

LEGAL REQUIREMENTS OF SETTING UP A GENERAL MEDICAL PRACTICE IN SINGAPORE

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SUMMARY

Numerous health laws exist in Singapore to regulate its healthcare facilities and services, health professionals, pharmaceuticals, medicinal products and health finance. This paper describes the legal regulations which are of particular importance, and that a general practitioner ought to know, when setting up medical practice. The licensing of a medical clinic, legal requirements and responsibilities of a licence holder and advertising are governed by the Private Hospitals and Medical Clinics Act and the Private Hospitals and Medical Clinics (Publicity) Regulations 2004. Who can practise is set out in the Medical Registration Act. As most clinics in Singapore dispense, it is important to be conversant with the legal requirements governing in-clinic dispensing as is set out in the Medicines Act, Poisons Act and Misuse of Drugs Act. The safe use of autoclave machines is regulated under the Factories Act. The safe conduct of infection control practices is regulated by the Infectious Diseases Act and the Infectious Diseases (Amendment no 2) Act 2003 – SARS. Finally, ignorance of the law is not a valid excuse in the court of law and the onus is upon the general practitioner to keep abreast of all revisions in these laws.

Keywords: legal requirements, general medical practice, Singapore

INTRODUCTION

Every year a small but significant number of doctors leave institutional practice to set up their own general medical practices. As of year 2002 there were approximately 1900 private medical clinics in Singapore, providing 80% of her primary healthcare needs.¹

Setting up a medical practice requires one to possess knowledge and skills in disease management, practice issues (issues concerning patient-doctor and doctor-colleagues), practice management (healthcare service delivery and business aspect of running the clinic) and ethical and legal considerations. Many doctors, including those with long years of experience in running their own practices, admit to being ignorant of or only vaguely aware of the various health laws currently enacted in Singapore.

Ignorance of the law is not a valid excuse in the court of law and the onus is upon the general practitioner (GP) to familiarize himself with these rules and regulations.

SOURCES OF INFORMATION

The information sources used in the writing of this paper is listed under the section “Recommended Sources of Information” below.

AREAS GOVERNED BY HEALTH LAWS

The areas with a need to meet the local health laws in the context of setting up a GP practice are:

1. Licensing of a medical clinic
2. Advertising
3. Licensing of autoclave machines
4. In-clinic dispensing
5. Infection control practices

The relevant health laws related to these areas are given in Table 1.

Table 1 : Health Laws Relevant To Setting Up Practice

Health Legislation*	Area of Relevance to Setting Up Practice
<ul style="list-style-type: none"> Private Hospitals and Medical Clinics Act 1980; Revised 1999 Medical Registration Act 1997; Revised 1998 	Licensing of clinic
<ul style="list-style-type: none"> Private Hospitals and Medical Clinics (Publicity) Regulations 2004 Medicine Act 1985, Revised 2000 	Advertising
<ul style="list-style-type: none"> Medicines (Labelling) Regulation 2000 Poisons Act 1985; Revised 1999 Misuse of Drugs Act 1985; Revised 2001 	In-clinic dispensing
<ul style="list-style-type: none"> Infectious Diseases Act 1976; Revised 1999 SARS and the Infectious Diseases (Amendment No 2) Act 2003 	Infection control practices
<ul style="list-style-type: none"> Factories Act 1990 	Licensing of autoclave machine

* Footnote: With the exception of the Factories Act, the rest are regulated by the Ministry of Health.

LICENSING OF CLINIC

In Singapore, with effect from 1993, all medical clinics and for that matter all hospitals have to be licensed. The law governing licensing is the Private Hospitals and Medical Clinics Act.

The Private Hospitals and Medical Clinics (PHMC) Act
The Private Hospitals and Medical Clinics (PHMC) Act (Chapter 248) was passed in 1980 and its Regulations published in December 1991. It came into operation on 1 January 1993. The PHMC (Amendment) Act, a revised

edition, was passed in 1999. It is administered by the Ministry of Health (MOH).

