

**THE PROVINCE OF
GAUTENG**



**DIE PROVINSIE
GAUTENG**

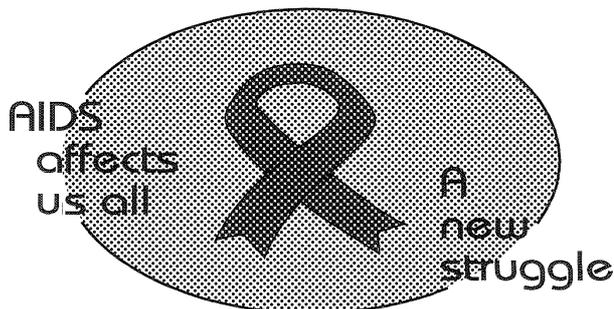
Provincial Gazette Extraordinary Buitengewone Provinsiale Koerant

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No. 51

We all have the power to prevent AIDS



Prevention is the cure

**AIDS
HELPLINE**

0800 012 322

DEPARTMENT OF HEALTH

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GENERAL NOTICES

NOTICE 700 OF 2015

DEPARTMENT OF HEALTH

HEALTH ACT, 1977

(ACT NO. 63 OF 1977)

**CALL FOR COMMENTS ON THE DRAFT REGULATIONS GOVERNING
PRIVATE HEALTH ESTABLISHMENTS, 2014**

The Member of the Executive Council responsible for health regulation in the Province intends to, under section 44 of the Health Act, 1977 (Act No. 63 of 1977), make the Regulations in the Schedule.

Interested persons and organisations are invited to submit written comments on the Regulations, within 30 days from the date of publication of this notice. Written comments must be forwarded to Ms Patience Ntamane:

(a) by post:

Ms. Patience Ntamane

Department of Health

Private Bag X 085

Marshalltown

2107; or

(b) by hand:

Ms. Patience Ntamane
Gauteng Department of Health
37 Sauer Street
Cnr Albertinah Sisulu and Sauer Str.
14th Floor , Room 1408
Bank of Lisbon Building
Johannesburg; or

(C) email to:

Patience.Ntamane@gauteng.gov.za

(d) fax to:

Ms. P. Ntamane
(0) 86 242 6375



MS. Q. D. MAHLANGU

MEC: HEALTH

GAUTENG PROVINCIAL GOVERNMENT

DATE 27/10/2014

NOTICE 701 OF 2015

SCHEDULE 1

FEES PAYABLE TO THE GAUTENG DEPARTMENT OF HEALTH UNDER THE REGULATIONS GOVERNING PRIVATE HEALTH ESTABLISHMENTS IN THE PROVINCE R_____

The MEC for Health, Gauteng Province, has in terms of regulation 30 (1) (a) of the Regulations prescribed the following fees payable in terms of the said Regulations

1. In this Schedule "the Regulations" mean the Regulations Governing Private Health Establishments: Gauteng Province R_____/2015 (PN _____/2015) and any expression to which a meaning is assigned in the Regulations shall bear that meaning, unless the context indicates otherwise.
2. The following fees non-refundable fees shall, under the Regulations, be payable to the Gauteng Department of Health.

(a)	the exemption from the Regulations (regulation 2(2))	R 5000.00 for the applicable financial year.
(b)	the application fee for provisional approval of a private hospital (regulation 9(1))	Based on the number of beds and disciplines applied for in section (k): (i) and curbing at the minimum payment of R 20.000.00
(c)	the application fee for provisional approval of a focused health care establishment licence (regulation 9(1))	Based on the number of beds and disciplines applied and for in section (k): (ii) and curbing at the minimum payment of R 10.000.00
(d)	Application for provisional approval of alterations to a focused health establishment (regulation 9(2))	R10.000.00
(e)	Application for provisional approval of alterations to a private hospital (regulation 9(2)) (aa) Reallocation of beds	R 20.000.00 R 350.00 per bed, conversion to ICU bed R 300.00 per beds; conversion to High Care bed R 265.00 per bed; conversion to gen350.00 per bed, ICU bed

