Kong and the Hong Kong College of Physicians of the HKAM to further deliberate on the issue, taking into consideration the supplementary information on regulation of gastrointestinal endoscopy in overseas jurisdictions. Both Colleges indicated no objection to the proposed measure that diagnostic gastrointestinal endoscopy should be performed in regulate facilities after further deliberation within the respective College. Stakeholders' views and overseas regulation of gastrointestinal endoscopy are detailed at **Appendix VI**.

7.6 Some stakeholders expressed concerns about cost implications and difficulties for their practice to meet regulatory requirements, while other proposed more stringent regulation (e.g. shorten the maximum duration of procedures permitted in ambulatory setting). One organisation opined that the proposed regulation should aim at facility only but not professional performance of doctors. One organisation proposed to monitor credentialing of practitioners for selected procedures. The Working Group noted these views, and agreed that the credentialing of practitioners could be explored in future.

8 RECOMMENDATIONS

8.1 The Working Group puts forward the following recommendations for the consideration of the Steering Committee.

Recommendation (1)

High-risk procedures/practices should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals.

Recommendation (2)

A procedure is high-risk if it is so classified by ANY of the following three factors -

(a) the procedures is classified to be high-risk; or

(b) the anaesthesia involved is classified to be high-risk; or

(c) patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System[2].

When deciding whether a procedure is high-risk and whether a patient should undergo the procedure in ambulatory- or hospital-setting, medical practitioners and dentists should take into account the age, body size and other physical conditions of

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[2] 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

the patient, in addition to the criteria for defining high-risk and hospital-only procedures.

Recommendation (3)

Certain high-risk procedures should only be performed in hospital in view of its risk. Overall, high-risk procedures may be performed in ambulatory setting only if -

(a) the patient is discharged in the same calendar day of admission;

(b) the total duration of procedure and recovery does not exceed 12 hours; and

(c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologists (ASA) Physical Status Classification System.

Recommendation (4)

It is recommended to adopt the scope of high-risk and hospital-only procedures as set out in the **Annex I**.

Recommendation (5)

A statutory registration system should be introduced for ambulatory facilities where high-risk procedures are performed. An administrative listing system may be implemented before the mandatory registration system takes effect.

Recommendation (6)

Regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover –

(a) management of the facility;

(b) physical conditions;

(c) service delivery and care process;

(d) infection control; and

(e) resuscitation and contingency.

Regulated facilities will also be imposed further facility standards that are specific to the procedures being performed in the facilities, e.g. haemodialysis (**Annex II**), cytotoxic chemotherapy (**Annex III**) and anaesthesia[4].

Recommendation (7)

It is recommended that the regulatory authority will have a mechanism to devise, and review and update as required, the scope of regulation and standards with regard to the expert advice of the Hong Kong Academy of Medicine on -

(a) the range of high-risk procedures; and

(b) the relevant procedure-specific facility standards.

Recommendation (8)

Regulated ambulatory facilities should be subject to general requirements that are applicable to other comparable regulated healthcare facilities.

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[4] The "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine is recommended to be the regulatory standards on anaesthetic safety.

Chairperson,
Working Group on Defining High-risk
Medical Procedures/Practices Performed in Ambulatory Setting

Annex I - Recommended Scope of High-risk and Hospital-only Procedures

General Principles

1. A procedure is high-risk if it is so classified by ANY of the following three factors -

(a) the procedures is classified to be high-risk; or

(b) the anaesthesia involved is classified to be high-risk; or

(c) patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

2. Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only procedures, the age, body size and other physical conditions of the patient when deciding whether the procedure is high-risk and if a patient should undergo the procedure in ambulatory facility or in hospital.

A) Risk of Procedures

3. High-risk surgical procedures include the following procedures -

(a) Creation of surgical wound to allow access to major body cavity or viscus[5] (including access to central large joints) [except peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below)]

(b) Removal of tissue and/or fluid of a total volume of 500ml or above [except suprapubic tap]

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[5] Not including needle injection into joint cavity, intraocular injection with fine needle by ophthalmologists and injection of Botox

(c) Removal of tissue and/or fluid of any volume from deep seated organ in children aged under 12 years old

(d) Removal of any volume of fluid and/or tissue from thoracic cavity [except diagnostic pleural tapping]

(e) Insertion of any prosthesis (including tissue filler) [except prosthesis in ENT cavity, dental prosthesis and implants, extra-ocular prosthesis and implants, intrauterine or vaginal prosthesis, bulking agents of urethra, prostatic urethral stent, urethral slings, testicular prosthesis]

(f) Any core biopsy [except core biopsy of (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle]

(g) Any biopsy of organ or tissue requiring image guidance

(h) Fine needle biopsy of deep-seated organ

(i) Lumbar puncture

(j) Transplant of any cell, tissue and organ (including autograft, allograft and processed tissue or blood products[6]) or skin flap (including face lift) [except small skin graft less than 3 cm in any dimension, conjunctival autograft and transplant procedures which primarily involve dental-alveolar region]

(k) Termination of pregnancy

(l) Dilation and curettage

(m) Circumcision with use of skin sutures in paediatric patients

[6] Include platelet-rich plasma (PRP)

4. High-risk endoscopic procedures include the following -

(a) Endoscopic procedures requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))

(b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) [except cystoscopy[7]] or gastrointestinal tract

(c) Therapeutic endoscopic procedures (such as endoscopic resection), [except minor therapeutic procedures (such as removal of foreign body)]

(d) Bronchoscopy or pleuroscopy

5. High-risk dental procedures include the following -

- 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 except arthrocentesis and arthroscopy

(g) Harvesting of autogenous bone from outside the oral cavity

(h) Primary cleft lip and palate surgery

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

6. The following procedures are also classified as high-risk -

(a) Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication

(b) Image-guided core biopsy [except breast and superficial lymph node], or image-guided biopsy of deep seated organ

(c) Haemodialysis

(d) Transarterial catheterisation or deep venous catheterisation

(e) Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance

(f) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

B) Scope of High-risk Anaesthetic Procedures[8]

7. A procedure is considered to be high-risk if it involves any of the following modes of anaesthesia or sedation:

(a) General anaesthesia

(b) Neuroaxial blocks (spinal, epidural, caudal)

(c) Major plexus block (brachial, lumbar, sacral)

(d) Intravenous regional anaesthesia

(e) Intercostal nerve block

(f) Major nerve block:

- Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves;
- Sciatic and femoral nerves; or

[8] The risks of anaesthesia considered by the Working Group 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, disturbance/loss of major functions of vital organs, etc.