The PHMC Act provides for the 'control, licensing and inspection of private hospitals, medical clinics, clinical laboratories and healthcare establishments, to prohibit trading in human blood, and for purposes connected therewith'². Besides licensing of medical clinics, the PHMC Act also gives authorities wide-ranging power of inspection for the purpose of investigating if any provisions of the Act or regulations may have been contravened, lists out offences and penal sanctions, and discusses confidentiality and the use of information gained in the exercise of powers³.

Under the PHMC Act, directives may be issued by MOH from time to time as required, which must be complied with by all relevant medical establishments. An example of a recent regulation issued was the institution of preventive measures for the Severe Acute Respiratory Syndrome (SARS) in all medical clinics, during the SARS epidemic⁴.

The PHMC Act is thus a complete and all encompassing regulatory framework for all medical and healthcare establishments. With this Act, the operation and running of all such establishments become transparent, and can lead to further scrutiny, checks and inspections³.

Guidelines under the PHMC Act (1980) and Regulations (1991) is a useful publication by MOH that briefly summarizes the responsibilities of a licensee and manager and the minimum standards required to secure licensing⁵.

Securing the Licence

The first and most important legal requirement when setting up practice is to secure a licence to operate the clinic. The PHMC Act defines a medical clinic as 'any premises used or intended to be used by a medical practitioner, a dentist or any other person – a) 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 b) for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device ...' (Section 2)

Section 5 (1) states that 'no premises shall be used as a private hospital, medical clinic, clinical laboratory or healthcare establishment except under the authority and in accordance with the terms and conditions of a licence issued by the Director' (of Medical Services). Further, section 6 (4a) states that 'the Director, before issuing the licence applied for, may inspect the premises to be licensed, or cause such premises to be inspected by an authorized officer'.

Section 13 of the Medical Registration Act states that 'no person shall practise as a medical practitioner or do any act as a medical practitioner unless he is registered under this Act and has a valid practicing certificate...' Section 16 defines a 'legally qualified medical practitioner' as a medical practitioner or member of the medical profession 'who is registered under this Act and has a valid practicing certificate'.

Criteria for Issuing or Refusal of a Licence²

Various factors are considered in determining whether a licence is issued or refused. These include the character and fitness of the applicant, the ability of the applicant to operate and maintain a medical clinic in accordance with prescribed standards, suitability of the premises for use as a medical clinic and adequacy of nursing and other staff to be employed at the premises.

Before being issued a licence, an applicant may be required to make alterations or improvement to the premises. In the case of a person who has not been granted a licence, provisions are present for him to make an appeal to MOH.

Licensee versus Manager of a Medical Clinic

The applicant for the licence or *licensee* of a medical clinic can be a person or a corporate body⁶. The person need not be a medical practitioner. The corporate body may be a medical group, statutory board, factory or charitable organisation⁷.

The *manager* of a medical clinic must be a medical practitioner registered under the Medical Registration Act⁶. Such a doctor must have full registration with the Singapore Medical Council, and must also have a valid practicing certificate. Doctors under conditional or provisional registration are not allowed to set up their own practices.

At present, a doctor only needs to possess a registrable basic medical qualification of an MBBS degree (or equivalent) to set up a general medical practice. A graduate diploma or Masters degree in Family Medicine is not a requirement⁸.

Most solo GPs function as both licensee and manager of their clinics. Occasionally, a doctor may team up with a non-medical licensee. Many large multinational companies also have 'company' or 'factory' clinics to cater to the health needs of their employees. In this case the licensee may be the company itself, or it may be a medical group contracted by the company to run and manage the clinic.

In a group practice with several branch clinics, each clinic must be individually licensed⁷. It must be ensured that a manager is present in each clinic during the stipulated operating hours i.e. there must be an adequate number of doctors to run the clinics.

Responsibilities of a Clinic Licensee⁹

The licensee has the overall responsibility for ensuring that all relevant requirements in the PHMC Act, its Regulations & Guidelines and directives or guidelines issued from time to time by the Director of Medical Services (DMS), are complied with. He is not to display or use any name when referring to the medical clinic other than the name appearing in the licence. He must display the licence in a conspicuous place in the clinic.

