



KEMENTERIAN KESIHATAN MALAYSIA

ARAHAN KETUA PENGARAH KESIHATAN

BILANGAN 1 TAHUN 2014

MENGIKUT PERUNTUKAN AKTA KEMUDAHAN DAN PERKHIDMATAN JAGAAN KESIHATAN SWASTA 1998 [AKTA 586]

GARIS PANDUAN UNTUK MENUBUHKAN DAN/ATAU MENYEDIAKAN KEMUDAHAN DAN PERKHIDMATAN RENAL TRANSPLAN DI HOSPITAL SWASTA

TUJUAN

1. Arahan ini ditujukan untuk memberi panduan kepada pemohon atau pemegang lesen hospital swasta yang hendak menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan pemindahan buah pinggang di hospital swasta dan memastikan hospital swasta tersebut mengikut piawaian dan keperluan yang ditetapkan oleh Kementerian Kesihatan Malaysia (Kementerian) bagi menjamin keselamatan dan kualiti jagaan kesihatan pesakit.

LATAR BELAKANG

2. Akta 586 dan peraturan-peraturannya mula dikuatkuasakan pada 1 Mei 2006.
3. Garis panduan "*Guidelines to Establish and/or Provide Renal Transplant Facilities & Services In Private Hospitals*" bertarikh 30 Jun 2014 ini diwujudkan bagi menjelaskan secara terperinci keperluan khusus bagi menyediakan kemudahan dan perkhidmatan pemindahan buah pinggang di hospital swasta.

SUMBER KUASA

4. Arahan ini disediakan selaras dengan peruntukan Akta 586 seperti berikut:
 - 4.1. **Seksyen 76**, Akta 586 memberi kuasa kepada Ketua Pengarah untuk mengeluarkan arahan, perintah atau garis panduan berkaitan dengan

kualiti dan piawaian Kemudahan dan Perkhidmatan Jagaan Kesihatan Swasta (KPJKS) sebagaimana yang difikirkannya perlu.

- 4.2. **Seksyen 43**, Akta 586 memberi kuasa kepada Ketua Pengarah untuk mengeluarkan notis tunjuk sebab mengenai niatnya kepada pemegang lesen KPJKS untuk menggantung, membatalkan atau enggan memperbaharui lesen KPJKS tersebut sekiranya apa-apa arahan, perintah atau garis panduan yang diberikan kepadanya oleh Menteri atau Ketua Pengarah tidak dipatuhi sepertimana yang diperuntukkan di bawah **perenggan 44(d)**, Akta 586.

PEMAKAIAN

5. Arahan ini adalah terpakai ke atas hospital swasta yang berhasrat untuk menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan pemindahan buah pinggang dan mendapatkan lesen atau berlesen di bawah perenggan 19(a), Akta 586.

PEMATUHAN

6. Setiap pemohon atau pemegang lesen hospital swasta yang hendak menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan bagi pemindahan buah pinggang di hospital swasta perlu mematuhi garis panduan ini.

GARIS PANDUAN

7. Sebagai panduan untuk pemohon dan pegawai proses, garis panduan telah disediakan oleh Kementerian bertajuk "*Guidelines to Establish and/or Provide Renal Transplant Facilities & Services In Private Hospitals*" dated 30 June 2014 (rujuk Lampiran).

TARIKH KUAT KUASA

8. Arahan ini berkuat kuasa serta merta mengikut tarikh Arahan.


DATUK DR. NOOR HISHAM BIN ABDULLAH
Ketua Pengarah Kesihatan, Malaysia

Tarikh: **15 SEP 2014**

**PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998 [ACT 586]
&
PRIVATE HEALTHCARE FACILITIES AND SERVICES
(PRIVATE HOSPITALS AND OTHER PRIVATE HEALTHCARE FACILITIES)
REGULATIONS 2006**

**GUIDELINES TO ESTABLISH AND/OR
PROVIDE RENAL TRANSPLANT FACILITIES &
SERVICES IN PRIVATE HOSPITALS**

**PRIVATE MEDICAL PRACTICE CONTROL SECTION
MEDICAL PRACTICE DIVISION
MINISTRY OF HEALTH MALAYSIA**

30 JUNE 2014

WORKING COMMITTEE

The Working Committee was established on 14 February 2014. After several meetings and discussions, the Committee had formulated and agreed on the guidelines on 30 June 2014.

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INTRODUCTION

1. Private healthcare facilities and services (PHFS) in Malaysia is regulated and controlled in accordance to the Act 586. The Act 586 is enforced on 1st May 2006.
2. All PHFS listed under Section 3, Act 586 are required to comply with Act 586 and Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations, 2006 [P.U. (A) 138/2006].
3. Any private hospital intends or intended to establish or provide renal transplant facilities and services is required to comply with this guideline and it shall be read together with Act 586 and P.U. (A) 138/2006 to ensure patient safety and quality of care.

