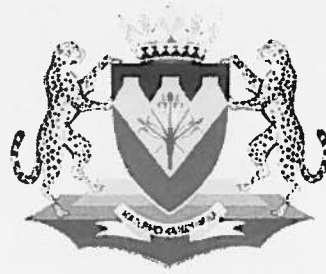


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PROVINCIAL NOTICE

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FOR COMMENT:

REGULATIONS GOVERNING PRIVATE HEALTH ESTABLISHMENTS, 2014

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PROVINCIAL NOTICE

[No. 60 of 2014]

FOR COMMENT: REGULATIONS GOVERNING PRIVATE HEALTH ESTABLISHMENTS

I, Dr Benjamin Malakoane, Member of the Executive Council responsible for Health in the Province, in terms of section 16(1)(i) of the Free State Hospital Act, 1996 (Act No. 13 of 1996), hereby publish the Regulations in the Schedule, for comment.

Interested persons are invited to submit comments or representations on the proposed Regulations not later than **18 August 2014** to:

The Head of Department
PO Box 227
4th Floor Block A West Bophelo House
BLOEMFONTEIN
9300

E-mail: FingerMJ1@fshealth.gov.za

Fax: (051) 408 1761

Any comments or representations received after the due date will be disregarded.

SCHEDULE

REGULATIONS GOVERNING PRIVATE HEALTH ESTABLISHMENTS

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Definitions

1. For the purposes of these Regulations, unless the context otherwise indicates –

“**acute care**” means short-term medical treatment, usually in a hospital, for patients having an acute illness or injury or conditions that may change within a few hours or days and that require prompt investigation, diagnosis and treatment, or recovering from surgery;

“**administrative control area**” means a room, separate from the nursing unit, with separate access, which is utilized for administrative control, enquiries, admission of patients and storage of records;

“**attending side**” means the side of a bed on the patient’s right hand side when lying supine;

“**B-BBEE Act**” means the Broad-based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

“**bed accommodation**” means the accommodation of clients, patients or mental health users in a bed, including day beds, cribs, cots and chairs in which the client, patient or mental health user receives clinical or psychiatric treatment for which intermittent or continuous clinical or psychiatric observation is required;

“**bed-count**” means the number of beds, including Intensive Care Unit beds, day beds, cribs and cots actually available for the accommodation of patients, but excluding trolleys;

“**chronic care**” means long term inpatient care and or treatment of patients relating to chronic conditions that require extended care of over 90 days;

“**clean utility room**” means a room in which separate and enclosed cupboard space is provided for the storage of clean linen, sterilised packs, dressings, sterile equipment and pharmaceutical supplies respectively;

“**cleaners’ room**” means a room for the storage of cleaning equipment, the drawing of clean water and the disposal of dirty water, washing and drying of cleaning equipment;

“**clinical**” in general, pertaining to observation, investigation, diagnoses and treatment of health conditions;

“**clinical hand washing-basin**” means a hands-free washing basin with hand drying facilities adjacent to it;

“**committee**” means the committee appointed in terms of regulation 7;

“**comprehensive inpatient rehabilitation unit**” means a facility that makes provision for therapeutic programs that enable the post-acute and medically stable patient, with remaining disabilities due to surgery, illness or trauma, to regain and maintain their optimal physical, sensory, intellectual and social functional levels, thus providing them with maximum levels of independence;

“**convalescent care**” means in-patient services for patients with medical conditions requiring nursing care of low intensity for a finite period of time, during which period improvement in the patient’s clinical condition is anticipated and the duration of admission is determined by improvement in the patient’s condition;

“**day beds**” means beds used for the accommodation of patients for a limited period of time and which does not include overnight accommodation;

“**day ward**” means a ward that accommodates patients in beds or chairs that require post-operative admission or observation, or other forms of care for any period less than 12 hours;

“**demarcated area**” means an area where access is both restricted and controlled to allow for maximum privacy and patient safety;

“**Department**” means the Provincial Department of the Free State responsible for health services;

“**dialysis facility**” means a facility that provides for haemo and peritoneal renal care;

“**dirty utility room**” means a room used for collection and temporary storage of used equipment and general ward material;

“**drainage area**” means the geographical area/s from which clients, patients or mental health users travel or are referred to for treatment;

“**emergency unit**” is a unit where emergency medical services are rendered to members of the public;

“**equipment store**” means a room used for the storing of monkey chains, traction kits and other general equipment;

“**floor area per bed**” refers to the bed area and the surrounding area dedicated to that bed;

“**floor area**” refers to the intended net floor area;