	(bb) Additional beds	R 300.00 per bed; High Care be R 265.00 per bed; general bed general bed (disciplines)
	(cc) Application for Refurbishment	R 5000.00
(d)	fee for approval of building plans (regulation 14(2))	R 5000.00
(e)	fee for approval of building plans (regulation 14(2)) recurrent submissions.	R 3000.00
(f)	for final inspection and approval of as-built plans (regulation 15(1)(c))	R 10.000.00
(g)	for approval of transfer of change of ownership (regulation 16(2))	R10.000.00
(h)	for approval of transfer of a licence (regulation 16(2))	R 10.000.00
(i)	the issuing of a certified extract from a register (regulation 17)	R 1000.00
(j)	request for amendment of an entry in the relevant register which does not involve a prescribed application process (regulations 18(4) or 18(5))	R 1000.00
(k)	Minimum annual fees, payable not later than 31 October of each year by-	R 20.000.00
	(i) a private hospital (regulation 20)	
	(aa) general beds	R 265.00 per bed
	(bb) High Care beds	R 300.00 per bed
	(cc) ICU beds	R 350.00 per bed
	(dd) Theatres	
	• Major theatre	R 1000.00
	• Minor Theatre	R 700.00
	• Procedure room	R 500.00
	• Delivery room	R 500.00
	• Cardiac Catheterization	R 5000.00
	• EP Lab, Hybrid, Robotic etc	R 5000.00
	• Sleep lab	R 2000.00
	• ECT	R 500.00
	(ee) accident and emergency facility	
	• Level 1	R 2500.00
	• Level 2	R 1000.00
	• Level 3	R 500.00

	(ii) focused health care establishment (regulation 20) in the category-	R 10. 000.00
	(aa) crisis facility	R 265.00 per bed
	(bb) day surgery facility	R 350.00 per bed
	(cc) dialysis / renal facility	R 500.00 per bed / couch/ bunker/ recliner
	(dd) midwife obstetric facility	R 300.00 per bed
	(ee) oncology treatment facility	R 500.00 per bed / couch/ bunker/ recliner
	(ff) psychiatric facility	R 265.00 per bed
	(gg) rehabilitation facility	R 265.00 per bed
	(hh) step-down facility	R 265.00 per bed
	(ii) sub-acute care facility	R 265.00 per bed
	(jj) termination of pregnancy facility	R 265.00 per bed
(l)	application fee for amendment of an existing license (regulation 9(2))	R 1000.00
(m)	a fee for restoration of the name of a licensed private health establishment to the relevant register (regulation 23)	R 1000.00
(n)	additional pre-licensing inspection fee-	
	(i) provisional approval	R 1000.00
	(ii) final approval	R 1000.00
(o)	post-licensing ad-hoc / on request inspection fee	R 1000.00
(p)	for lodging an appeal (regulation 29(6)(a))	R 5000.00
(q)	Failure to submit annual returns	R 1000.00
(r)	Failure to collect practising licence by 31 st January of each year	R 5000.00

“ An application fee of R 10 000.00 for new establishments must accompany all applications, R 10 000.00 for applications related to refurbishment, and alteration of existing facilities and R 10 000.00 for additional beds and later fees payable per bed (for additional and reallocation) will be applicable and different bed rates will be applicable as reflected in the table.

OFFENCES AND PENALTIES

Any person who contravenes a provision of these Regulations or fails to comply with any provision thereof is guilty of an offence and on conviction is liable to a fine not exceeding R 100 000.00 or imprisonment not exceeding five years or both such fine and imprisonment.

NOTICE 702 OF 2015
DEPARTMENT OF HEALTH

HEALTH ACT, 1997

(Act No. 63 of 1997)

REGULATIONS GOVERNING PRIVATE HEALTH ESTABLISHMENTS, 2015

The Member of the Executive Council responsible for health in the Province has, in terms of section 44 of the Health Act, 1977 (Act No. 63 of 1977), as assigned to the Province by Proclamation No. 152 of 1994, made the Regulations in the Schedule.

