



## KEMENTERIAN KESIHATAN MALAYSIA

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### ARAHAN KETUA PENGARAH KESIHATAN BILANGAN 2 TAHUN 2016

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

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### GARIS PANDUAN UNTUK MENUBUHKAN DAN/ATAU MENYEDIAKAN KEMUDAHAN DAN PERKHIDMATAN *WATER IMMERSION* DAN/ATAU *WATER BIRTH* DI HOSPITAL SWASTA

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#### TUJUAN

1. Arahan ini ditujukan untuk memberi panduan kepada pemohon atau pemegang lesen hospital swasta yang hendak menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan *water immersion* dan/atau *water birth* di hospital swasta bagi memastikan bahawa –
  - 1.1. hospital swasta tersebut mengikut piawaian dan keperluan yang ditetapkan oleh Kementerian Kesihatan Malaysia (Kementerian) bagi menjamin keselamatan dan kualiti jagaan kesihatan pesakit;
  - 1.2. rawatan hanya boleh dilakukan di hospital swasta yang telah mendapat kelulusan dan dilesenkan dari Kementerian untuk menyediakan kemudahan dan perkhidmatan *Water Immersion* dan/atau *Water Birth* tersebut; dan
  - 1.3. rawatan hanya boleh diberikan oleh pengamal perubatan dan dibantu oleh profesional jagaan kesihatan yang mempunyai latihan dan pengalaman untuk menyediakan perkhidmatan *Water Immersion* dan *Water Birth* (*Credentialed and Privileged by Ministry of Health in collaboration with relevant healthcare professional bodies*).

## LATAR BELAKANG

2. Akta 586 dan peraturan-peraturannya mula dikuatkuasakan pada 1 Mei 2006.
3. Garis panduan "*Guidelines to Establish and/or Provide Water Immersion and Water Birth Facilities & Services in Private Hospitals*" bertarikh 29 Julai 2016 ini diwujudkan bagi menjelaskan secara terperinci keperluan khusus bagi menyediakan kemudahan dan perkhidmatan *water immersion* dan *water birth* di hospital swasta.
4. Selaras dengan konsep "*primum non nocere, first, do no harm*", Kementerian sentiasa memberi keutamaan supaya keselamatan pesakit terpelihara dan kualiti jagaan kesihatan yang disediakan untuk pesakit sentiasa terjamin.

## SUMBER KUASA

5. Arahan ini disediakan selaras dengan peruntukan Akta 586 seperti berikut:
  - 5.1. **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.
  - 5.2. **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

6. Arahan ini adalah terpakai ke atas hospital swasta yang berhasrat untuk menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan *water immersion* dan *water birth* dan mendapatkan lesen atau berlesen di bawah perenggan 19(a), Akta 586.

## PEMATUHAN

7. Setiap pemohon atau pemegang lesen hospital swasta yang hendak menubuhkan dan/atau menyediakan kemudahan dan perkhidmatan *water immersion* dan *water birth* di hospital swasta perlu mematuhi garis panduan ini.

## GARIS PANDUAN

8. Sebagai panduan untuk pemohon dan pegawai proses, garis panduan telah disediakan oleh Kementerian bertajuk "*Guidelines to Establish and/or Provide Water Immersion and Water Birth Facilities & Services in Private Hospitals*" dated 29 July 2016 (rujuk Lampiran).

## TARIKH KUAT KUASA

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



**DATUK DR. NOOR HISHAM BIN ABDULLAH**

Ketua Pengarah Kesihatan Malaysia

Tarikh: 21 NOV 2016

**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  
WATER IMMERSION AND/OR WATER BIRTH  
FACILITIES & SERVICES  
IN PRIVATE HOSPITALS**

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

**29 JULY 2016**

## **WORKING COMMITTEE**

**The final meeting was done on 22 July 2016.**

Datuk Dr. Jeyaindran Tan Sri Sinnadurai  
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Deputy Director General of Health (Medical)  
Ministry of Health

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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 1<sup>st</sup> 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 and/or provide water immersion and water birth 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.
4. Those private hospitals licenced with water immersion and water birth facilities and services shall be fully responsible to ensure the facilities and services are provided by qualified, trained, experienced and skilled healthcare professionals. The consultant in-charge is responsible to comply with the guidelines.