“**hand washing-basin**” means a hand washing-basin with hand drying facilities adjacent to it;

“**Head of Department**” means the head of the Department responsible for health services in the Free State;

“**height**” means the vertical dimension from the top of the finished floor to the underside of the ceiling;

“health establishment” means the whole or part of a private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;

“holding area” or **“induction room”** means an area or room where pre-operative patients in transit to a procedure room/theatre are identified, continuously monitored by nursing personnel and prepared for surgery/invasive procedures until such time as such patients are transferred to the theatre unit;

“hospice care” means multidisciplinary in-patient services or residential care specialised in the medical and psychosocial treatment of people who are terminally ill;

“impervious” means impenetrable to liquid substances;

“inpatient” means a patient admitted to a health facility for observation, investigation, diagnoses and treatment of a health condition;

“inspecting officer” means an official appointed in terms of the Public Service Act, 1994 or any duly authorised employee of a designated accreditation body, authorised in writing by the Head of Department to carry out inspections;

“level 1 care” means delivered by general practitioners, medical officers or a primary healthcare nurse in the absence of any specialist other than a family medicine specialist;

“level 2 care” means care that requires the expertise of specialist led teams which include general surgery, orthopaedics, general medicine, paediatrics, obstetrics and gynaecology, psychiatry, emergency medicine, radiology and anaesthetics;

“level 3 care” means care that requires the expertise of a specialist working in a registered sub-specialty;

“outpatient care” means services provided by and requiring the skills of a general medical practitioner, a medical specialist or an allied health professional to which patients are referred, usually by appointment, for more specialised opinions or care. These will include referrals to general medical or surgical etc outpatients as well as referrals to specialist clinics. They will also include referrals within a primary health care facility with or without appointment where these professionals deliver outreach services and/or where they provide services from private rooms or “surgeries”;

“licence” means a licence issued in terms of regulation 21;

“long-term care” means predominantly low-intensity nursing care of in-patients in whom significant improvement in clinical condition and a return to independent living is unlikely or for whom such improvement will occur over a period of long duration;

“**main kitchen**” means a facility equipped for the receipt, storage and preparation of meals, special diets and beverages;

“**maternity unit**” means a unit where babies are delivered and postnatal care is given to mothers and infants;

“**MEC**” means the Provincial Member of the Executive Council of the Free State responsible for health;

“**medical waste disposal**” means the safe, effective and hygienic disposal of medical waste;

“**minor theatre**” means an operating theatre in which minor surgical procedures are performed under local anaesthesia, anxiolysis, conscious sedation and deep sedation, but excluding regional and general anaesthesia;

“**non-acute care establishment**” means any health care establishment, whether of a multidisciplinary or a specifically nursing nature, providing care after or instead of acute hospitalisation to an in-patient either following an acute illness, injury or exacerbation of an existing illness or as a result of a long-standing chronic condition, and may include sub-acute care, rehabilitation care, step-down care, hospice care, convalescent care and long-term care;

“**non-attending side**” means the side of a bed opposite the attending side;

“**nurse station**” means the control point for all activities in the patient care areas;

“**operating room**” means a room within an operating theatre unit in which surgical or other invasive procedures are carried out;

“**operating theatre unit**” refers to rooms within the demarcated area where surgical interventions are performed or support is provided to these surgical activities;

“**plan dimensions**” means the horizontal dimensions between finished wall surfaces excluding projections;

“**private health establishment**” means a health establishment that is not owned or controlled by the state;

“**procedure room**” means a room in which certain restricted procedures generally taking less than one hour can be performed without making use of general anaesthetics, including suturing lacerations, endoscopies, local anaesthetics, removal of skin lesions, biopsies, closed reductions and other similar procedures;

“**recovery room**” or “**recovery area**” means the section of the operating theatre unit specially set aside for the immediate post operative recovery, resuscitation, nursing and special care of patients, until such time as such patients are considered to have recovered sufficiently to be safely removed from the operating theatre unit;

“**rehabilitation facility**” means supervised, goal-orientated, multidisciplinary health facility aimed at improving the level of functioning of a patient to the point where the patient may be discharged or moved to a different level of care and where the duration of admission is finite and is defined by the rehabilitation program;

“**sluice room**” means a room used for the emptying, cleaning and storage of bedpans and urine bottles;

“**soiled linen and waste room**” means a room used for the collection and temporary storage of soiled linen and waste;

“**special care facility**” means a designated room or rooms in which clients, patients or mental health care users are accommodated in order to receive constant, direct or indirect observation or clinical treatment by clinical personnel due to the unstable nature of their medical or psychiatric condition;