- Posterior tibial nerve, pudendal nerve or para-cervical block

(g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation[9] for a significant percentage of a group of patients

(h) Tumescent anaesthesia

C) Patient's condition

8. A procedure is considered high-risk if it is performed on a patient whose physical status is Class 3-unstable or worse (i.e. Class 3-unstable, Class 4 or Class 5) as classified by the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

D) Hospital-only procedures

9. The following high-risk procedures should only be performed in hospitals:

(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 /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

(h) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

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[9] Definition of "deep sedation" should refer to the "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine.

Annex II - Regulatory Standards for Facilities Providing Haemodialysis

Requirements/Standards	References		
	Infection Control Guidelines[a]	**Code of Practice[b]**	**Accreditation Guide[c]**
1 Staffing 1.1 Requirements on advisor and medical in-charge for the facility 1.2 Requirements on nurse in-charge for the facility 1.3 Requirements on other staff and operator of the facility	–	Section 21.1	Section III
2 Accommodation and equipment 2.1 Minimum requirements on design and space 2.2 Resuscitation equipment 2.3 Back-up electricity 2.4 Maintenance of haemodialysis machines and back-up machines 2.5 Provision of service during maintenance work	Section 7.1, 7.3, 7.4	Section 21.2	Section II, IV
3 Infection control 3.1 Infection control policies 3.2 Water treatment system 3.2.1 Disinfection 3.2.2 Test for residue 3.2.3 Microbiological testing 3.3 Haemodialysis machines 3.3.1 Disinfection 3.3.2 Test for residue/contaminant 3.3.3 Microbiological testing 3.4 Serology screening 3.5 Immunisation	Section 3,4,5,6,7	Section 9.6	Section V, VI, VII, VIII, IX
4 Occupational safety 4.1 Blood and body fluid exposure 4.2 Chemical disinfectants	Section 9	Section 9.4	–
5 Other requirements 5.1 Emergency transfer 5.2 Regular assessment by nephrologists 5.3 Medication management 5.4 Chemical and waste management	Section 7.5, 7.7	Section 21.1, 21.3, 34.5	–

[a] Infection Control Guidelines on Nephrology Services in Hong Kong (Second Edition) issued jointly by Infection Control Branch, Centre for Health Protection, Department of Health and Central Renal Committee, Hospital Authority

[b] Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (April 2010) promulgated by the Department of Health

[c] Accreditation of Renal Dialysis Unit issued by the Hong Kong College of Physicians and Central Renal Committee, Hospital Authority (accessed on 3 July 2013)

Annex III – Regulatory Standards for Facilities Providing Parenteral Chemotherapy (Cytotoxic) Treatment

(1) Introduction

1.1 This set of standards serves as facility standards specific for facilities providing parenteral chemotherapy (cytotoxic) treatment.

1.2 Chemotherapy (cytotoxic) is defined as cytotoxic drugs used in medical treatments.

(2) General standards

2.1 Resuscitation equipment should be available in the facility.

2.2 An appropriate and well-functioning biosafety cabinet or isolator should be installed if reconstitution of chemotherapy (cytotoxic) would take place in the facility.

(a) The reconstitution of chemotherapy (cytotoxic) should be performed in a Class II biosafety cabinet (Type A2 or B), a Class III biosafety cabinet (BSC)[*] or isolator to protect both staff safety and product quality.

(b) If volatile chemotherapy (cytotoxic), i.e. chemotherapy (cytotoxic) that may evaporate under room temperature, is to be reconstituted, an exhaust vent to outdoor should be installed to the biosafety cabinet or isolator, or alternatively, an appropriate activated charcoal filter should be installed to the biosafety cabinet or isolator.

(c) The biosafety cabinet or isolator should be regularly serviced and maintained.

(d) Closed-system drug transfer device could also be used for the reconstitution of chemotherapy (cytotoxic) inside the biosafety cabinet to further improve staff safety. The closed-system drug transfer device does not replace the role of biosafety cabinet.

2.3 Healthcare professionals responsible for reconstitution of chemotherapy (cytotoxic) should have completed training in the safe and proper use of the

[*] Class II (Type A2 or B) or Class III Biosafety Cabinet according to the classification of biological safety cabinet by US Centers for Disease Control and Prevention.

biosafety cabinet, infection control and occupational safety.

2.4 Proper procedures should be established for the preparation, reconstitutions and administration of chemotherapy (cytotoxic).

2.5 Suitable and adequate personal protective clothing should be provided to the operators (disposable gowns and impervious gloves are recommended).

2.6 Spill kit should be available to handle any spillage of chemotherapy (cytotoxic).

2.7 During the course of intravenous infusion, at least one competent and trained healthcare professional should be present in the facility to oversee the process. Medical practitioner should attend to the patient in case of medical emergencies.

(3) Standards on occupational safety and health

3.1 A safe system of work should be put in place to ensure safe handling of chemotherapy (cytotoxic) in an ambulatory setting which includes their storage, preparation, transport and disposal. In particular, the system should cover the following aspects:

(a) The person-in-charge of the facility should assess the health and safety risk related to the handling of chemotherapy (cytotoxic) in the workplace and the assessment should be documented. If there are any significant changes, the risk should be re-assessed and remedial measures should be implemented accordingly. The re-assessment and any remedial measures implemented should also be documented.