OBJECTIVES

4. To provide guidance for the applicant in relation to the establishment and provision of renal transplant facilities and services in a private hospital.
5. To ensure renal transplant facilities and services provided by the private hospitals are in accordance to the standard and requirements set up by the Ministry of Health to uphold patient safety and quality of care.
6. To facilitate the application process by officers in Private Medical Practice Control Section and Units (CKAPS & UKAPS) in accordance with Act 586 and this guideline.

REQUIREMENTS ON FACILITIES AND SERVICES

7. In a private sector, renal transplant facilities and services **may only** be provided as inpatient services in a private hospital which fulfils the set criteria and standard.
8. A newly established renal transplant hospital or centre shall perform a minimum number of 12, preferably 20, renal transplants per year.

9. Healthcare facilities and services which are required to be provided by such private hospital, shall include but not limited to:

9.1. Inpatient Facilities & Services

- (a) Nephrology;
- (b) Urology; and
- (c) Critical Care.;

9.2. Support Facilities & Services

- (a) Anaesthesia;
 - (b) Radiology and Imaging;
 - (c) Access to Pathologist (Histopathologist with expertise in transplant histopathology);
 - (d) Central Sterilizing and Medical-Surgical Supply Department (CSSD);
 - (e) Blood Bank or access to Blood Bank;
 - (f) Nursing;
 - (g) Pharmaceutical:
 - i. Immunosuppressive therapy; and
 - ii. Therapeutic drug monitoring.;
 - (h) Laboratory:
 - i. Routine clinical biochemistry;
 - ii. Microbiology and virology studies;
 - iii. Access to tissue typing, cross matching and donor-specific antibody assay; and
 - iv. Access to radio nuclear medicine for renal isotope study.;
- Note: Item ii, iii & iv may be outsourced.*

9.3. Ambulatory Care Services

- (a) Haemodialysis; and
- (b) Peritoneal Dialysis.;

9.4. Outpatient Facilities & Services

- (a) Nephrology;
- (b) Urology;
- (c) Independent donor advocate (trained person/psychiatrist);
- (d) General/Vascular Surgery; and
- (e) Internal Medicine.

10. The facilities intended or intends to be established and provided in the private hospitals shall comply with the regulations and requirements, listed as below:
- 10.1. Part X: General Provisions for Standards of Private Healthcare Facilities or Services, P.U. (A) 138/2006;
 - 10.2. Part XV: Standards for Surgical Facilities and Services, P.U. (A) 138/2006, with additional requirements for the Operation Theatre as stated below:
 - (a) Shall be but not limited to 2 dedicated major operation theatres;
 - (b) The 2 major operation theatres shall be adjacent or opposite each other; and
 - (c) The equipment and consumables necessary for carrying out the renal procurement and transplant should be dedicated and made available at all times.
 - 10.3. Part XVI: Special Requirements for Critical Care Unit or Intensive Care Unit, P.U. (A) 138/2006, with additional requirements for the Intensive Care Unit as stated below:
 - (a) Shall have at least 1 isolation room for the recipient, equipped with related medical equipment; and
 - (b) There shall be at least 1 high dependency bed for the live donor.
 - 10.4. Part XXII: Special Requirements for Haemodialysis Facilities and Services, P.U. (A) 138/2006, with additional requirements for the Haemodialysis Facilities as stated below:
 - (a) There shall be facilities for the support of both acute and chronic haemodialysis; and
 - (b) There shall be facilities for plasmapheresis and plasma exchange
 - 10.5. Part XIX: Special requirements for Central Sterilizing and Medical-Surgical Supply Facilities and Services, P.U. (A) 138/2006.

REQUIREMENTS ON PERSONNEL

11. Each renal transplant programme in a private hospital shall be managed by a coordinated and established team consists of qualified, trained, experienced and skilled healthcare professionals including dedicated nephrologists and transplant surgeon.