“**step-down facility**” means a facility that provides care for short-stay, transitional units, being a substitute for continued hospital stay and serving patients whose illness demands significant medical involvement and skilled nursing care of more than three hours on average per day, as well as pharmaceutical and laboratorial support;

“**sterilisation and disinfections unit**” means a facility for the receiving, decontamination, preparation, packing, sterilising, storing and issuing of sterile and disinfected instruments and other reusable materials;

“**sub-acute care**” means goal-orientated, comprehensive, co-ordinated and multidisciplinary health care for an in-patient immediately after or instead of acute hospitalisation for an acute illness, injury or exacerbation of a disease process requiring frequent patient assessment of the clinical course and treatment plan, and the duration of which is a limited period of time determined by the time taken for a condition to stabilise or for completion of a predetermined course;

“**visible building activities**” means an erf on which a foundation has been laid or a building structure, with progressive building, has been erected;

“**ward kitchen**” means the room that forms an integral part of a nursing unit or units, for the preparation of snacks and beverages but not the preparation and cooking of meals; it also includes the area for the heating, storage and refrigeration of meals.

Application of regulations

2. (1) Subject to regulation 31 and subregulation (2), these Regulations apply to all private health establishments in the Free State.
- (2) The MEC may grant a private health establishment exemption from all or any of the provisions of these Regulations, if good grounds exist for doing so.

- (3) The MEC may proclaim in the *Provincial Gazette* and designate certain areas in the Province as priority areas requiring establishment of private health facilities and declare other areas as oversubscribed.

Registration requirements of a private health establishment

3. (1) A person may not –
 - (a) erect, establish, maintain, manage or control a health establishment; or
 - (b) render or permit to be rendered a service in a private health establishment; or
 - (c) establish, maintain, control or manage Step Down Facility, Rehabilitation Facility, Dialysis Unit; or
 - (d) extend or alter a private health establishment or the service or services rendered in that establishment,

unless, such person's application in terms of subregulations (a), (b) or (c) has been approved and registered in the Register for Private Health Establishments as contemplated in regulation 15(7) and a licence has been issued in terms of regulation 20(3).
- (2) An approval granted in terms of this regulation is subject to Regulation 21(3), not transferable.
- (3) A license issued in terms of these Regulations is valid for one calendar year.

Application for registration of licence

4. (1) A person who wishes to obtain the registration of a private health establishment and the concomitant licence or the amendment thereof contemplated by regulation 3, must submit to the Head of Department an application on the appropriate form prescribed in Annexure "A" together with the prescribed supporting documents.
- (2) An application must be an original which must be hand delivered or mailed to the Office of the Head of Department.
- (3) An applicant may withdraw the application at any time and the Department is not liable for any costs incurred by the applicant.

Obtaining of additional information

5. (1) The Head of Department must within 7 working days of receipt of an application contemplated by regulation 4(1) consider the application to determine whether it has been properly completed or whether any additional information is required.

- (2) If the Head of Department decides that the application has not been properly completed or that additional information is required, he or she must in writing inform the applicant and request the applicant to rectify the application or supply the additional information required, as the case may be, by the date specified for this to be done.
- (3) If an applicant fails to correctly complete an application or to supply any additional information by the date specified by the Head of Department in terms of subregulation (2) or any extension granted, the applicant will be regarded as having withdrawn the application.

Publication and comments

6.
 - (1) The applicant must within 30 days prior to submission of an application for a license, publish notification in a section of a daily newspaper circulating in the area where the service exists or is to be provided or the project exists or is to be located.
 - (2) The notice must specify that any interested party has 30 days from the date of publication of notice to submit written comments to the Head of Department.
 - (3) The Head of Department must notify the applicant where comments have been received and provide the applicant with copies of the comments.
 - (4) No application may be accepted unless accompanied by proof that the publication has been made within the prior 30 day period.

Advisory Committee

7.
 - (1) The Head of Department must appoint an advisory committee.
 - (2)
 - (a) Appointment of members of the committee must be in writing.
 - (b) The Head of Department must appoint a chairperson from the members referred to in regulation 8 after consultation with the MEC.
 - (c) The Members must in the absence of the Chairperson appoint a Chairperson from among member to must preside over a meeting.

Composition of Members of the Advisory Committee

8. The Advisory Committee shall consist of at least 7 members who must have experience and knowledge in either of one of the following fields or qualifications:

- (a) Members of Senior Management of the Department with relevant expertise in –
 - (i) Standard Compliance;
 - (ii) Health Economics;
 - (iii) Finance;
 - (iv) Private Facilities;
 - (v) Law;
 - (vi) Infrastructure;
- (b) Any other person appointed by the MEC;
- (c) Co-opted members provided they will not have a casting vote; and
- (d) Standard Compliance Unit will provide Secretariat and administrative Support Unit to the Committee.