(b) Proper procedures should be established for the preparation, reconstitution and administration of chemotherapy (cytotoxic) to ensure the safety and health of the operators.

(c) Isolated areas or separate rooms should be designated for the preparation and administration of chemotherapy (cytotoxic).

(d) An isolator or a BSC of Class II (Type A2 or B) should be used for preparation or reconstitution of injectable chemotherapy (cytotoxic) under aseptic technique. The exhaust of the isolator or BSC shall be fitted with HEPA filter. The isolator or BSC should be regularly serviced and maintained. Use of needleless and closed-system drug transfer device in preparation or reconstitution of chemotherapy (cytotoxic) inside the

isolator or BSC is preferable.

(e) Suitable and adequate personal protective clothing should be provided to the operators – Disposable gowns and impervious gloves are recommended.

(f) Proper arrangements and facilities should be provided for the storage and labelling of chemotherapy (cytotoxic) which shall be kept in locked cabinets with warning signs in both Chinese and English.

(g) Proper arrangements and facilities should be provided for the transport of chemotherapy (cytotoxic) - Secure facilities shall be used for transport to prevent breakage and leakage.

(h) Spillage handling procedures should be established, with suitable spillage handling kits provided.

(i) Suitable hazardous waste disposal procedures and facilities (with warning signs in both Chinese and English) should be provided for handling and disposal of spent and unwanted chemotherapy (cytotoxic) and contaminated containers according to the applicable legislation.

(j) Adequate information, instruction and training should be provided to the operators on the handling of chemotherapy (cytotoxic). The topics covered should include health and safety hazards of chemotherapy (cytotoxic), safe operating procedures, spillage handling techniques, proper care and use of personal protective equipment.

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Medical Procedures/Practices Performed in Ambulatory Setting
May 2014

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Appendix I - Composition of the Working Group

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Appendix II - Membership of Expert Groups

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Dr TSE Hung-hing	(Hong Kong Medical Association)
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Dr Paul LAM	(Hong Kong College of Orthopaedic Surgeons)
Dr Daniel LEE	(Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons)
Dr John LOW	(Specialist in Anaesthesiology)
Dr Raymond NG	(Specialist in Plastic Surgery)
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Dr LEUNG Wing-cheong	(Hong Kong College of Obstetricians and Gynaecologists)
Dr MAN Chi-wai	(College of Surgeons of Hong Kong)
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Expert Group on Chemotherapy and Radiological Procedures (EG4)

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Dr LAU Kam-ying	(Specialist in Radiology)
Mr Eric WONG	(Pharmacist)

Expert Group on Haemodialysis, Cardiac Catheterisation and Lithotripsy (EG5)

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Dr TONG Kwok-lung	(Hong Kong College of Physicians)

Appendix III - Overseas Regulatory Framework on Private Healthcare Facilities

The main features of regulatory regimes for private healthcare facilities in five overseas countries are summarised below:

Australia

Legislation

1. States and territories of Australia each have their own legislation in regulating private ambulatory health facilities.
   - Australian Capital Territory: Public Health Act 1997, ACT Health Care Facilities Code of Practice 2001
   - New South Wales: Private Health Facilities Act 2007, Private Health Facilities Regulation 2010
   - Queensland: Private Health Facilities Act 1999, Private Health Facilities Regulation 2000, Private Health Facilities (Standards) Notice 2000
   - Victoria: Health Services Act 1988, Health Services (Private Hospitals and Day Procedure Centres) Regulation 2002
   - Western Australia: Hospitals and Health Services Act 1927, Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987

Scope of Regulation

Australian Capital Territory

2. Operators of health care facilities are required to obtain a license from the Health Protection Service of ACT Government Health Directorate. "Health care facility" means a premises upon which prescribed medical and dental procedures are carried out and/or a premise in which overnight patient stays are provided prior to or after receiving medical treatment. "Prescribed medical and dental procedures" means procedures undertaken for medical or cosmetic reasons by a health care professional that involves -
   - The administration of a general, spinal, epidural or major regional block anaesthetic or intravenous sedative for the purpose of performing an elective procedure, but does not include mandibular blocks
   - Endoscopy

- Dialysis, haemofiltration or haemoperfusion
- Prolonged intravenous infusion of a single cytotoxic agent or sequential intravenous infusion of more than one cytotoxic agent; or
- Cardiac catheterization

Regulatory Standards

3. Apart from general licensing standards for all licensed facilities, additional regulatory standards for facilities providing specialty services are either stipulated in the legislation (e.g. New South Wales) or in guidelines or codes issued by health authority (e.g. "Clinical Services Capability Framework" of Queensland, "Licensing Standards for the Arrangement for Management, Staffing and Equipment – Day Hospitals" of Western Australia), which outline the minimum support services, staffing, safety standards and other requirements required to ensure safe and appropriately supported clinical services for each particular class of specialty services. Health authorities monitor compliance with licensing standards/codes through onsite visits, paper audits, telephone or written contact.

<u>New South Wales (NSW)</u>

4. All private health facilities shall be registered with the Private Health Care Unit under the NSW Ministry of Health. "Private health facility" means a premises at which any person is admitted, provided with medical, surgical or other prescribed treatment and then discharged, or premises at which a person is provided with prescribed services or treatments, excluding public hospitals/health institutions and nursing homes.