It is an offence to practise in an unlicensed premise or to fail to comply with any of the Regulations. A licensee is liable on conviction to a fine not exceeding \$20,000 or to

imprisonment for a term not exceeding 2 years or both.

Although not directly related to the setting up of a new practice, it is worthwhile noting these points:- a) The licence issued is not transferable. A fresh application for a new licence is required should there be change in licensee for any reason (e.g. resignation or retirement), or relocation of the clinic; b) The licensee should inform the authorities beforehand of any change in the manager of the practice. He must also notify DMS in writing at least 30 days before the cessation of operation, letting, sale or disposal of his medical clinic.

Responsibilities of a Clinic Manager¹⁰

The clinic manager must not be absent from the clinic for any length of time. When the doctor has to be away (e.g. maternity leave, overseas vacation or in-camp reservist training), arrangements must be made for the clinic to be placed under the supervision of a person who is similarly qualified to manage the clinic.

The manager is responsible for the supervision of all personnel in the clinic, other than registered pharmacists. He is also responsible for the activities involved in the preparation and dispensing of medicinal products, including the maintenance of appropriate records. In other words, he is responsible for all the activities performed by his clinic assistants.

The manager cannot delegate to other staff any duty that can only be performed by him. Only the manager performs all clinical procedures, and he must have adequate training and experience in the use of any equipment used for carrying out such procedures.

Offences And Penalties Under The PHMC Act

A licensee who has contravened any regulation under the PHMC Act may be ordered by the Director or an authorized officer to make the necessary alterations or improvements, or remove / stop the use of any appliance, practice or procedure. Should the licensee fail to comply with the order, he is considered guilty of an offence and may be liable on conviction to a fine, imprisonment term or both. Table 2 lists some offences and the corresponding composition amounts payable.

MEDICAL REGISTRATION

In setting up practice, it is useful to review the Medical Registration Act and note its provisions.

The Medical Registration Act

The Medical Registration Act (Chapter 174) was enforced in 1997, and was revised in May 1998. It is an act to 'provide for the registration of medical practitioners, and for matters connected therewith'¹¹.

The overall purpose of the Medical Registration (MR) Act is to 'enhance the role and structure of the Singapore Medical Council, raise standards of medical conduct and practice and to tighten the laws governing the medical profession so as to cater to tremendous changes in the medical sector since the 70s'¹².

The MR Act covers issues concerned with privileges and registration of medical practitioners (qualifications to practice and penalty for unauthorized persons; different types of registration). It also spells out the constitution, structure and function of the Singapore Medical Council (SMC), establishment and function of the Specialist Accreditation Board, application for and cancellation of practicing certificates, and the general procedure for disciplinary proceedings and health committee inquiries. A valid registration with the SMC is necessary before one can practise Western medicine in Singapore.

ADVERTISING

The recent proliferation of advertisements by medical clinics in the classified ads section is a sign of the current revolution (albeit in a quiet and dignified manner) that is shaking the healthcare sector. The traditionally conservative stand of the medical community has now given way to the enlightened view that there is not only a place, but that it is also a necessity, for dissemination of information about doctors' services.

The regulations on advertising is governed by the Private Hospitals and Medical Clinics (Publicity) Regulations 2004.

Private Hospitals and Medical Clinics (Publicity) Regulations 2004¹³

The PHMC (Publicity) Regulations came into operation on 17th May 2004. Section 3 states that 'the licensee of a

Table 2 : Selected Compoundable Offences and Composition Amount under the PHMC Act

Provision/Section No	Nature of Offence	Composition Amount
Licences for private hospitals, medical clinics, clinical laboratories, HCEs 5	<ul style="list-style-type: none"> o Premises used as HCEs without a valid licence, because of relocation extension of unit, change of name/licensee of clinic o Licensed HCEs used otherwise than in accordance with the terms & conditions of its licence 	\$1,000
Persons who may manage HCEs 10 (1)	Unqualified person managing a medical clinic or clinical laboratory, maternity home or nursing home	\$1,000
Display of licence 7	No display of current licence	\$300
Notification of cessation 9	Ceased operation without notification of intention in writing	\$300

healthcare institution may publicise or cause to be publicized the services of a healthcare institution'. In short, advertising is permitted, provided that the regulations are adhered to.