## **OBJECTIVES**

5. To provide guidance for the applicant and processing officer in Private Medical Practice Control Section (CKAPS), Medical Practice Division in relation to establish and provide water immersion and water birth facilities and services in private hospital.
6. To ensure water immersion and water birth facilities and services provided by the private hospitals are in accordance to the standard and requirements set up by the Ministry of Health to ensure patient safety and quality of care.

## **REQUIREMENTS ON FACILITIES AND SERVICES**

7. The facilities intended or intends to be established and provided in the private hospitals shall comply with the Regulations, listed as below:
  - 7.1. Part X: General Provisions for Standards of Private Healthcare Facilities or Services, P.U. (A) 138/2006;

- 7.2. Part XI: Standards For Obstetrical Or Gynaecological Care, P.U. (A) 138/2006 with additional requirements for the Labour-Delivery Room as stated below:
    - (a) Minimum dimension of each labour-delivery room shall be at least 3.7m with a minimum clear area of at least 17.0m<sup>2</sup> exclusive of fixed or movable cabinets and shelves, patient's bed, resuscitation equipments and area for mother and baby; and
    - (b) Easily accessible to Operation Theatre;
  - 7.3. Part XII: Standards For Newborn Nursery Facilities, P.U. (A) 138/2006;
  - 7.4. Part XIII: Standards For Paediatric Patient Care, P.U. (A) 138/2006;
  - 7.5. Part XIV: Standards Relating To Anaesthesia, P.U. (A) 138/2006;
  - 7.6. Part XV: Standards For Surgical Facilities and Services, P.U. (A) 138/2006;
  - 7.7. Part XVI: Special Requirements For Critical Care Unit or Intensive Care Unit, P.U. (A) 138/2006;
  - 7.8. Part XIX: Special Requirements For Central Sterilizing and Medical-Surgical Supply Facilities and Services, P.U. (A) 138/2006; and
  - 7.9. Part XXIX: Miscellaneous P.U. (A) 138/2006.;
8. Other healthcare facilities and services that are required to be provided by the private hospital, shall include but not limited to:
- 8.1. Inpatient facilities & services
    - (a) Obstetrics & Gynaecology;
    - (b) Neonates/Paediatric; and
    - (c) Critical Care.;
  - 8.2. Support facilities & services
    - (a) Anaesthesia;
    - (b) Nursing (*post basic*);
    - (c) CSSD;
    - (d) Blood bank/Access to blood bank services;
    - (e) Laboratory:
      - (i) Routine clinical blood investigations; and
      - (ii) Microbiology.;



- 8.3. Outpatient Facilities & Services:
  - (a) Obstetrics & Gynaecology; and
  - (b) Neonatology/Paediatric.; and
  
- 8.4. Emergency Services
  - (a) The private hospital shall provide immediate emergency care services which include life-saving procedure.
  - (b) They must have the ability to treat any emergency that may arise to either the mother or the baby during and after the process of labour.

## **REQUIREMENTS ON EQUIPMENT**

9. Pool finishes shall be of non-toxic material, easy to clean and maintain, non-skid, and access to good drainage system.
  
10. Adequate treated water supply with water depth up to mother's fundal height and pool water temperature maintained at 37°C – 37.5°C.
  
11. Appropriate equipment (capable of underwater foetal monitoring) which can be used to monitor both mother and foetus during the process of labour. Foetal surveillance should be done with intermittent auscultation using a hand held Doppler device or electrical foetal monitoring using wireless telemetry.
  
12. Minimal resuscitation equipment for neonates:
  - (a) Resuscitation warmer, towel, or blankets;
  - (b) Bulb syringe, mechanical suction and suction tubing, 10F and 12F suction catheter;
  - (c) Meconium aspirator;
  - (d) Infant stethoscope;
  - (e) Oxygen tubing, mask for term and preterm babies, oxygen;
  - (f) Self-inflating bag with reservoir or T-piece resuscitator with appropriate adapter;
  - (g) Pulse oxymeter and probe for newborn use;
  - (h) Laryngoscope with straight blade size 0 and size 1;
  - (i) ETT tube sizes 2.5, 3.0 and 3.5;
  - (j) Stylet (optional);
  - (k) Scissors, securing tape;
  - (l) Medication – adrenaline 1:10000, normal saline 500mls, naloxone;
  - (m) Assorted syringes, needles;
  - (n) Chemically activated warming pad or food grade plastic wrap (for keeping preterm infant warm);

- (o) Transport incubator;
- (p) Portable oxygen and air cylinders; and
- (q) Equipment for emergency placement of umbilical venous catheter (optional).