5. A private health facility may fall into one or more of the 18 classes of facilities :
   (a) anaesthesia (general, epidural or major regional anaesthetic or sedation resulting in more than conscious sedation, but does not include sedation provided in connection with dental procedures),
   (b) cardiac catheterisation (passing of a catheter, or other instrument, through a major blood vessel and into the heart for a diagnostic or therapeutic purpose),
   (c) cardiac surgery (surgery within, or on, the heart),
   (d) chemotherapy (parenteral treatments using one or more cytotoxic agents),

(e) emergency (care of patients injured in accidents, or those suffering from medical or other emergencies, through the provision of reception, resuscitation, medical and surgical treatment and use of life support systems),

(f) gastrointestinal endoscopy (use of a flexible endoscope with an internal lumen for the passage of an instrument to examine the upper or lower gastrointestinal tract),

(g) intensive care (level 1 or level 2) (observation, care and treatment of patients with life threatening or potentially life threatening illnesses, injuries or complications, from which recovery is possible, in a facility that is specially staffed and equipped for that purpose),

(h) interventional neuroradiology (diagnosis and treatment of diseases and conditions of the brain or spinal cord using procedures involving the passing of a catheter or other instrument through the spinal canal, the cranial cavity or through a major blood vessel, to the brain or spine),

(i) maternity (maternity care, including antenatal care related to child birth, assistance and care associated with normal child birth, surgical intervention in achieving childbirth and care and assistance of a mother admitted to the facility immediately after childbirth),

(j) medical (diagnosis or treatment by a procedure or technique not referred to elsewhere in this clause, where the patient is admitted overnight),

(k) mental health (provision of mental health care to admitted patients),

(l) neonatal (provision of care and treatment to a baby under the age of 28 days),

(m) paediatric (provision of care and treatment to admitted patients between the age of 28 days and 14 years),

(n) radiotherapy (treatments involving the use of ionising radiation from a radioactive substance),

(o) rapid opioid detoxification (use of one or more opioid antagonists, in particular naltrexone or naloxone or a combination of the two, in a person who is physiologically dependent on opioids for the purpose of accelerating opioid withdrawal in the person and rendering the person opioid free),

(p) rehabilitation (rehabilitation, including long-term rehabilitation and specialised physical rehabilitation where the patient is admitted overnight),

(q) renal dialysis (provision of haemodialysis),

(r) surgical (surgical procedures performed on patients who are administered

general, epidural or major regional anaesthetic or sedation resulting in more than conscious sedation, but does not include a surgical procedure carried out by a dentist).

Queensland

6. In Queensland, all private hospital and day hospital shall be registered with Queensland Health. A "day hospital" is defined as a facility at which day health services are provided to persons who are admitted to, and discharged from, the facility on the same day. "Day health service" means any of the following services -
    (a) A diagnostic, surgical or other procedure performed by a medical practitioner involving-
        - administration of a general, spinal or epidural anaesthetic; or
        - sedation, other than simple sedation (which means the administration of one or more drugs that depress the person's central nervous system to allow a procedure to be performed in a way that (i) allows communication with the person to be maintained during the procedure; and (ii) makes the loss of the consciousness unlikely.)
    (b) A diagnostic, surgical or other procedure
        - performed by, or under the direction, of a medical practitioner and
        - involving a significant risk that a person on whom the procedure is performed may, because of cardiac, respiratory or other complications arising from the procedure, require resuscitation, and
        - prescribed under a regulation, which now include
            (i) Cardiac stress test not performance in compliance with Specialty Health Services Standard
            (ii) Cytotoxic infusion, other than cytotoxic infusion performed as maintenance therapy within an established treatment regime
            (iii) Haemodialysis;
            (iv) gastrointestinal endoscopy, other than proctoscopy and sigmoidoscopy

Victoria

7. All day procedure centres shall be registered with the Department of Health. A "day procedure centre" is defined as premises where a major activity carried on

is the provision of prescribed health service(s) for which a charge is made; and persons to whom treatment is provided are reasonably expected to be admitted and discharged on the same date, but does not include a hospital. "Prescribed health services" include –

- medical health services (diagnosis and non-operative treatment AND requiring nursing supervision or care);
- surgical health services (including laser device that disrupts the integrity of epithelial tissue or stroma, cannulae penetration to remove body fluid and/or fat); and
- specialty health services (artificial insemination, assisted reproductive treatment, cardiac services, emergency medicine, endoscopy, intensive care, mental health services, neonatal services, obstetrics, oncology, renal dialysis, or specialist rehabilitation services).

Western Australia

8. All day hospital facilities shall obtain a license from the Department of Health. A "day hospital facility" means premises not attached to or set apart from a hospital, at which persons are received for professional attention and at which overnight accommodation is not provided. The following professional medical services are determined to be "professional attention" -
   - any procedure that involves the administration of a general spinal or epidural anaesthetic
   - any procedure performed under sedation, plexus blockade or Biers Block
   - any procedure that involves the invasion of a sterile body cavity
   - peritoneal dialysis and haemodialysis for the treatment of end stage renal failure

Canada (Ontario)

9. Ontario licensed private diagnostic and ambulatory care facilities as Independent Healthcare Facilities (IHF) under the Independent Health Facilities Act. In order to operate, IHFs need to apply for a license from the Ministry of Health and Long Term Care and comply with the regulations under the IHF Act.

10. Provided by law, the College of Physicians and Surgeons of Ontario registers and inspects "Out-of-Hospital Premises (OHP)" which is any non-hospital site at

which a physician engages or proposes to engage in -

- an act that is performed under the administration of (i) general anaesthesia, (ii) parenteral sedation, or (iii) regional anaesthesia, except for a digital nerve block; or
- an act performed with the administration of a local anaesthetic agent, including, but not limited to (i) any tumescent procedure involving the administration of dilute, local anaesthetic; (ii) surgical alteration or excision of any lesions or tissue performed for cosmetic purposes; (iii) injection or insertion of any permanent filler, autologous tissue, synthetic device, materials or substances for cosmetic purposes; (iv) a nerve block solely for the treatment or management of chronic pain; or (v) any act that is in nature to those set out in subclauses (i) to (iii) and that is performed for a cosmetic purpose;

  but does not include (a) surgical alteration or excision of lesions or tissue for a clinical purpose, including for the purpose of examination, treatment or diagnosis of disease, or (b)minor dermatological procedures including without being limited to, removal of skin tags, benign moles and cysts, nevi, seborrheic keratosis, fibroepithelial polyps, haemangioma and neurofibromata.