Advertising in the Publicity Regulations refers to printed advertisements in any form of mass medium (electronic or otherwise) for communication produced or for use by a healthcare institution. Most striking about these new guidelines is that only broad principles and 'out-of-bound' markers are given i.e. they state what is not permissible, as opposed to what is allowed. In general, as stated in Section 4 (1): -

- a) the information 'must be factually accurate and capable of being substantiated, and must not be exaggerated, false, misleading or deceptive'
- b) 'The publicity must not be offensive, ostentatious or in bad taste such as to undermine the honour and dignity of the medical profession'
- c) (ii) must not 'compare and contrast the quality of services with other healthcare institutions, or 'deprecate the services' of others
- d) 'must not contain any laudatory statements or superlatives' to describe the services
- e) 'must not contain any testimonial or endorsement of the services, including the services of any employee...'
- f) 'must not provide any information in such a manner as to solicit or encourage the use of the services provided...'

Advertising in newspapers, directories, medical journals, magazines, brochures, leaflets, pamphlets and the Internet is allowed. Publicity of the services of the healthcare institution may be disseminated in conjunction with any activity, event or programme of any person (section 6), through interviews (section 7) and in any country outside Singapore (section 11) as long as all relevant requirements under the PHMC (Publicity) Regulations are complied with at all times.

Advertising Related to Setting Up Practice

The main forms of advertising employed by GPs when setting up practice are i) announcement of commencement of practice in printed media ii) conducting 'opening' ceremonies iii) clinic signboards and nameplates iv) namecards, stationery, brochures, leaflets and pamphlets.

It is to be noted that while the PHMC Regulations – Advertising Guidelines issued in May 1997 explicitly stated what information was permissible in advertisements, nameplates, signboards, business cards and stationary, brochures leaflets and pamphlets, these are conspicuously absent in the PHMC (Publicity) Regulations 2004.

A 'Frequently Asked Questions' section in the June 2004 issue of SMA News added these clarifications on the regulations¹⁴:

- 1) A healthcare institution (HCI) cannot publish its services in media not listed e.g. billboard / light box, banner, poster.
- 2) There are no limits to the number of times that HCIs can publish information about their services.
- 3) There is no restriction on the size of the media for publishing of information.

- 4) Only factual information such as the types of services provided, clinic address, contact numbers, opening hours and charges (actual prices) are allowed.

The statement "the publicity must not provide information to the public in such a manner as to amount to soliciting or encouraging the use of services provided by or at any HCI" includes the use of such phrases such as 'discounts', '0% instalments', preferential rates' or 'free screening'.

- 5) HCIs are allowed to tie up with a club or society, and provide preferred rates or special treatment packages to members of the club or society. However, again, publicity by the HCI on such an arrangement must conform to point (4) above.

- 6) HCIs are not allowed to conduct such promotions as souvenirs, promotional coupons, lucky draws and sale campaigns as these amount to soliciting or encouraging the use of services provided by the HCI.

- 7) Some examples of laudatory phrases are 'best medical care available', 'world class medical services' and 'state of the art technology'.

- 8) HCIs can advertise or promote their services outside Singapore, but they must ensure that they comply with the relevant laws and advertising rules of that country.

- 9) HCIs can engage the services of an advertising company or a third party to publish information on their services.

IN-CLINIC DISPENSING

A unique feature of private medical practices in Singapore is in-clinic dispensing. This tradition looks set to stay as it offers several advantages, including convenience and cost-effectiveness to the patient. 'The Singapore Medical Association supports this system that has evolved to meet the needs of most Singaporeans, and believes that it has a very important part to play in cost-effective delivery of high-quality primary healthcare in Singapore'¹⁵.