Functions of the Committee

- 9. (a) To provide advisory role regarding compliance and governance with regard to private facilities;
- (b) To recommend to the Head of Department regarding the outcomes of assessment on applications for private facilities licences;
- (c) To conduct inspections of facilities providing private health care and monitor the adherence to classification, number of beds, bed utilization, services rendered and compliance to prescribed norms and standards as well as quality of services;
- (d) To recommend to the Head of Department to consider approval or disapproval of applications;
- (e) To recommend to the Head of Department a partial or total closure of a private health care facility that violates the conditions of the licence and requirements specified for operation;
- (f) When considering an application, the committee must consider all relevant laws, by-laws, rules, regulations and ethical standards applicable to the application;
- (g) To render advice regarding policy development and review applicable health provincial legislation;

- (h) To adjudicate on all applications for licensing of private facilities;
- (i) To draw up and comply with the code of conduct for all its members;
- (j) To formulate and revise policies as the need arise;
- (k) To prepare annual reports and recommendations; and
- (l) To provide report of compliance of all licenced private facilities.

Meetings of the Committee

- 10.
- (1) At the first meeting of the committee, the chairperson must determine meeting procedures, and the committee must establish a code of conduct for members.
 - (2) The chairperson may, in the consideration of an application call upon any person to participate in the committee if the chairperson is satisfied that the person will be able to assist the committee to make a recommendation but that person may not vote.
 - (3) A quorum for a meeting is 4 members of the committee.
 - (4) A decision of the majority of members present at a meeting of the committee is a decision thereof, and in the event of an equality of votes the chairperson has a casting vote in addition to a deliberative vote.
 - (5) The members of the committee must declare their interest before the meeting.

Term of Office

- 11.
- (1) The term of office of the Advisory Committee is 5 years.
 - (2) A member of the Advisory Committee is eligible for re-appointment.
 - (3) A member may resign by giving 14 days written notice to the Head of Department of his or her intention to resign.
 - (4) The Head of Department may terminate membership of a member on good cause shown.
 - (5) If a vacancy occurs as a result of events stated at subregulation (3) and (4), the Head of Department must ensure that it is filled by appointing a replacement member qualified for the category of the vacant position.

Allowance for members of the Committee

12. (1) Members of the Committee who are not public servants will be given a sitting allowance for each sitting, which is determined by the MEC in consultation with the MEC for Finance; and
- (2) Members of the Committee who are public servants may submit their claims for reasonable and necessary subsistence and travelling allowances.

Prohibition concerning members of committee

13. (1) A member of the committee may not be present during, or take part in, any discussion of or the making of decisions or recommendations on, any application before the committee in which –
- (a) that member or a spouse, immediate family member, business partner, associate or employer (other than the State) of that member; or
- (b) a business partner, associate, immediate family member or employer (other than the State) of the spouse of that member, has a direct or indirect financial interest or had such an interest during the previous 12 months.
- (2) For the purpose of subregulation (1) –
- (a) “spouse” includes a person with whom the member lives as if they were married or with whom the member habitually cohabits; and
- (b) “immediate family member” means a parent, child, brother or sister, whether or not such a relationship results from birth, marriage or adoption.
- (3) A person may not, while he or she is a member of the committee, accept any form of employment, gift or reward from any person who has a direct financial interest in a Private Facility, or a person who has applied for a licence in terms of regulation 3.

Consideration of application

14. (1) When considering an application in order to determine whether there is a need for the proposed private health establishment the committee may take into account the following:
- (i) the need to ensure consistency of health service development in terms of national, provincial and municipal planning;
- (ii) the need to promote equitable distribution and rationalisation of health services with a view to correcting inequities based on racial, gender, economic and geographical factors;