11. Under the law, physicians shall not commence using the OHP for performance of the abovementioned procedures until he has given a notice to and passed the inspection by the College.

Regulatory Standards

12. The regulatory standards for IHFs, namely the Clinical Practice Parameters and Facility Standards, are developed and published by the College of Physicians and Surgeons of Ontario. The College also developed a set of OHP Standards for its OHP Inspection Programme. Facility standards outlines regulatory requirements in areas of facility set-up, staff profile and qualifications, policies and procedures, equipment and supplies, documentation, infection control and quality assurance.

13. Continuous quality improvement is mandated for both IHFs and OHPs. The College of Physicians and Surgeons of Ontario was responsible for carrying out

quality assurance assessments in all IHFs.

Singapore

Legislation

14. No premises may be used as a private hospital (including maternity and nursing home), medical (including dental) clinic, clinical laboratory or healthcare establishment, unless it is licensed under the Private Hospitals and Medical Clinics Act ("PHMC Act") and its Regulations ("PHMC Regulation") by the Ministry of Health.

15. A "medical clinic" is defined as any premises used or intended to be used by a medical practitioner, a dentist or any other person-
    - for the diagnosis or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body; or
    - for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device requiring the use of electricity, heat or light,

    but does not include any such premises which are maintained by the Government or the National University of Singapore; or form part of the premises of a licensed private hospital.

16. PHMC Regulations require medical clinics that provide special care services (as listed in the Third Schedule in the Regulation) to obtain prior approval from the Director of Medical Services before commencement of such services, which include:
    - Blood & blood product collection, processing, storage, distribution & transfusion services (including Autologous blood transfusion)
    - Ambulatory surgery (including minimally invasive surgery, laparoscopy & liposuction)
    - Endoscopy
    - Assisted reproduction services
    - Lithotripsy
    - Renal dialysis
    - Specialised cardiac investigation

- Specialised diagnostic radiology

17. Definitions of selected types of special care services are highlighted below.
    - Ambulatory Surgical Centre: It refers to any institution or building or part of a building devoted primarily to the maintenance and operation of facilities for the performance of surgical procedures which shall not require lodging or accommodation of patients for a period exceeding 12 hours (excluding the period that a patient, who is certified fit to be discharged, may wait at the Centre, so that he may be discharged at a time that is reasonably convenient for him and his caregiver).

    - Endoscopy: A medical clinics is considered to be providing endoscopy if it performs inspection of body organs or cavities by the use of the endoscope, except where the procedures are considered an integral part of a routine examination; examples of which are nasopharyngoscopy in ENT examinations, proctoscopy or rigid sigmoidoscopy in general surgical/medical examinations, and colposcopy in obstetric examinations. Endoscopy, in this context, refers only to diagnostic endoscopic procedures, including minor therapeutic endoscopy such as removal of small polyps and injection of undiagnosed bleeding ulcers during routine diagnostic endoscopy. Therapeutic endoscopy, as a general rule, should only be performed in ambulatory surgical centres in hospitals, which are equipped with full resuscitation facilities and surgical backup.

    - Lithotripsy: A medical clinic is providing lithotripsy (extracorporeal and intracorporeal) in the treatment of renal stones if it employs the technique of crushing of a calculus in the bladder, urethra, kidneys or ureter without invasive surgical intervention.

    - Renal dialysis centre means any institution, place or building designed for the primary purpose of providing outpatient dialysis treatment for patients with end stage renal failure.

Regulatory Standards

18. The PHMC ACT and Regulations set out requirements for registration of healthcare institutions. A set of "Guidelines under the PHMAC Act and PHMAC Regulations" was published to assist the licensees of healthcare institutions in

complying with the requirements under PHMAC Act and PHMAC Regulations. Registration requirements cover the following aspects

- Registration procedure
- Requirements on licensee and duty of a manager
- Quality assurance committees and quality assurance activities
- General requirements for the facility and service delivery, e.g. environment, equipment, staffing, resuscitation facilities, medical records, information on charges, infection control, etc.

19. For medical clinics providing special care services (e.g. liposuction, aesthetic procedures, endoscopy, lithotripsy, renal dialysis) must comply with additional licensing conditions/directives/guidelines issued by the authority (e.g. Guidelines for Private Healthcare Institutions Providing Endoscopy: Regulation 4 of the PHMC Regulations).

United Kingdom (England)

Legislation

20. In England of the United Kingdom, provision of health and social services is governed by the Health and Social Care Act 2008 (HSC Act), the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (HSC Regulation) and the Care Quality Commission (Registration) Regulations 2009. The Care Quality Commission (CQC) is an independent regulatory body of all health and social care services in England under the general guidance of the Secretary of State.

21. Any person who carries on a regulated activity as prescribed under HSC Regulation shall register themselves as "service provider" with CQC. Regulated activities prescribed in HSC Regulation include, among others, -

    - Treatment of disease, order or injury – the provision of treatment for a disease, disorder or injury by or under the supervision of a healthcare professional;

    - Surgical procedures (including all pre-operative and post-operative care associated with such procedures) carried out by a health care professional for -
        - The purpose of treating disease, disorder or injury

- Cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
- The purpose of religious observance

but does not include (only when carried out without anaesthesia or using local anaesthesia)-

- Nail surgery and nail bed procedures carried out by a health care professional on any area of the foot
- Surgical procedures involving the curettage, cautery or cryocautery of warts, verrucae or other skin lesions carried out by a health care professional on any area of the foot
- "cosmetic purposes" do not include (a) piercing of any part of the human body; (b) tattooing; (c) subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance; and the removal of hair roots or small blemishes on the skin by the application of heat using an electric current

- Diagnostic and screening procedures including –
  - procedures involving the use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging
  - use of instruments or equipment which are inserted into the body to (i) view its internal parts, or (ii) gather physiological data
  - removal of tissues, cells or fluids from the body for the purposes of discovering the presence, cause or extent of disease, disorder or injury
  - the use of equipment in order to examine cells, tissues and other bodily fluid for the purposes of obtaining information on the causes and extent of a disease, disorder or injury
  - the use of equipment to measure or monitor physiological data in relation to the audio-vestibular system, vision system, neurological system, cardiovascular system, respiratory system, gastro-intestinal system, or urinary system

- Management of supply of blood and blood derived product – supply of blood or blood products for transfusion, tissues for transplant

- Maternity and midwifery services

- Termination of pregnancies, and

- Services in slimming clinics consisting of the provision of advice or

treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for weight reduction.