The Medicines Act 1985, the Poisons Act 1985 and the Misuse of Drugs Act 1985 provide for the regulation of various activities involving medicinal products. The Medicines Act revised edition 2000 has new subsidiary legislation on, among others, labeling and licensing of medicines.

The Medicines Act 1985, Revised Edition 2000

This act provides for a licensing authority, MOH, to license all wholesale dealers, manufacturers and importers of medicinal products as well as all medicinal products themselves (Sections 5 and 6). Regulations governing pharmacies, labelling and identification of containers, promotion of sales of medicinal products and medical advertisements are also covered.

GPs do not require a licence to dispense medication, as stated in Section 7 (4) 'the restrictions imposed by Sections 5 and 6 shall not apply to the preparation, dispensing and assembly of any medicinal product by or under the

supervision of a practitioner for the purpose of administration to a patient or animal under his care'¹⁶. However, a GP can only limit his in-house dispensing activities to his own patients and for (not anyone else or any other purpose) administration of medicinal products to these same patients. They are responsible for the dispensing activities of their clinic assistants¹⁷.

The Act prohibits adulteration of medicinal products, by the addition or abstraction of any substance, so as to 'affect injuriously the composition of the product' (Section 31).

The Medicines (Labelling) Regulations 2000

This regulation concerns proper labeling and marking of containers and packages. The labeling requirements are listed under Regulation 4, and include :-

a) name of the patient; b) name and address of medical practice dispensing the product; c) date of dispensing; d) direction for use of the product; e) name of medicinal product, either the appropriate non-proprietary name or proprietary designation; f) where the non-proprietary name is used, the appropriate quantitative particulars of the active ingredients¹⁸.

Poisons Act 1985, Revised Edition 1999¹⁹

The Poisons List is a comprehensive list that includes most medications used by GPs for treatment of both acute and chronic conditions. This act provides for a practitioner to supply poisons to his patients for the purposes of medical treatment of his own patients, provided that the following criteria, as listed in Section 7 (3) are met:- 'On the day on which the medicine is supplied or dispensed, or if that is not reasonably practicable, on the day next following that day, there shall be entered in a book which is kept and used regularly for the purpose of this provision...'

a) 'the date on which the medicine was dispensed' and 'serial or identification number or mark relating to the medicine'
b) 'the ingredients of the medicine' or 'the name of the medicine and the quantity thereof supplied'
d) 'the name and address of the person to whom it was supplied'.

The act also states the requirements for the proper storage of poisons.

Misuse Of Drugs Act 1985, Revised Edition 2001

This act is concerned with the regulation of controlled drugs, which is a list of drugs found in Part I, II and III of the First Schedule of the act. Some commonly used controlled drugs are morphine or pethidine preparations, certain hypnotics/tranquilizers such as Flunitrazepam (eg Rohypnol), Nimetazepam (eg Erimin) and Triazolam (eg Somese) and CNS stimulants and anorectics that contain Amphetamine and Methylphenidate (eg Ritalin).

Regulations in the Misuse of Drugs Regulations 1990 that are relevant to doctors who stock up on controlled drugs include Regulations 14, 15 and 17 which govern the requirement to keep a controlled drugs register, in the form of a bound book, that documents separately both receipt from suppliers and dispensing to patients. The format for registers is given in the Fifth Schedule and is to be adhered to strictly. Cancellation, obliteration and alteration of any entry in the register is not allowed^{15,17,20}.

What a GP Ought to Know

In-clinic dispensing brings with it, its own host of problems. Doctors are responsible for mistakes made by their clinic assistants, hence it pays to invest in training them! All medications must be labeled properly and adequately. A dispensing record book is required for all poisons dispensed, and this must be kept on the premises for 2 years from the date of the last entry. A controlled drug register (separate from the dispensing record book) is also required, and this must be kept on the premises for 3 years from the date of last entry^{15,21}.

Due to the hassle involved in having controlled drugs, including the occasional break-in by drug addicts, many GPs choose not to stock up any controlled drugs at all.