- (iii) the need to promote an appropriate mix of public and private health care services with a view to the demographic and epidemiological characteristics of the populations to be served, the total and target population in the area, their ages and gender composition, their morbidity and mortality profiles;
- (iv) the need to promote the optimal use of spare capacity in provincial health establishments;
- (v) the need to promote the optimal mix of levels 1, 2 and 3 beds;
- (vi) the bed-to-population ratios and public-to-private bed ratios in the establishment's feeder areas and in the surrounding health district, region and province;
- (vii) the availability of alternative sources of health care;
- (viii) the need to promote high-quality services which are accessible, affordable, cost-effective and safe;
- (ix) the potential advantages and disadvantages of the application for existing public and private health services and for any affected communities;
- (x) the need to protect or advance persons or categories of persons designated in terms of the Employment Equity Act, 1998 (Act No. 55 of 1998) and the emerging small, medium and micro-enterprise sector;
- (xi) the potential benefits of training, research and development with a view to the improvement of health service delivery;
- (xii) the need to ensure that ownership of facilities does not create perverse incentives for health service providers to overservice patients or refer them inappropriately;
- (xiii) where applicable, the quality of health services rendered by the applicant in the past;
- (xiv) the probability of the financial sustainability of the health establishment or health agency;
- (xv) the need to ensure the availability and appropriate utilisation of human resources and health technology;
- (xvi) whether the private health establishment is for profit or not;
- (xvii) compliance by the holder with national operational norms and standards for health establishments and health agencies, as the case may be; and

- (xviii) any condition regarding –
 - (aa) the nature, type or quality of services to be provided by the health establishment or health agency;
 - (bb) human resources and diagnostic and therapeutic equipment and the deployment of human resources or the use of such equipment;
 - (cc) public private partnerships; and
 - (dd) types of training to be provided by the health establishment or health agency.

- (2) The Committee must adhere to the B-BBEE Principles in the processing of applications in the following manner:
 - (a) Applicants must comply with all five (5) Codes of the B-BBEE Code of Good Practice;
 - (b) The department will enforce strict compliance to all five (5) Codes of the B-BBEE Code of Good Practice;
 - (c) As part of the application process, applicants will be required to make a presentation to the Advisory Committee for verification of ownership and Management Control Codes;
 - (d) The Committee shall, when it is deemed necessary, conduct its own investigation during the processing of the application which may include interviews with the B-BBEE Partners/Directors;
 - (e) BEE Status, Level of contributor: Preference points will be awarded to an applicant for attaining the B-BBEE status level of contribution;
 - (f) Points in paragraph (e) above must be substantiated by means of valid B-BBEE certificate issued by an accredited verification agency;
 - (g) Consortium or Joint Venture must submit a consolidated B-BBEE status level Certificate;
 - (h) Any authorisation awarded on account of false information knowingly furnished by or on behalf of the applicant in respect of its broad-based black economic empowerment status or where there is fronting, will be cancelled.

- (i) The Department may, on its own discretion, advise or direct on change of ownership of the enterprise or change of management as a condition for processing of application in order to advance certain categories of persons in compliance with the B-BBEE Act.
- (3) Scoring and qualification criteria are set out in Annexure "C".

Committee's recommendations

15. (1) Subject to regulation 5.1, the committee must render its recommendation to the Head of Department within 30 working days of receipt of the application concerned.
- (2) The committee may, in respect of an application in terms of these Regulations, recommend to the Head of Department –
- (a) that the application should be granted, subject to certain conditions or unconditionally;
 - (b) that the application should be granted subject to conditions requiring –
 - (i) inspections or monitoring by the Inspectorate;
 - (ii) that appropriate data-reporting mechanisms on key indicators; or
 - (iii) that the applicant changes its ownership or Management to advance the principles of B-BBEE Act.
 - (c) that the application should be refused.

Head of Department's decision on application

16. (1) The Head of Department must, within 5 working days of receipt of a recommendation of the committee contemplated by regulation 13(1), decide the application by –
- (a) confirming the committee's recommendation; or
 - (b) reversing the committee's recommendation if there is sufficient reason for doing so; or
 - (c) in the event that the committee has recommended that the application should be approved subject to conditions, confirm the recommendation but may amend the conditions.
- (2) The Head of Department must, within 5 working days of receipt of a final recommendation in terms of subregulation (4), decide in accordance with subregulation (1) and inform the applicant accordingly.

- (3) If the application is refused or conditionally granted, give written reasons for the refusal and inform the applicant of the right of Appeal in terms of regulation 16.
- (4) If the Head of Department has confirmed the committee's recommendation that an application should be approved, the Head of Department must cause the private health establishment to be registered in a Register of Private Health Establishments and inform the applicant in writing that this has been done.