22. Registration with CQC is required for all private clinics. Individual medical practitioners practising privately in a surgery or consulting room are exempt if they (as individuals) have practising privilege with a registered provider and are on medical performers list for a designated body (e.g. NHS), unless they provide the following services:

    - Treatment carried out under anaesthesia or intravenously sedation
    - Dental treatment carried out under general anaesthesia
    - Obstetric services and medical services in connection with childbirth
    - Termination of pregnancies
    - Cosmetic surgery
    - Haemodialysis or peritoneal dialysis
    - Endoscopy
    - Hyperbaric therapy

Regulatory Standards

23. All registered providers of regulated activities are required to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (HSC Regulation) and the Care Quality Commission (Registration) Regulations 2009, which set out requirements in respect of premises, equipment, staffing, infection control, patient care, quality management, etc. The CQC issued "Essential Standards of Quality and Safety" as a guidance to assist providers in complying with regulatory requirements.

United States

24. In the United States, regulation of ambulatory surgery centres (ASCs) varies state-by-state. Most state health departments license ASCs. ASCs entering into agreement with the Centers for Medicaid and Medicare Services must obtain

its certification and approval, which in some states are sufficient for state licensure.

25. Regulation of office-based surgery (OBS) owned by physicians varies widely among states, and is often overseen by the Boards of Medical Examiners, or Medical Boards, which regulate physicians. Some states regulate OBS by requiring accreditation by a third party. New York State, which regulates office-based surgery, defines office-base surgery as any surgical or invasive procedures requiring moderate to deep sedation/analgesia or general anaesthesia, excluding minor procedures and procedures requiring minimal sedation, outside a hospital.

26. The regulation of ASCs in Pennsylvania is chosen as an example here.

<u>Pennsylvania</u>

The Legislation

27. Ambulatory surgical facilities in Pennsylvania are regulated under the Ambulatory Surgical Center PA Regulations (Title 28) by the Department of Health, Division of Acute and Ambulatory Care. The regulation is promulgated under Health Care Facilities Act (Chapter 8).

28. "Ambulatory surgical facility" (ASF) means a facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. This does not include individual or group practice offices of private physicians or dentists, unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis.

29. "Ambulatory surgery" means a surgery performed-

- On an outpatient basis in a facility which is not located in a hospital, and
- On patients who do not require hospitalization but who do require constant medical supervision following the surgical procedure performed and whose total length of stay does not exceed the standards in the regulation.

30. Ambulatory surgical procedures are limited to those that do not exceed a total of 4 hours of operating time and a total of 4 hours directly supervised recovery. The time limits above may be exceeded only if the patient's condition demands care or recovery beyond the 4-hour limit and the need for the additional time could not have been anticipated prior to surgery.

31. Ambulatory surgical facilities are classified into 3 classes based on the procedure, patient status (PS) by ASA Physical Status Classification System and anaesthesia used. (PS-1: a normal healthy patient, PS-2: patient with mild systemic disease, PS-3: patient with severe systemic disease, PS-4: patient with severe systemic disease that is a constant threat to life, PS-5: moribund patient who is not expected to survive without the operation)

    - Class A – A private or group practice office of practitioners where procedures performed are limited to those requiring administration of local or topical anesthesia, or no anesthesia at all and during which reflexes are not obtunded.

    - Class B – A single-specialty or multiple-specialty facility with a distinct part used solely for ambulatory surgical treatments involving administration of sedation analgesia or dissociative drugs wherein reflexes may be obtunded.

      Patient's PS is limited to PS-1 or PS-2.

    - Class C – A singly-specialty or multiple-specialty facility used exclusively for the purpose of providing ambulatory surgical treatments which involve the use of a spectrum of anesthetic agents, up to and including general anesthesia.

      Patient's PS is limited to PS-1, PS-2 or PS-3.

32. A Class-A ASF does not require a license to operate but is required to register annually with the Department of Health with a copy of its accreditation survey by a nationally recognized accrediting agency. Facilities of Classes B and C are required to obtain a license from the Department. An ASF license shall designate the licensed facility as either a Class B or Class C.

Regulatory Standards

33. An ASF shall comply with requirements set out in the Health Care Facilities Act for ASFs, which cover governance and management, medical staff and nursing services, pharmaceutical services, medical records, laboratory and radiology services, environmental, fire and safety services, construction standards and quality assurance.