LICENSING OF AUTOCLAVE MACHINES

For doctors who choose to do their own autoclaving of surgical instruments, dressings and disposals, there is a need to know the legal requirements of ensuring the safety of their autoclaves.

Licensing of autoclave machines used in medical clinics was made compulsory several years ago. Understandably, there was some unhappiness in the GP community initially when this requirement was passed. It is essential to understand the rationale behind this regulation.

Use of the autoclave machine comes under the purview of the Factories Act, which is implemented by the Occupational Safety Department (OSD) of the Ministry of Manpower (MOM). An autoclave machine is a 'pressure vessel' of the steam boiler type. It is potentially hazardous, and any design or fabrication fault or misuse of the vessel could lead to an explosion. In fact, several explosions involving pressure vessels have occurred both locally and abroad causing damage to buildings and deaths. Stringent control is essential to ensure that they are safe for use. The OSD implements such controls by registering these pressure vessels and ensuring that they are inspected periodically²².

A GP who wishes to have an autoclave machine in his clinic must buy a type-approved autoclave and have it inspected annually. A list of type-approved tabletop autoclaves and their suppliers is available online. Inspection is usually arranged for by the supplier but may also be made directly to the OSD.

INFECTION CONTROL

Infection control is regulated by legal statutes too. These are the Infectious Diseases Act (Revised edition 1999) and the Infectious Diseases (Amendment No 2) Act 2003.

Infectious Diseases Act (Revised Edition 1999)

The Infectious Diseases Act is an act relating to quarantine and the prevention of infectious diseases. First enacted in 1976, it has undergone several revisions over the years. It is a wide-ranging act covering all aspects of control of infectious diseases within Singapore, control of AIDS and HIV infection, prevention of introduction of infectious disease into Singapore, vaccination and powers of arrest of the authorities in relation to offences connected with the above. The act allows for the Director to 'prescribe any general or specific measures or procedures for investigating into any infectious disease and for the treatment of any infected person, and all medical practitioners shall comply with such order' [section 10 (1)]²³.

SARS And The Infectious Diseases (Amendment No 2) Act 2003

The Severe Acute Respiratory Syndrome epidemic that began locally in March 2003 gave rise to the Infectious Diseases (Amendment No. 2) Act 2003. A new Fifth and Sixth schedule, both listing the SARS disease, was included into the Act. Issues pertaining to suspected or probable SARS cases or their contacts, included isolation, surveillance, medical examination and treatment, post-mortem examination, wakes and disposal of corpses²⁴.

During the SARS epidemic, the MOH ordered for SARS preventive measures to be instituted in every medical clinic. Among the requirements were i) triaging of patients to separate febrile patients from others and the need to fill up a declaration form ii) institute infection control measures such as the use of personal protective equipment including the N95 mask, proper hand washing technique after every patient and disinfection of all equipment and facilities iii) monitoring of temperature of all staff at least twice daily iv) and a system in place to enable contact tracing of all staff, patients and accompanying persons who were in the clinic at the same time as the suspected SARS patient⁴.

The Infectious Diseases Act, in Relation to Licensing of a Clinic and Setting Up Practice

Infection control practice measures constitutes one of the decisive factors in whether a clinic is given the go ahead to start operating. Basic requirements are the availability of puncture-resistant containers for disposal of needles and other sharp items, and hand washing and hand drying facilities in the clinic. All infectious waste is to be removed either by licensed contractors or to be disinfected thoroughly before disposal into the general waste²⁵.

Relevant sections that a doctor should know prior to setting up practice are the need to notify both infectious diseases and vaccination, as stated under section 6 (1) – 'every medical practitioner who has reason to believe or suspect that any person attended or treated by him is suffering from an infectious disease or is a carrier of that disease shall forthwith give notice in the prescribed form to the Director', and section 48 (2b) every medical practitioner shall 'within the prescribed period after carrying out any vaccination or intradermal test, notify in the prescribed manner, the Director...' ²³.

RECOMMENDED SOURCES OF INFORMATION

Attendance by GPs at seminars focusing on the topic of health law in general, which the author found to be very practical and beneficial, is highly recommended. The website of the SMA Centre for Medical Ethics and Professionals also provides valuable information. GPs may also want to read the full-text versions of the acts and regulations.