Appeal

17. (1) An applicant may lodge an appeal in writing with the MEC against any decision made by the Head of Department and must include the grounds of the appeal. An appeal must be lodged within 14 working days of being notified of the decision of the Head of Department.
 - (2) The MEC must, within 5 working days of receipt of an appeal, submit a copy thereof to the Head of Department and must request the Head of Department to respond to the appeal.
 - (3) The Head of Department must within 5 days of receipt of a copy of an appeal, submit a response thereto to the MEC.
 - (4) The MEC may appoint a committee to advise him / her on the appeal.
 - (5) The MEC may uphold or refuse an appeal and may, in the event that the appeal is upheld, replace the decision of the Head of Department with any decision to grant the application which the Head of Department could have taken.
 - (6) The MEC must communicate the decision on the appeal in writing to the appellant and, if the appeal is refused, give the reasons therefore.
 - (7) If the MEC upholds an appeal, this fact must be communicated in writing to the Head of Department who must make the necessary entry in the Register of Private Health Establishments.
 - (8) If the MEC has refused an appeal, he or she must advise the applicant of his or her right to take the matter on review in the High Court.

Submission of building plans

18. (1) If an application to erect or extend or otherwise alter a private health establishment has been approved, the building plans approved by the relevant Municipality must be submitted to the Head of Department within 12 months of the date on which the applicant was informed that the application had been approved.

- (2) If the building plans contemplated by this regulation are not submitted within the relevant 12 months, the approval of the application will lapse, but the Head of Department may, if good grounds exist, grant an extension of time not exceeding 12 months.
- (3) An application for the extension of time to submit building plans must be submitted to the Head of Department before the lapse of the initial 12 month period.
- (4) The building plans must be accompanied by a confirmation from the local authority that land is available for the purpose of erecting a private health establishment.
- (5) The building plans contemplated by subregulation (1) must show clearly the nature and construction of the building or buildings or the extension or alteration, as the case may be. All relevant services such as electrical, sewer, and mechanical, including the legend for the nature of services that will be provided by the health facility must be included in separate site plan layout.
- (6) Room names, dimensions and square measurements must be attached in the form of a schedule to the plan.
- (7) All plans must be drawn to the scale of 1:100 and must be submitted in duplicate.
- (8) The building plans must be drafted on the basis that the building or buildings or extension or alteration, as the case may be, when completed will comply with the specifications set out in Annexure "B" to these Regulations.
- (9) The applicant shall furnish the Head of Department with proof, in writing, that the local authority concerned has no objection to the private hospital or unattached operating-theatre unit being conducted on the premises concerned. In the case of a building still to be erected or converted, the applicant shall furnish proof, in writing, that the plan has been passed by the local authority concerned.

Approval of building plans

19. (1) The Head of Department must, within 30 working days of receipt of building plans contemplated by regulation 18, inform the person submitting the building plans in writing whether the plans are approved.
- (2) In the event that the Head of Department informs the person submitting the building plans that they are not approved, the Head of Department must supply written reasons therefor.
- (3) Approval of building plans by the Head of Department in terms of these Regulations does not free the person concerned from the requirements of any other law regarding the submission of building plans for approval.
- (4) No person may proceed with construction of the building unless building plans have been approved by the Head of Department.

Commencement of building activities

20. (1) Visible building activities must have commenced within 12 months of the date of approval of the building plans contemplated by regulation 19.
- (2) If the visible building activities –
- (a) have not commenced as required by subregulation (1); or
 - (b) having commenced as so required have ceased for a period of 12 months, both the approval of the original application and the approval of the building plans will lapse.
- (3) A building approved in terms of regulation 19(1) must be completed and inspected within a period of three years, failing which both the approval of the original application and the approval of the building plans will lapse and the Department shall not be held liable for any cost incurred by the applicant thus far.
- (4) The Head of Department may, if good grounds exist, grant an extension of time not exceeding 12 months for the completion and the inspection of the building.

Licence for private health establishment

21. (1) Once a private health establishment for which approval has been granted in terms of these Regulations has been finally constructed, the applicant must within 30 days of such completion, request the Head of Department in writing to inspect by a duly authorised inspecting officer, the establishment in order to establish that it meets with the specifications set out in Annexure "B".
- (2) The building may not be occupied before an inspection is done.
- (3) If the Head of Department is satisfied that a private health establishment contemplated by subregulation (1) meets with the specifications set out in Annexure "B", the Head of Department must issue to the applicant a licence for the private health establishment.
- (4) A licence contemplated by subregulation (3) must contain the following:
- (a) The name of the owner of the private health establishment;
 - (b) The name of the private health establishment;
 - (c) The geographical location of the private health establishment;
 - (d) Type of service or types of services to be rendered in the private health establishment;

- (e) The number of beds, theatres, procedure rooms and delivery rooms the private health establishment may operate;
- (f) The functional classification of beds permitted in the private health establishment; and
- (g) Any other condition which the Head of Department considers should be stated on the licence.