Appendix IV - Ordinances Relevant to the Operation of Healthcare Institutions

Relevant regulatory bodies /enforcement departments	Ordinances
Buildings Department	Buildings Ordinance, Cap. 123
Councils and boards for registered health professionals	Pharmacy and Poisons Ordinance, Cap. 138 Dentists Registration Ordinance, Cap. 156 Medical Registration Ordinance, Cap. 161 Midwives Registration Ordinance, Cap. 162 Nurses Registration Ordinance, Cap. 164 Supplementary Medical Professions Ordinance, Cap. 359 Chiropractors Registration Ordinance, Cap. 428 Chinese Medicine Ordinance, Cap. 549
Council on Human Reproductive Technology	Human Reproductive Technology Ordinance, Cap. 561
Department of Health	Dangerous Drugs Ordinance, Cap. 134 Antibiotics Ordinance, Cap. 137 Offences Against the Persons Ordinance, Cap. 212 (Section 47A- Medical termination of Pregnancy) Undesirable Medical Advertisements Ordinance, Cap. 231 Prevention and Control of Disease Ordinance, Cap. 599
Electrical and Mechanical Services Department	Gas Safety Ordinance, Cap. 51 Lifts and Escalators (Safety) Ordinance, Cap. 327 Electricity Ordinance, Cap. 406
Environmental Protection Department	Air Pollution Control Ordinance, Cap. 311 Wastes Disposal Ordinance, Cap. 354 Water Pollution Control Ordinance, Cap. 358
Fire Services Department	Fire Services Ordinance, Cap. 95 Dangerous Goods Ordinance, Cap. 295 Fire Safety (Commercial Premises) Ordinance, Cap. 502 Fire Safety (Buildings) Ordinance, Cap. 572
Food and Environmental Hygiene Department	Public Health & Municipal Services Ordinance, Cap. 132
Human Organ Transplant Board	Human Organ Transplant Ordinance, Cap. 465
Immigration Department	Births & Deaths Registration Ordinance, Cap. 174

Relevant regulatory bodies /enforcement departments	Ordinances
Judiciary	Mental Health Ordinance, Cap. 136 Coroners Ordinance, Cap. 504
Labour Department	Occupational Safety and Health Ordinance, Cap. 509
Office of the Privacy Commissioner for Personal Data	Personal Data (Privacy) Ordinance, Cap. 486
Planning Department	Town Planning Ordinance, Cap. 131
Radiation Board	Radiation Ordinance, Cap. 303
Social Welfare Department	Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance, Cap. 566
Water Supplies Department	Waterworks Ordinance, Cap. 102

Note: The list is for reference only and not exhaustive.

Appendix V - List of organisations consulted on draft recommendations

Statutory professional/training institutions

Hong Kong Academy of Medicine
Hong Kong College of Anaesthesiologists
Hong Kong College of Community Medicine
College of Dental Surgeons of Hong Kong
Hong Kong College of Emergency Medicine
Hong Kong College of Family Physicians
Hong Kong College of Obstetricians and Gynaecologists
College of Ophthalmologists of Hong Kong
Hong Kong College of Orthopaedic Surgeons
Hong Kong College of Otorhinolaryngologists
Hong Kong College of Paediatricians
Hong Kong College of Pathologists
Hong Kong College of Physicians
Hong Kong College of Psychiatrists
Hong Kong College of Radiologists
College of Surgeons of Hong Kong
Hospital Authority
The Provisional Hong Kong Academy of Nursing

Academic institutions

Faculty of Dentistry, University of Hong Kong
Faculty of Health and Social Sciences, the Hong Kong Polytechnic University
Faculty of Medicine, the Chinese University of Hong Kong
Li Ka Shing Faculty of Medicine, the University of Hong Kong

Private healthcare institution

Hong Kong Private Hospitals Association

Practitioners' associations

Association of Hong Kong Nursing Staff
Association of Private Medical Specialists of Hong Kong
Government Doctors' Association
Hong Kong Association of Community Oncologists
Hong Kong Association of Cosmetic Surgery
Hong Kong Association of Oral and Maxillofacial Surgeons
Hong Kong College of Cardiology
Hong Kong Dental Association
Hong Kong Doctors Union
Hong Kong Medical Association
Hong Kong Organisation Doctors' Association
Hong Kong Public Doctors' Association
Hong Kong Society of Nephrology
Hong Kong Society of Plastic, Reconstructive and Aesthetic Surgeons
Hong Kong Society of Rheumatology
Hong Kong Specialist Medical Association
Hong Kong Urological Association
The Association of Licentiates of Medical Council of Hong Kong
The Federation of Medical Societies of Hong Kong
The Pharmaceutical Society of Hong Kong
The Practising Pharmacists Association of Hong Kong
The Society of Hospital Pharmacists of Hong Kong

Appendix VI – Divergent views regarding classifying diagnostic gastrointestinal endoscopy as a high-risk endoscopic procedure

Views on classifying diagnostic gastrointestinal (GI) endoscopy as a high-risk endoscopic procedure

1. The members of the Working Group and stakeholder organisations expressed divergent views on whether diagnostic GI endoscopy should be classified as a high-risk procedure, in the view that polypectomy may be performed during the procedure.

2. Some members of the Working Group and stakeholder organisations opined that the risk of bleeding and perforation as a result of polypectomy in diagnostic GI endoscopies was low. On the other hand, some members and organisations opined that GI endoscopies should be regulated regardless of intention, as polypectomy could be high-risk depending on the size, location and depth of involvement, which were difficult to predict before the procedure. If facilities providing diagnostic endoscopies were not regulated, patients found to have polyp might have to repeat the endoscopy for polypectomy in another licensed facility and subject to procedural and anaesthetic risks a second time.

3. The Working Group suggested that the Hong Kong College of Physicians and the College of Surgeons of Hong Kong should further deliberate on whether diagnostic GI endoscopy should be classified as high-risk, taking into consideration supplementary information on regulation of GI endoscopy in overseas jurisdictions, which was provided to the Colleges and the Working Group. After deliberation, both Colleges indicated that they had no objection to regulating facilities providing diagnostic GI endoscopy.

Regulation of Facilities Providing Gastrointestinal Endoscopy in Overseas Jurisdictions

4. Regulation of endoscopy in overseas jurisdictions is set out in the Table below.

5. In summary, endoscopic procedures are regulated in the jurisdictions reviewed, and differential regulatory control, if any, is commonly determined by level of anaesthesia, not by whether they are diagnostic or therapeutic, except in Singapore, where registered medical clinics providing diagnostic endoscopy are imposed with endoscopy-specific standards whereas therapeutic endoscopy

should, as a general rule, only be performed in ambulatory surgical centres in hospitals which are equipped with full resuscitation facilities and surgical backup. Details are in the table below.