SCHEDULE

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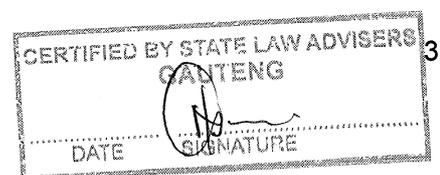
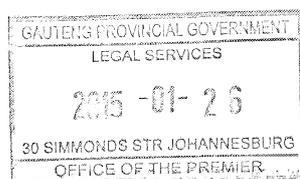
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CHAPTER 1
DEFINITIONS, APPLICATION AND EXEMPTION AND CATEGORIES OF PRIVATE
HEALTH ESTABLISHMENST

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act has that meaning unless the context indicates otherwise -

"**advisory committee**" means the committee appointed in terms of Regulation 4;

"**appeal committee**" means the committee appointed in terms of Regulation 31;

"**as-built plans**" means building plans of the completed private health establishment which comply with the requirements of Regulation 14(3) in respect of a licensed private health establishment and which are submitted in terms of Regulation 15(1)(b);

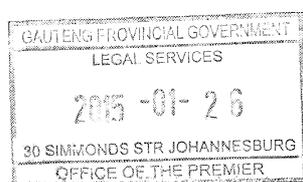
"**building plans**" means the proposed building plans to erect a private health establishment for which provisional approval has been granted in terms of Regulation 13 and which comply with the requirements in Regulation 14(3) and are submitted and approved in terms of regulation 14(5);

"**committee of inquiry**" means a committee appointed in terms of Regulation 27 to conduct an inquiry into unacceptable service delivery or contravention of these Regulations;

"**Department**" means the Department responsible for health services in the Province;

"**focused health care establishment**" means any place, other than a private hospital, at which health care services are provided to members of the public, and includes the following facilities recognised as sub-categories of focused a health care establishment, for purposes of licensing them in terms of these Regulations and prescribing minimum technical requirements with which such facilities have to comply with:

- (a) day surgery facility;
- (b) dialysis facility;
- (c) midwife obstetric facility;
- (d) oncology treatment facility;
- (e) psychiatric facility;
- (f) rehabilitation facility;
- (g) sub-acute care facility;
- (h) termination of pregnancy facility;



- (i) such other focused health care facilities identified and acknowledged by the MEC by notice in the Provincial *Gazette*, and listed in Schedule 4;

"**full record**" refers to the minutes, the attendance register, the application letter, application form, comments and objections from the relevant stakeholders, and the recommendations and findings of the technical team;

"**HOD**" means the Head of the Department who is the authorised representative of the Department discharging the duties imposed on and exercising the powers conferred to the Department in terms of these Regulations;

"**inspecting officer**" means any person appointed by the HOD to perform inspections in terms of these Regulations;

"**licence**" means the written authority issued in terms of Regulation 15 to operate a private health establishment in the Province;

"**licensed beds**" means the high care-, intensive care-, medical-, obstetrics-, psychiatric-, or specialised beds licensed to a private health establishment in terms of these Regulations to accommodate adult patients or pediatric patients, and where applicable, neonatal patients and adolescent patients;

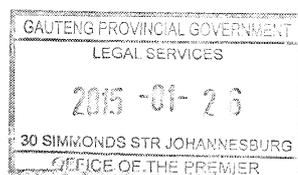
"**local authority approval**" means proof of zoning or rezoning of the land or proposed premises for the building of or conversion to a private health establishment;

"**MEC**" means the Member of the Executive Council responsible for health in the Province;

"**private health establishment**" means a private hospital or a focused health care establishment;

"**private hospital**" means any hospital, institution or facility at which provision is made for the treatment and care of cases requiring medical or surgical treatment and nursing care, and excludes—

- (a) a public health establishment as defined in section 1 of the National Health Act, 2003 (Act No. 61 of 2003);
- (b) any consulting room, surgery or dispensary of a medical practitioner or dentist which does not provide any bed accommodation;
- (c) a focused health care establishment licensed in terms of these regulations;



"**proforma complainant**" means the person appointed by the HOD in terms of these Regulations to represent the actual complainant and to present the complaint to the relevant committee in an informal or formal inquiry;

"**Province**" means the province of Gauteng;

"**provisional approval**" means the approval granted in terms of Regulation 13 to establish, alter or amend or to operate a private health establishment in the Province;

"**respondent**" means a private health establishment in respect of whom a complaint of unacceptable service delivery or contravention of these Regulations is being investigated in terms of Regulation 26 or cited as such in an appeal in terms of Regulation 31;

"**responsible person**" means a natural person who is appointed and nominated by the owner of a licensed private health establishment, is ostensibly in charge or in control of and is responsible and accountable for compliance with the provisions of these Regulations that establishment and liable for non-compliance or a person who is ostensibly in charge or in control of of an unlicensed business or premises operating as a private health establishment;