12. Renal transplant operation may only be performed after thorough pretransplant medical evaluation are done on the patient (recipient) and donor (living donor) including tests for blood type and other matching factors that determine the recipient body will accept an available kidney and to ensure the patient and donor (living donor) are healthy enough for the surgeries.
13. The list of healthcare professional shall include but not limited to:
- (a) Two (2) resident Nephrologists;
 - (b) One (1) resident Transplant Surgeon;
 - (c) One (1) resident or visiting consultant Urologist/Surgeon;
 - (d) Two (2) anaesthetists one of whom is a resident anaesthetist;
 - (e) One (1) resident Radiologist;
 - (f) Two (2) registered nurses with post basic training in perioperative care;
 - (g) One (1) registered nurse with post basic training in renal nursing for each patient at all times;
 - (h) One (1) registered nurse with post basic training in intensive care for each patient at all times;
 - (i) One (1) Transplant coordinator; and
 - (j) One (1) Pharmacist.
14. There shall be **at least but not limited to 2 renal transplant teams** at all times which include a renal procurement team (for the donor) and a renal transplant team (for the recipient).
15. Detailed criteria for each healthcare professional mentioned above, are as listed below:
- 15.1. All healthcare professional are registered with a valid practicing certificate under law regulating their registration and in the absence of such law, hold such qualifications and possess such experience as recognised by Ministry of Health Malaysia.
- 15.2. All medical practitioners are registered under the Medical Act 1971 [Act 51] with a valid practicing certificate (APC or TPC), and all medical and surgical specialists are registered with National Specialist Register (NSR).
- 15.3. Resident Nephrologists
- i. Has documented experience and training in the management of renal transplantation;

- ii. In possession of duly recognised professional degree and postgraduate certificates;
- iii. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate); and
- iv. There shall be at least 2 Nephrologists trained in the management of renal transplant recipients and donors.

15.4. Renal procurement team (donor)

(a) Consultant Urologist/Surgeon

- i. Had assisted in at least 5 donor nephrectomies;
- ii. Had performed the first 3 donor nephrectomies with a Senior Colleague/Trainer as a first assistant;
- iii. In possession of a duly recognised professional degree and postgraduate certificates;
- iv. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate); and
- v. Exhibited a commitment and dedication to transplant services.

(b) Anaesthetist

- i. Had renal transplant related work experience;
- ii. In possession of a duly recognised professional degree and postgraduate certificates;
- iii. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate); and
- iv. Exhibits commitment and dedication to transplant services.

(c) Registered nurse with post basic training in perioperative care

- i. In possession of recognised related qualifications, registration and annual practicing certificates; and
- ii. Dedicated to transplant services.

15.5. Renal transplant team (recipient)

(a) Resident Transplant Surgeon

- i. Completed formal Urological training at a recognised institution either locally or overseas. By virtue of this, recognised by the Board of Urology and/or NSR certified;
- ii. Working or attached to an accredited Renal Transplant Centre;

- iii. Have a documented long term interest and commitment to renal transplantation and willing to work closely as a team especially with fellow Nephrologists;
- iv. Assisted as a first assistant in at least 5 renal transplant operations either locally or overseas;
- v. Performed the first 3 renal transplant operations successfully under supervision of a senior colleague;
- vi. Shall be able to perform the renal transplant operation independently;
- vii. Able and available to manage any surgically related complications which arose from the renal transplant operations;
- viii. In possession of a duly recognised professional degree and postgraduate certificates; and
- ix. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate).

Note: **Resident Transplant Surgeon shall be responsible for the overall comprehensive management of both living donor and recipient. (In the case of deceased donors, the donor may be in a different, non-transplant hospital)*

(b) Resident Anaesthetist

- i. Had renal transplant related work experience;
- ii. In possession of a duly recognised professional degree and postgraduate certificates;
- iii. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate); and
- iv. Exhibits commitment and dedication to transplant services.

(c) Registered nurse with post basic training in perioperative care

- i. In possession of recognised related qualifications, registration and annual practicing certificates; and
- ii. Dedicated to transplant services.

15.6. Other healthcare professionals and technical staff

(a) Resident Radiologist

- i. Has experience and training in all aspects of evaluation of radiological assessment on donor and recipient whether pre-operative, intra operative and post-operative;

- ii. In possession of a duly recognised professional degree and postgraduate certificates;
- iii. In possession of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate);
- iv. Able and available to do emergency radiological assessment of the transplanted kidney including Doppler ultrasound assessment both intra operative and post operatively, and diagnostic procedures as required; and
- v. Shall be able to perform image guided, diagnostic and therapeutic procedures which may include but not limited to emergency nephrostomy tube insertion, allograft biopsy and percutaneous drainage procedures.

(b) Transplant Coordinator

- i. A registered nurse with the relevant experience; and
- ii. Dedicated to the transplant services.

(c) Registered nurse with post basic training in renal nursing

- i. Related work experience and training in dialysis; and
- ii. In possession of recognised related qualifications, registration and annual practicing certificates.

(d) Registered nurse with post basic training in intensive care

- i. In possession of recognised related qualifications, registration and annual practicing certificates.