The details are : -

1. Seminars on Bioethics and Health Law
This is an ongoing series organized jointly by the SMA Centre for Medical Ethics and Professionals and Tan Tock Seng Hospital, that was started in year 2001. Invited lawyers explain the different acts, using medical cases that were dealt with in court, for illustration.
2. Website of the SMA Centre for Medical Ethics and Professionals
<http://www.sma.org.sg/cmep>
3. SMA Private Practice Handbook
4. Full-text versions of various acts and regulations, available from:
SNP Corporation Ltd – Legal Publications
491 River Valley Road
01 – 19/20 Valley Point
Singapore 248371

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http://www.sma.org.sg/cmep/practice/PRA2/PRA2A.html.</p> | <p>16. Medicines Act 1985.</p> <p>17. SMA Private Practice Handbook. I. The Medicines Act 1985 II. The Poisons Act 1985 III. The Misuse of Drugs Act 1985. Pg 63-5.</p> <p>18. Medicines Act – Subsidiary Legislation Revised Edition 2000.</p> <p>19. Poisons Act Revised Edition 1999.</p> <p>20. Misuse of Drugs Act Revised Edition 2001.</p> <p>21. SMA Private Practice Handbook. Guidelines to Medical Practitioners for Proper Maintenance of Drugs and Dispensing Records. Pg 69-77.</p> <p>22. http://www.mom.gov.sg Pressure vessels.</p> <p>23. Infectious Disease Act Revised Edition 1999.</p> <p>24. Infectious Diseases (Amendment No. 2) Act 2003.</p> <p>25. http://www.moh.gov.sg eServices. Guide for Preparation of Licensing of Medical & Dental Clinics.</p> |
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TAKE HOME MESSAGES

- o GPs should be aware of the various health laws enacted in Singapore, with particular emphasis on laws relevant to managing a practice. Ignorance as an excuse is not acceptable in the court of law.
 - o The PHMC Act and its Regulations governs the licensing of the clinic and the duties and responsibilities of the licensee. It is an important and powerful Act. One has to be knowledgeable of its requirements in the context of setting up practice.
 - o Advertising not only creates awareness among colleagues and patients, it also heralds an auspicious start to what hopefully will become a successful practice. GPs should refer to the Regulations prior to advertising their services, so as not to step afoul of the existing laws governing advertising.
 - o GPs should be mindful of the regulations governing in-clinic dispensing, including on the proper and adequate labelling of medication, the need for a dispensing record book and a controlled drug register. GPs are responsible for mistakes made by their clinic assistants.
 - o GPs must buy type-approved autoclave machines and have these inspected annually.
 - o Though the SARS epidemic has long been over, it is not inconceivable that a resurgence of another epidemic may occur e.g. SARS, avian flu or influenza virus. An applicant for a clinic licence should proactively establish a workflow for handling infectious-disease related cases, e.g. allocating a separate room for isolation of such patients.
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Multiple Choice Questions : one or more answers are correct