"**statutory authorities**" means approval of the site development plans by the relevant building approval entity, including the Road Agency, Water Board, City Parks, City Power or Eskom, Fire Department, Pick It Up, Environmental Management, Transportation, Building Controls, Land Use management or other relevant authorities;

"**the Act**" means the Health Act , 1977 (Act No. 63 of 1977) and includes these Regulations; and

"**unacceptable service delivery**" means delivery of a health care service in or by a private health establishment which does not comply with these Regulations or which does not comply with universally acceptable norms for delivery of such service.

Application of and exemption from regulations

2. (1) Subject to subregulation (2), these Regulations apply to all private health establishments in the Province.

(2) The MEC may, on application and payment of the fee prescribed in Schedule 1 and on good cause shown by, in his or her discretion and grant a private health establishment exemption in writing from any of the provisions of these Regulations and on the conditions and for the period the MEC may determine.



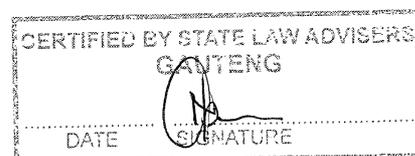
Categories of private health establishments

3. The MEC may by notice in the Provincial *Gazette* determine—
- (a) categories of private health establishments;
 - (b) minimum technical requirements for such categories for purposes of licensing private health establishments;
 - (c) conditions for licensing the various categories; and
 - (d) additional focused health care services for purposes of licensing a facility that provides such services as a separate additional focused health care establishment and of listing in terms of Schedule 2 and 4 of these Regulations.

CHAPTER 2 ADVISORY COMMITTEE

Appointment of Advisory Committee

4. (1) The MEC must appoint an advisory committee to evaluate and make recommendations to the HOD on applications submitted in terms of these Regulations and to advise the HOD on all matters concerning registration of private health establishments in the Province.
- (2) The advisory committee appointed in terms subregulation (1) must consists of at least—
- (a) one person appointed on account of his or her knowledge of the law, and without limiting the foregoing, knowledge of the fundamental rights in the Bill of Rights in Chapter 2, of the Constitution and national legislation required by and enacted in terms of Chapter 2 of the Constitution of the Republic of South Africa, 1996;
 - (b) one person appointed on account of his or her knowledge of the technical requirements prescribed in Schedule 2;
 - (c) two persons employed by the Department and nominated by the HOD;
 - (d) one person nominated by a recognised representative consumer body; and
 - (e) one person nominated by, on account of his or her knowledge of, the private health establishment industry in South Africa.



(3) The person contemplated in subregulation (2)(a) must be appointed as the chairperson of the advisory committee, and in his or her temporary absence, the members may choose one of the other members present amongst themselves to act as chairperson.

(4) if the person or body contemplated in subregulation(2)(d) or (e) fails to make a nomination, or to timeously make a nomination contemplated thereon, the advisory committee may nevertheless be duly constituted, and all acts performed by the advisory committee, without such member being nominated, are lawful and valid.

Procedure for meetings of Advisory Committee

5. (1) At the first meeting of the advisory committee, the chairperson must determine meeting procedures, and the committee must establish a code of conduct for its members.

(2) Subject to Regulation 4(4), a quorum for a meeting is 4 members of the advisory committee.

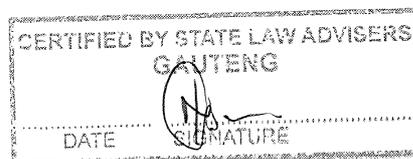
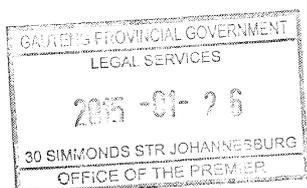
(3) A decision of the majority of members present at a meeting of the advisory committee is the decision of the committee, and in the event of an equality of votes the chairperson has a casting vote in addition to a deliberative vote, which he or she is not obliged to exercise.

(4) The chairperson may at any stage during the consideration of an application call upon any person to participate in the proceedings of the advisory committee if the chairperson is satisfied that that person will be able to assist the committee to better evaluate or make a recommendation: Provided that such a person may not vote on any matter: Provided further that such a person is not prohibited to participate by reason of the provisions of Regulation 7.