(e) Pharmacist

- i. Shall have experience in the use of immunosuppressive therapy in transplantation;
- ii. Shall be able to do and interpret therapeutic drug monitoring of drugs used in transplantation; and
- iii. Shall provide counselling and monitoring services to ensure medical adherence.

STANDARD OPERATING PROCEDURES (SOP)

16. Every renal transplant centre shall have SOP which shall be made available and readily accessible to all personnel and inspector as stated below but not limited to:

- 16.1. SOP and policies of management of any complication; before, during and after the transplant operation;
- 16.2. SOP and management on handling of the kidney before being transplanted to the recipient; and
- 16.3. SOP and policies of management of what will be done to the kidney should the kidney be removed from the donor but unable to be transplanted to the recipient.

HOW TO APPLY

17. A new private hospital (applicant) may apply to establish and/or to provide the renal transplant facilities and services through procedures *(available on the Medical Practice Division's website, <http://medicalprac.moh.gov.my>, click CKAPS then Pendaftaran, Kelulusan dan Pelesenan)* stated as follows:
 - 17.1. Application of no objection on location (**zoning approval**) of a private hospital (submitted with renal transplant service).
 - Please refer to "Garis Panduan Permohonan Kelulusan Zoning (Lokasi) bagi Penubuhan Hospital Swasta"
 - 17.2. Application of approval to establish or maintain (**Form 1**) of a private hospital (with renal transplant service).
 - Please refer to "Prosedur Permohonan-Permohonan berkaitan Perakuan Kelulusan dan Lesen bagi Hospital Swasta dan Senarai Semak Borang 1 Hospital Swasta"; and
 - 17.3. Application for a licence to operate or provide (**Form 3**) of a private hospital (with renal transplant service).
 - Please refer to "Prosedur Permohonan-Permohonan berkaitan Perakuan Kelulusan dan Lesen bagi Hospital Swasta dan Senarai Semak Borang 3 Hospital Swasta".
18. An existing licensed private hospital (applicant) may apply to establish and/or to provide the renal transplant facilities and services through procedures stated as follows:

18.1. Application for extension or alteration (**Form 5**) to a licensed private hospital.

- Please refer to “Prosedur Permohonan-Permohonan berkaitan Perakuan Kelulusan dan Lesen bagi Hospital Swasta dan Senarai Semak Borang 5 Hospital Swasta”; and

18.2. Application to amend the particulars of Licence (**in writing**) of a private hospital. Applicant have to submit information and documents as stated below:

- (a) Written application to the Director General of Health to add on the renal transplant facilities and services.
- (b) Authorisation letter to the applicant to apply for and signed by the board of directors ($\geq 51\%$).
- (c) Certified true copy of national identity card of the applicant.
- (d) Details and support documents for every professional and paraprofessional providing the renal transplant services
 - i. Details of every professionals (registered medical practitioner) (*name, IC number, date of birth, gender, race, nationality, residential address, principal place of practice, telephone number, professional qualifications, MMC registration number, annual practicing certificate number, work experience in renal transplant service, and work status either full time, visiting, locum or honorarium*);
 - ii. Details of every nursing staff and other healthcare professionals according to category and ratio (*name, IC number, date of birth, gender, race, nationality, professional qualifications, registration number and annual practicing certificate number with a regulatory board (if related), work experience in renal transplant service, and work status either full time, part time or volunteer*);
 - iii. Details of every paraprofessional staffs according to category and ratio (if related) (*name, IC number, date of birth, gender, race, nationality, related qualification, registration number and annual practicing certificate number with a regulatory board (if related), work experience in renal transplant service, and work status either full time, part time or volunteer*);
 - iv. Agreement letter from an affiliated specialist (if related);

- v. Certified true copies of professional and postgraduate certificates; and
 - vi. Certified true copies of professional registrations certificates (full registration with MMC, annual practicing certificate and NSR certificate).
- (e) Original licence of the private hospital.
- (f) Processing Fee of RM300 in the form of money order or bank draft made payable to 'Ketua Setiausaha Kementerian Kesihatan Malaysia'.

OTHER MATTERS

19. Unrelated Living Organ Donation – Policy and Procedures is applicable to renal transplant involving unrelated living donor.

REFERENCES

1. Private Healthcare Facilities And Services Act 1998 [Act 586]
2. Private Healthcare Facilities And Services (Private Hospitals And Other Private Healthcare Facilities) Regulations 2006 [P.U. (A) 138/2006]
3. Malaysian Society of Nephrology newsletter 2/2002 (July 2002)
4. Unrelated Living Organ Donation – Policy and Procedures, Transplantation Unit, Medical Development Division, Ministry of Health (2011)