1. **About the Private Hospitals and Medical Clinics Act, which of the following are correct?**
 - (a) The PHMC Act provides for the control, licensing and inspection of private hospitals and medical clinics only.
 - (b) This Act allows directives to be issued from time to time as required, that must be complied with by all relevant medical establishments.
 - (c) This Act gives authorities, at any time and without warrant, the power to enter, inspect and search a medical clinic, in order to investigate whether any regulations in the Act have been contravened.
 - (d) This Act gives authorities the power to seize and remove from a medical clinic, any record, document, apparatus, blood or tissue sample, or pharmaceutical substance that may be connected with the commission of an offence under the Act.
 - (e) Its regulations are enforced by the Ministry of Manpower.
2. **About the licensee/ licence/ licensing inspection of a medical clinic, which of the following are correct?**
 - (a) The licensee must be a medical practitioner registered under the Medical Registration Act, with a valid practicing certificate.
 - (b) The licensee need not be a medical practitioner or medical group.
 - (c) In group practice, one common licence is issued to all the branches.
 - (d) Upon the sale of a clinic, the new licensee needs to apply for a fresh licence not less than 2 months before the expiry of the licence held by the previous licensee.
 - (e) The Licensing and Accreditation Branch of the MOH only inspects clinics, before a licence is issued (pre-licensing inspection) and every 2-yearly, upon renewal of the licence.
3. **About the manager of a medical clinic, which of the following is correct?**
 - (a) must be a medical practitioner under the Medical Registration Act, with a valid practicing certificate.
 - (b) need not be a medical practitioner.
 - (c) may hold a conditional registration with the Singapore Medical Council.
 - (d) may have provisional or temporary registration with SMC.
 - (e) is accountable for errors in dispensing of medication made by his clinic assistants.
4. **About in-clinic dispensing, which of the following are correct?**
 - (a) A medical practitioner requires a licence from MOH to dispense medication to his patients.
 - (b) Proper and complete labelling on dispensed medication includes the name of the patient, the name of the medicinal product and instructions for use of the product only.
 - (c) The dispensing record book must be filled in on the same day (or by the following day) and is to be kept in the premises for 2 years from the date of last entry.
 - (d) Controlled drugs dispensed to patients must be entered in the 'controlled drugs register' section of the dispensing record book.
 - (e) Doctors are legally required to report a patient, whom he suspects to be a drug addict, to both the Director of Medical Services and Director of Central Narcotics Bureau.
5. **About, advertising in relation to setting up a medical practice, which of the following are correct?**
 - (a) Opening ceremonies are not allowed.
 - (b) Advertising in local newspapers, the Yellow Pages, Singapore White Pages, Internet, radio and television are allowed.
 - (c) Advertisements in different newspapers must appear on the same day, and for one day only, within 3 months from the date of issue of the new licence.
 - (d) A photograph of the clinic manager may be inserted in the Yellow Pages.
 - (e) Previous posts held while in institutional practice, e.g. 'deputy doctor-in-charge of X Polyclinic' or 'honorary secretary of Y specialist society' may be inserted into the advertisements.

EXPLANATORY NOTES

Question 1

- (a) False. Clinical laboratories and healthcare establishments are also covered.
- (b) True. Section 22 – ‘The Minister may make regulations for any purpose for which regulations are required to be made under this Act and generally for carrying out the purposes and provisions of this Act’.
- (c) True. Section 12 (1)
- (d) True. Section 12 (2g)
- (e) False. Ministry of Health

Question 2

- (a) False. The licensee need not be a medical practitioner.
- (b) True. The licensee need not have a medical background.
- (c) False. All branches must be individually licensed.
- (d) False. The licence is not transferable. Upon the sale of a clinic, a fresh application is required for a new licence.
- (e) False. Inspection is done as and when required. E.g. Inspections are now conducted more often, in view of the SARS epidemic.

Question 3

- (a) True.
- (b) False. Manager must be a doctor.
- (c) False. Full registration only (not conditional/provisional/temporary)
- (d) False. Full registration only (not conditional/provisional/temporary)
- (e) True. Responsible for errors of clinic assistants.

Question 4

- (a) False. Section 7 (4) of Medicines Act 1985
- (b) False. Name and address of the medical practice dispensing the product, and date of dispensing must also be included.
- (c) True.
- (d) False. The controlled drugs register (in the form of a bound book) is to be separate from the dispensing record book.
- (e) True. This must be done within 7 days of seeing such a person. Information to be provided are name of patient, NRIC no, sex, age, address and the drug to which the person is believed to be addicted.

Question 5

- (a) False. Opening ceremonies are allowed as long as undue publicity is not created.
 - (b) False. In general, advertising in radio and television are not allowed.
 - (c) False. In the PHMC (Publicity) Regulations 2004, there are no limits to the number of times that healthcare institutions can publish information about their services.
 - (d) False. Only photograph/illustration of the exterior of the medical clinic is allowed.
 - (e) False. Past or present appointments of the doctor in other institutions should not be included.
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