(5) The chairperson must ensure that a full record is kept of attendance, the proceedings and deliberations, and the recommendations made at any meeting of the advisory committee.

Powers and functions of Advisory Committee

6. (1) The advisory committee must consider and evaluate an application and all comments and responses received in respect of an application to determine whether there is a need for the proposed private health establishment and whether the application complies with the requirements for licensing of such establishment, and in doing so must take the applicable technical requirements prescribed in Schedule 2 and criteria prescribed in Schedule 3 into account.



(2) The advisory committee must make a recommendation to the HOD within 90 days of an application contemplated in subregulation (1) being referred to it.

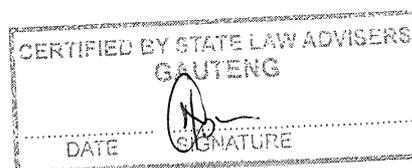
(3) The advisory committee may, in respect of an application in terms of these Regulations, recommend to the HOD—

- (a) that the application be approved;
- (b) that the application be approved subject to conditions which the committee considers appropriate, including but not limited to—
 - (i) the nature, type or quantum of services to be provided by the private health establishment;
 - (ii) requirements for insurance cover to be carried by such private health establishment and any health care practitioner in that private health establishment;
 - (iii) human resource requirements;
 - (iv) training to be provided to personnel at that private health establishment;
 - (v) type and frequency of monitoring to be done by the Department or a monitory officer;
 - (vi) grievance and complaints procedures for patients to be implemented and reporting obligations of such incidents to be complied with; or
 - (vii) data-reporting mechanisms on key indicators;
- (c) the type of licence that may be issued with regard to the categories and sub-categories of private health establishments which may be licensed in terms of these Regulations; or
- (d) that the application must be refused.

(4) The advisory committee must furnish the HOD with written reasons for its recommendation made in terms of subregulation (2) and (3).

Conflict of Interest

7. (1) A member of the advisory committee may not take part in any discussion, or the taking of a decision on an application serving before the advisory committee in which—



- (a) that member or his or her spouse, an immediate family member, business partner or an associate or employer, other than the State; and
- (b) a business partner or an associate, immediate family member or employer, other than the State, of the spouse, or an immediate family member of that member,

has a direct or an indirect financial interest or has had such an interest during the previous 12 months.

(2) A member of the advisory committee may not, while he or she is a member of the advisory committee—

- (a) accept any form of employment; or
- (b) accept a gift or any other benefit or remuneration ,

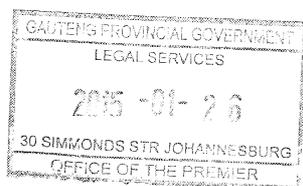
from a person who has a direct or indirect financial interest in a private health establishment or a person applying for a licence to operate a private health establishment.

(3) For the purpose of this Regulation—

“**business partner or associate**” means a person, whether personally or through his or her immediate family members, who has or obtains any interest in any business or enterprise that may conflict or interfere with the proper performance of that member’s functions as a member of the advisory committee;

“**immediate family member**” means a parent, sibling, child, including an adopted child or a step child (whether by statute, custom or religion), or spouse, and that includes a person who is separated from that member by no more than two degrees of natural or adopted consanguinity or affinity; and

“**spouse**” means a person who is the permanent life partner or spouse or civil union partner of a member in accordance with the Marriage Act, 1961 (Act No. 25 of 1961), the Recognition of Customary Marriages Act, 1998 (Act No. 120 of 1998), the Civil Union Act, 2006 (Act No. 17 of 2006), or the tenant of a religion.



CHAPTER 3 LICENSING

General requirements and conditions for licensing

8. A person may not—

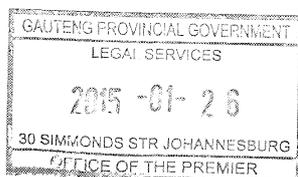
- (a) erect, establish, operate, maintain, manage, control or have a beneficial interest in or derive income from the operation of a private health establishment, or render or permit a health service which may only be rendered in a licensed private health establishment, unless that person or the establishment have been licensed in terms of these Regulations; or
- (b) extend, equip or in any way prepare any premises for use as a private health establishment or alter the conditions of the licence of a private health establishment, or extend or alter the service or services which that person is licensed to render in that establishment, or amend the type and number of licensed beds, unless the licensee has applied for the extension or alternation of the licence of that establishment or the extension or alteration of the service or services which are provided in that establishment and the licensee has obtained written approval from the HOD.