Amendment of licence and of building plans

22. (1) Where the holder of a licence has successfully applied for the extension, alteration or relocation of the private health establishment or the extension, alteration or relocation of the services to be rendered in that establishment and the relevant extension, alteration or relocation has been effected, that holder must submit the licence to the Head of Department with a request that the licence be amended accordingly.
- (2) If the Head of Department is satisfied that the extension(s), alteration(s) or relocation contemplated by subregulation (1) have been satisfactorily effected, the Head of Department must issue an amended licence to the holder concerned.
- (3) If the ownership of a private health establishment changes, the owner of the establishment must surrender the licence to the Head of Department who may re-issue a licence after being satisfied that the new applicant complies with the requirements for licensing.
- (4) The provisions of subregulation (3) apply, with the necessary changes, if the name of a private health establishment is changed.
- (5) If an applicant wants to amend his or her original building plans, he or she should submit such amended building plans to the Head of the Department before the lapse of the initial 12 month period by which time visible building activities should have commenced, as contemplated in regulation 20(1).
- (6) Where the holder of a licence wishes to amend his or her original building plans, the procedure as contemplated in regulation 18 would apply.

Display of licence

23. The person to whom a licence is issued must ensure that the licence is at all times displayed on the premises of that establishment that it is easily visible to members of the public.

Application for renewal

24. (1) An application for renewal of a licence to operate a private health establishment service shall be submitted not earlier than 90 days and not later than 60 days prior to the date of expiry of the licence. The application must be accompanied by proof of payment of fees as contemplated in Annexure "D".
- (2) On receipt of an application for renewal and prior to issuing a licence, the Head of Department shall cause an inspection to be made of the private establishment. The private health establishment shall be responsible for the costs of the inspection as contemplated in Annexure "D".
- (3) In addition to the inspection prescribed in subregulation (2), the Head of Department may cause periodic inspections to be made of any private establishment before or at any time after a licence is issued, provided the proprietor will not be responsible for the fees.
- (4) If the Head of Department is satisfied that the application for renewal meets the requirement, he/she must issue the applicant with a licence: provided that whenever such a licence is issued after 30 October, such a licence shall be issued for a period up to 31 December of the following year.

Findings and recommendations of inspecting officers

25. (1) Subject to patients' rights to privacy and confidentiality, the proprietor or the management of a private health establishment must render to an inspecting officer acting in terms of regulation 24 all information that the officer may require with regard to the organisation and management of that private health establishment and the accommodation, nursing and treatment of the patients. All registers, clinical records and any other records in connection with patients and staff must also be available for inspection. The inspecting officer may, if authorised by the Head of Department to do so, call for any other information, including but not limited to, facility performance data.
- (2) Subject to patients' rights to privacy and confidentiality, a person may not in any way obstruct any inspecting officer carrying out her or his inspection or refuse to furnish to the best of her or his knowledge any information requested by the officer or to show any apparatus or place or thing or to unlock any storage area.
- (3) A duly authorised inspecting officer acting in terms of regulation 24 must within 30 working days of completing an inspection submit a written report on the findings to the Head of Department and to the holder of the licence.

Fees

26. (1) An application for a licence must be accompanied by a fee of as set out in "Annexure D".
- (2) The fees referred to in Regulation 24(1) and (2) are as set out in Annexure "D".
- (3) The fee for the renewal of a licence becomes payable each year on completion of the annual inspection contemplated in regulation 24 (2).
- (4) Fees as contained in Annexure "D" are reviewable each year by the MEC in consultation with Member of the Executive Council responsible for Finance.
- (5) The MEC may exempt an applicant from payment of fees on good cause shown.

Liability insurance

27. The applicant shall maintain liability insurance with a limit of indemnity not less than R10 000 000.00 (Ten Million Rand) for any claim in respect of any neglect, error or omission on the part of the applicant in the performance of its obligations under these Regulations for the duration of the licence.

Closure of private health establishment or withdrawal of licence

28. (1) The proprietor of a private health establishment registered or regarded as being registered in terms of these Regulations must give not less than three months 'notice in writing of the intended closure of that facility to the Head of Department, but in exceptional circumstances, the Head of Department may authorise a shorter period of notice.
- (2) Subject to subregulation (3), the Head of Department may, after having considered the report of a duly authorised inspecting officer, decide to suspend the licence, close a facility or withdraw the licence if she or he is of the view that the private health establishment -
- (a) compromises patient safety;
 - (b) compromises staff safety;
 - (c) compromises public safety; or
 - (d) contravenes provisions of these Regulations or any other relevant provincial or national health legislation or policy.
- (3) Before closing the establishment the Head of Department must, unless it is an emergency, inform the establishment of the reasons for the proposed action and provide it with an opportunity to respond in writing thereto. The written response from the establishment must be delivered within 14 working days of receipt of the Head of Department's notice.