## REQUIREMENTS ON PERSONNEL

10. There shall be **at least 1 resident O&G specialist** with relevant qualification, training, experience and skills in water immersion and water birth (*\*Credentialing & Privileging*)
11. The list of healthcare professionals shall include but not limited to:
  - (a) One (1) resident Obstetric & Gynaecologist;
  - (b) One (1) resident Paediatrician;
  - (c) One (1) resident Anaesthetist;
  - (d) One (1) registered nurse with post basic training in midwifery for each patient at all times;
  - (e) One (1) registered nurse with post basic training in perioperative care for each patient at all times; and
  - (f) One (1) registered nurse with post basic training intensive care for each patient at all times.
12. Detailed criteria for each healthcare professional mentioned above, are as listed below:
  - 12.1. All healthcare professionals are registered with a valid practicing certificate under the 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.
  - 12.2. All medical practitioners shall be a registered medical practitioner who is registered under the Medical Act 1971 [*Act 51*] and holds a valid annual practicing certificate (APC) and registered with the National Specialist Register (NSR).
  - 12.3. Resident Obstetric & Gynaecologist
    - (a) Has documented training and experience in providing water immersion and water birth facilities and services (*\*Credentialed and privileged*);
    - (b) In possession of duly recognised professional degree and postgraduate certificates; and
    - (c) In possession of professional registrations certificates (full registration with MMC, APC and NSR certificate).

- 12.4. Resident Paediatrician
- (a) In possession of duly recognised professional degree and postgraduate certificates; and
  - (b) In possession of professional registrations certificates (full registration with MMC, APC and NSR certificate).
- 12.5. Resident Anaesthetist
- (a) In possession of duly recognised professional degree and postgraduate certificates; and
  - (b) In possession of professional registrations certificates (full registration with MMC, APC and NSR certificate).
- 12.6. Registered nurse (with post basic in midwifery) with related work experience and training in water immersion and water birth
- (a) Has documented training and experience in providing water immersion and water birth facilities and services (\*Credentialed and privileged); and
  - (b) In possession of related qualifications, registration and APC;
- 12.7. Registered nurse with related work experience and training in intensive care nursing (post basic in intensive care)
- In possession of related qualifications, registration and APC.
- 12.8. Registered nurse with related work experience and training in neonatal nursing care (post basic in neonate)
- In possession of related qualifications, registration and APC.
- 12.9. Registered nurse with related work experience and training in perioperative care (post basic in perioperative)
- In possession of related qualifications, registration and APC.

### **REQUIREMENTS ON STANDARD OPERATING PROCEDURES (SOP)**

13. Every centre shall have SOP and be made available and readily accessible to all personnel and inspector as stated below but not limited to:
- 13.1. SOP of patient's selection criteria
- (a) Inclusion criteria:
    - (i) Healthy women with uncomplicated pregnancy at 37 completed weeks to 40 weeks, spontaneous labour, including singleton pregnancy, cephalic presentation, not a carrier of/infected with HIV, Hepatitis B or Hepatitis C virus,

pre-pregnancy or at booking visit body mass index (BMI) equal or less than 35, previous uncomplicated pregnancy and delivery; and

- (ii) Adhere to healthcare professional's advice including regarding maternal monitoring, foetal monitoring and decision to abort the procedure.;

(b) Exclusion criteria:

- (i) Unhealthy women with/without complicated pregnancy, for example multiple pregnancy, abnormal lie, carrier of/infected with HIV, Hepatitis B or Hepatitis C virus, pre-pregnancy or at booking visit body mass index (BMI) equal or less than 35 previous complicated pregnancy or delivery and rupture of membrane more than 18 hours; and

- (c) The hospital may only accept the number of patients based on its capacity to cope with availability of its facility and staff.