Licence application process

9. (1) A person who wishes to operate a private health establishment must submit an application and supporting documents as required in terms of the application form and pay the fee prescribed in Schedule 1 to these Regulations.

(2) A person licensed to operate a private health establishment who wishes to extend or alter the licensed facility, which extension or alteration will have an effect on the licensed service or services which are provided in that establishment, must submit an application to the HOD, together with the supporting documents as are required in terms of the application form and pay the fee prescribed in Schedule 1 of the Regulations.

(3) An application submitted in terms of subregulation (1) or (2) must be delivered by hand to the office of the HOD, and the applicant must obtain an acknowledgement of receipt in respect thereof.



(4) An applicant may in writing withdraw the application at any time before it has been adjudicated by the HOD.

Additional information

10. (1) The HOD must, within 30 days of receipt of an application contemplated in Regulation 9(1) or 9(2), review the application to determine whether it complies with these Regulations and the application form, and whether any additional information is required.

(2) If the HOD considers that the application has not been properly completed or that additional information is required, he or she must in writing notify the applicant of the nature of the non-compliance and request the applicant to correct or supply the additional information required, as the case may be, by the date specified in the notice.

(3) If an applicant fails to complete an incomplete application or to supply additional information by the date specified by the HOD in terms of subregulation (2), it must be deemed that the applicant has in terms of regulation 9(4) withdrawn the application.

Technical requirements

11. An application for a licence to establish or operate a private health establishment in the Province must comply with the applicable technical requirements prescribed in Schedule 2 read with the application form.

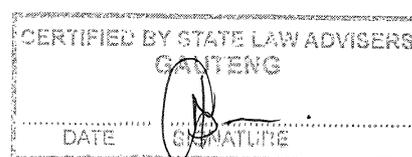
Publication for comment

12. (1) The HOD must, within 14 days of receipt of an application in terms of Regulation 9(1), publish a notice of the application and request written comments on the application in the Provincial *Gazette*.

(2) The notice must specify that an interested party has 30 days from the date of publication of the notice to submit written comments to the HOD.

(3) If written comments are received in terms of subregulation (2), the HOD must, within 10 days of the lapsing of the period permitted for the submission of the written comments—

- (a) notify the applicant in writing that written comments have been received;
- and



(b) provide the applicant with a copy of the written comments against payment of the fee prescribed in Schedule 1.

(4) The applicant has 15 days from receipt of the notice and the copy of the written comments in terms of subregulation (3), in which to respond in writing to the HOD, failing which it will be deemed that the applicant has opted not to respond and cannot hold the Department liable for any future dissatisfaction.

(5) The HOD must submit an application in terms of these Regulations to the advisory committee within 10 days of expiry of the notice period in subregulation (4) together with all the written comments and responses received in respect of an application.

Provisional approval

13. (1) The HOD must, within 30 days of receipt of the recommendation of the advisory committee contemplated in Regulation 7(3), decide on the application by—

- (a) accepting the committee's recommendation and provisionally approve the application;
- (b) not accepting the committee's recommendation and refuse the application and furnish reasons for doing so; or
- (c) in the event that the committee has recommended that the application should be provisionally approved subject to specified conditions, accepting the recommendation and provisionally approve the application or accept the recommendation but amend the conditions.

(2) The HOD may, prior to taking a decision in terms of subregulation (1), refer an application back to the committee for reconsideration of its recommendation, with reasons for doing so.

(3) The advisory committee must, within 30 days of receipt thereof, make a final recommendation on an application referred back to it in terms of subregulation (2).

(4) The HOD must, within 20 days of receipt of a final recommendation in terms of subregulation (3), decide on the application in accordance with subregulation (1).

(5) The HOD must, within 20 days of deciding on an application as contemplated in subregulation (1) or (4), inform the applicant in writing of the decision and, if the application is



refused, give written reasons for the refusal and inform the applicant of the right of appeal in terms of Regulation 31.