Table - Overseas Regulation of ambulatory facilities performing endoscopy

Jurisdiction (Type of regulated facility)	**Endoscopic procedures to be performed in regulated facilities**
Australia	
Australian Capital Territory (Health care facility)	Health care facility in which "prescribed medical and dental procedures" are carried out is required to be licensed. "Prescribed medical and dental procedures" include endoscopy.
New South Wales (Private health facility)	All private health facilities shall be registered. Private health facilities includes facilities licensed for the use of a flexible endoscope with an internal lumen for the passage of an instrument to examine the upper or lower gastrointestinal tract.
Queensland (Day hospital)	Facilities providing day hospital health services shall be registered. Day hospital health services include, among other things, gastrointestinal endoscopy other than proctoscopy and sigmoidoscopy.

Jurisdiction (Type of regulated facility)	Endoscopic procedures to be performed in regulated facilities
Canada	
Ontario (Independent health facilities/ Out-of-hospital premises)	Ontario government licensed private diagnostic and ambulatory care facilities as "**Independent Healthcare Facilities** (IHFs)". The College of Physicians and Surgeons of Ontario ("the College", which licenses medical practitioners) was responsible for setting regulatory standards, namely the Clinical Practice Parameters and Facilities Standards, including a "Clinical Practice Parameters and Facilities Standards for Endoscopy" issued in 2006"^. Other **Out-of-Hospital Premises** (e.g. physicians' offices) where physicians engage in diagnostic or therapeutic procedures which, when performed in accordance with accepted standard of practice, involve parenteral sedation or regional/general anaesthesia, or cosmetic procedures under local anaesthesia, are also required by law to be registered with the College and subject to its inspection. For endoscopy premises, the College issued a "Guide to Applying the Out-of-Hospital Standards in Endoscopy/ Colonoscopy Premises"^

^ In September 2014, the College published "Applying the Out-of-Hospital Premises Inspection Program (OHPIP) Standards in Endoscopy/Colonoscopy Premises and Independent Health Facilities (IHFs)" as a companion document to the "Out-of-Hospital Premises Standards (2013)".

Jurisdiction (Type of regulated facility)	**Endoscopic procedures to be performed in regulated facilities**
Singapore	
Singapore (Approved clinic or private hospital)	A medical clinic is providing **endoscopy** if it performs inspection of body organs or cavities by the use of endoscope, except those considered to be an integral part of a routine examination, such as nasopharyngoscopy in ENT examination, proctoscopy and rigid sigmoidoscopy in general surgical/medical examination and colposcopy in O&G examination. **Endoscopy, in this context, refers to diagnostic endoscopic procedures,** including minor therapeutic endoscopy such as removal of small polyps and injection of undiagnosed bleeding ulcers during routine diagnostic endoscopy. **Therapeutic endoscopy**, as a general rule, should only be performed in ambulatory surgical centres in hospitals, which are equipped with full resuscitation facilities and surgical backup. Every licensee of a medical clinic providing endoscopy shall comply with "Guidelines for Private Healthcare Institutions Providing Endoscopy : Regulation of Cap 248, Rg1"

Jurisdiction (Type of regulated facility)	**Endoscopic procedures to be performed in regulated facilities**
United Kingdom	
England (Health services providers)	Persons who carry on regulated activities should be registered as "service provider" to Care Quality Commission. Regulated activities include diagnostic and screening procedures involving the use of instrument or equipment which are inserted into the body to view its internal parts or gather physiological data. Medical practitioners in certain specified independent practice may be exempt from registration but their provision of treatment in the surgery or consultation room must not include, among other things, endoscopy other than using a device which does not have a lumen or other channel for the purpose or design of passing fluid or instruments through, or removing body tissue or fluid or any other item from, a person's body.

	Endoscopic procedures to be performed in regulated facilities
United State	
New York State (Office-based surgery)	The state licenses office-based surgery, which means any surgical or invasive procedures requiring moderate to deep sedation/analgesia or general anaesthesia, excluding minor procedures and procedures requiring minimal sedation, outside a hospital. Minor procedures means (1) procedures that can be performed safely with a minimum discomfort where the likelihood of complications requiring hospitalisation is minimal; (2) procedures with local or topical anaesthesia; or (3) liposuction under 500cc under local anaesthesia. The licensing authority further defines "invasive procedures" as - procedures performed for diagnostic or treatment purposes which involve puncture, penetration or incision of the skin, insertion of an instrument through the skin or a natural orifice, or insertion of foreign material other than medication into the body. Examples of Office-based Surgery include, but are not limited to, upper endoscopy and colonoscopy. In sum, the regulatory control is mainly based on level of analgesia/ sedation/ anaesthesia. Procedure-wise, NY state does not differentiate the level of regulatory control of endoscopy by whether they are therapeutic or diagnostic or whether polypectomy is involved.

	Endoscopic procedures to be performed in regulated facilities
Pennsylvania (Ambulatory surgical facility)	Facilities for surgical procedures (such as endoscopy) that require constant medical supervision after procedure but not hospitalisation are regulated as "ambulatory surgical facilities (ASFs)". ASFs are classified mainly by level of anaesthesia and patient condition (ASA classification), not type of surgical procedures. ASFs in the **lowest** class (i.e. Class A ASF where surgical procedures involve only local, topical or no anaesthesia) are not licensed. Some endoscopies are allowed in ASFs in this class. But Class A ASFs are still required to register annually with health department with a copy of accreditation survey by a nationally recognised accrediting agency. Class B (administration of sedative analgesic or dissociative drugs) and Class C (use of anaesthetic agents up to and including general anaesthesia) are licensed. In sum, there is regulatory oversight for all classes of ASFs providing endoscopy service.