- (4) The Head of Department may only decide to close a private health establishment after considering the merits of the situation and concluding that the only available option is to close the private health establishment. This decision and the reasons therefore must be submitted by the Head of Department to the private health establishment within 14 working days after receiving the relevant written response to the notice contemplated by subregulation (3).
- (5) If a facility ceases to operate for more than 6 months, such facility shall be closed down, but the Head of Department may grant an extension if good grounds exist.
- (6)
 - (a) A person whose licence has been cancelled or suspended may at any time apply for the reinstatement of the licence or the lifting of its suspension.
 - (b) Regulation (3) applies, with the changes required by the context, in respect of an application for the reinstatement of a licence.
 - (c) Before the Head of Department reinstates a licence or lifts its suspension, an inspecting officer must inspect the Private Establishment concerned and make a recommendation to the Head of Department.

Sanctions and remedies

29. (1) If a registered private health establishment does not comply with –
- (a) any provision of these Regulations; or
 - (b) any condition of registration,
- the Head of Department must issue a written notice of the defect or non-compliance to the holder of the licence applicable to the establishment concerned.
- (2) A written notice of non-compliance issued in terms of subregulation (1) must state –
- (a) the nature and extent of the defect or non-compliance which must be rectified, and
 - (b) that failure to rectify the defect or non-compliance within the specified time will lead to the removal of the name of the private health establishment from the Register of Private Health Establishments.
- (3) In the event that, at the expiry of the time period specified in terms of subregulation (2)(b), the relevant defect or non-compliance has not been rectified to the satisfaction of the Head of Department, she or he may remove the name of the private health establishment from the Register of Private Health Establishments.

- (4) The Head of Department must in writing inform the person in control of a private health establishment which has been removed from the Register of Private Health Establishments of that fact and that the licence is no longer valid and must be returned to the Head of Department immediately.

Offences and penalties

30. Any person who contravenes a provision of these Regulations or fails to comply with Regulation 3 (1), 13 (3), 19 (4), 21 (2), 25 (1) and (2) thereof is guilty of an offence and on conviction is liable to a fine of R100 000.00 or to imprisonment not exceeding five years or both such fine and such imprisonment.

Maintenance of Records

31. (1) Every private health establishment shall ensure that written record relating to history, assessment and treatment of each patient are kept appropriately.
- (2) Each Private Establishment shall retain a copy of the records described in subregulation (1) for a period of 5 years from the date of service of the patient. In the case of minor children, for a period of 22 years.
- (3) The Head of Department may request routine statistics relating to the treatment of patients and, or clients, as the case may be, in health establishments registered in terms of these Regulations. The private health establishment must comply with such request.

Structural and installation requirements

32. Registered private health establishments must comply with the minimum structural and installation requirements that are set in Annexure "B".

Delegations

33. The Head of Department may delegate any power or function conferred or imposed upon her or him in terms of these Regulations to any official employed by the Department, except the power to decide an application in terms of these Regulations.

Repeal of legislation

34. The Regulations Governing Private Hospitals and Unattached Operating Theatre Units, Regulation R158 of 1 February 1980 published in *Government Gazette* No. 6832 of 1980, are hereby repealed in so far as they apply or relate to private hospitals and unattached operating-theatre units in the Province.

Transitional provisions

35. (1) (a) Subject to the provisions of subregulation (b), a health establishment which, at the commencement of these Regulations, was validly registered in terms of any applicable legislation, is deemed as being registered in terms of these Regulations.
- (b) Any alteration to a private health establishment referred to in subregulation (a) or the services rendered therein must be applied for in terms of these Regulations, the provisions of which apply to such alteration.
- (c) Applications for establishment of new private health facilities as well as applications for renewals must comply with the provisions of these Regulations.
- (2) The proprietor of a private health establishment not registered in terms of the regulations referred to in subregulation (1)(a) must within 90 days ensure that the private health establishment complies with the provisions of these Regulations, but the specifications set out in Annexure "B" serve only as guidelines and not as absolute requirements.

Savings

36. Any notice, order, decision, approval, permission, authority, information or document issued, made, granted or furnished and any other action taken under any provision of Regulation R158 must, if not inconsistent with the provisions of these Regulations, be deemed to have been issued, made, granted, furnished or taken under the corresponding provisions of these Regulations.

Short title and date of commencement

37. These Regulations are called the Private Health Establishment Regulations, 2014.