13.2. SOP and policies on maintenance and cleaning of pool;

13.3. SOP and policies on infection control procedures including:

- (a) Birth attendants should not be allowed in the pool;
- (b) Protective clothing must be worn by birth attendants including long water tight gloves and aprons;
- (c) All birthing pools and other equipment (e.g. mirrors & thermometers) should be disposed of or thoroughly cleaned and dried after every use, in accordance with infection control policies; and
- (d) Disposable sieves should be made available to ensure the pool remains free from maternal faeces and debris.;

13.4. SOP and policies on monitoring of mother and foetus at appropriate intervals while immersed including:

- (a) Ensuring mother's temperature is not more than 37.5°C;
- (b) Adhering to current practice guidelines or Perinatal Care Manual by Ministry of Health Malaysia for low risk pregnancies; and
- (c) Foetal surveillance should be done with intermittent auscultation using a hand held Doppler device or electrical foetal monitoring using wireless telemetry.;

13.5. Management of the 3<sup>rd</sup> stage of labour should be done out of the pool;

- 13.6. SOP and policies on moving mothers out of the pool during 3<sup>rd</sup> stage of labour including measures to prevent hypothermia and risk of injuries to mother and staff from slippery floor;
- 13.7. SOP and policies on preventing hypothermia to babies;
- 13.8. SOP and policies on moving mothers out of the pool if maternal or foetal complications develop;
- 13.9. SOP and policies on management of obstetric and neonatal emergencies; and
- 13.10. Patient consent.

#### HOW TO APPLY (OBTAIN APPROVAL FROM MOH)

14. A new private hospital (applicant) may apply to establish and/or to provide the water immersion and water birth facilities and services through procedures stated as follows:
  - 14.1. Application of no objection on location (**zoning approval**) of a private hospital (submitted with water immersion and water birth facilities and services).
    - Please refer to “Prosedur Permohonan Kelulusan Zoning (Lokasi) bagi Penubuhan Hospital Swasta”.
  - 14.2. Application of approval to establish or maintain (**Form 1**) of a private hospital (with water immersion and water birth facilities and services).
    - Please refer to “Prosedur Permohonan-Permohonan berkaitan Perakuan Kelulusan dan Lesen bagi Hospital Swasta dan Senarai Semak Borang 1 Hospital Swasta”; and
  - 14.3. Application for a licence to operate or provide (**Form 3**) of a private hospital (with water immersion and water birth facilities and services).
    - Please refer to “Prosedur Permohonan-Permohonan berkaitan Perakuan Kelulusan dan Lesen bagi Hospital Swasta dan Senarai Semak Borang 3 Hospital Swasta”.
15. An existing licensed private hospital (applicant) may apply to establish and/or to provide the water immersion and water birth facilities and services through procedures stated as follows:

- 15.1. 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
- 15.2. 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 water immersion and water birth 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 para-professional providing the water immersion and water birth 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, registration number, APC number, work experience and \*credentialed & privileged in water immersion and water birth services, and work status either full time, visiting, locum or honorarium*);
    - (ii) Details of every nursing staff and other health care 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 and \*credentialed & privileged in water immersion and water birth services, and work status either full time, part time or volunteer*);
    - (iii) Details of every para professional 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 and \*credentialed & privileged in water immersion and water birth services, and work status either full time, part time or volunteer*);

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

**Note:** \*Credentialed & Privileged by Ministry of Health in collaboration with relevant healthcare professional bodies

## 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 Health Technology Assessment Section (MaHTAS) on Water Birth Executive Summary (2013)
4. National Health Service (NHS) on Guideline for the Management of Water Birth in Community (June 2014)
5. Royal College of Obstetricians and Gynaecologist/ Royal College of Midwives on Immersion in Water During Labour and Birth (April 2006)
6. The American College of Obstetricians and Gynaecologist and American Academy of Paediatrics on Immersion in Water During Labour and Delivery (April 2014)
7. The Royal Australian and New Zealand College of Obstetricians and Gynaecologist on Warm Water Immersion During Labour and Birth (July 2014)