(6) If the HOD approves the application, he or she must issue the applicant with a provisional approval and cause it to be entered in the relevant register kept for that category of private health establishments and furnish the applicant with the signed original of such approval.

(7) A provisional approval issued in terms of this Regulation authorises the applicant to submit building plans for approval in terms of Regulation 14.

Building plans and approval

14. (1) The advisory committee must consider, evaluate and make recommendations to the HOD in respect of building plans submitted to it in terms of Regulation 14(4).

(2) Building plans for the erection, extension or alteration of a private health establishment must be submitted to the HOD, together with the application fee prescribed in Schedule 1, for approval within 6 months of obtaining the provisional approval in terms of Regulation 13 or approval in terms of Regulation 8(b), as the case may be.

(3) The building plans contemplated in subregulation (1) must—

(a) comply with—

- (i) generally accepted principles in the building industry
- (ii) SABS requirements, if applicable; and
- (iii) local authority requirements for approval of such plans.

(b) be drawn to a scale of 1:100;

(c) be submitted in duplicate;

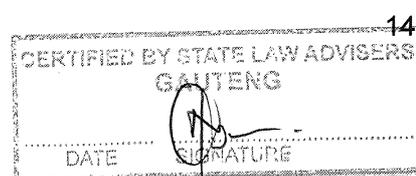
(d) indicate the treatment areas, room names, dimensions and measurements on the plans or in a schedule to the plans;

(e) reflect compliance with the technical requirements prescribed in Schedule 2 applicable to the private health establishment; and

(f) reflect the location of the licensed beds being applied for.

(4) The HOD must submit the building plans to the advisory committee for evaluation and for purposes of making recommendations to the HOD, and the advisory committee may recommend—

(a) that the building plans be approved with or without conditions; or



(b) that the building plans be rejected, and furnish written reasons for its recommendations.

(5) The HOD must, within 10 days of receipt of the recommendations of the advisory committee contemplated in subregulation (4), approve the building plans by—

- (a) accepting the committee's recommendations and approve the building plans with or without conditions;
- (b) not accepting the committee's recommendations and rejecting the building plans and furnish reasons for doing so; or
- (c) in the event that the committee has recommended that the building plans should be approved subject to specified conditions, accept the committee's recommendations and approve the building plans subject to those conditions or its own amended conditions.

(6) The HOD must, within 30 days of deciding on an application as contemplated in subregulation (1) or (4), inform the applicant in writing of the decision and, if the building plans are rejected, give written reasons for doing so and inform the applicant of the right of appeal in terms of Regulation 31.

(7) The applicant must furnish the HOD in writing, with proof that the building plans have been approved by other statutory authorities as may be required by the law.

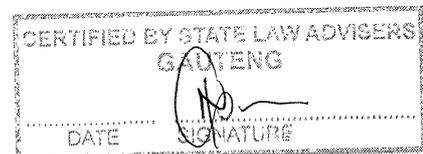
(8) No building operations to erect, alter or renovate a private health establishment may be commenced with until all the required statutory approvals have been obtained.

(9) If the building activities—

- (a) have not commenced within 12 months of the approval of the building plans in terms of these Regulations; and
- (b) having commenced as required, but have ceased for a period of 12 months,

both the provisional approval and the approval of the building plans will automatically lapse and will be regarded as having been cancelled, and the HOD must remove the entry in respect of the provisional approval of that private health establishment from the relevant register: Provided that the HOD may grant extension of time to comply.

(10) A person who has obtained provisional approval to operate a private health establishment in terms of Regulation 13 or approval of building plans in terms of Regulation 14(5), or a licensee, may request the HOD in writing and on payment of the fee prescribed in Schedule 1,



to carry out an inspection of the private health establishment during the course of the construction process.

(11) The HOD may, whenever necessary, in writing, request progress reports on the construction of the private health establishment, from the holder of the provisional approval.

Final approval and licensing

15. (1) A person who has obtained provisional approval to erect and operate a private health establishment in terms of Regulation 13 and approval of building plans in terms of Regulation 14(5) must —

- (a) in writing request the HOD to carry out an inspection of the completed private health establishment;
- (b) provide the HOD with as-built plans and copies of the approvals of all other statutory authorities required to be obtained within 90 days of the inspection report in terms of subregulation (3) being submitted; and
- (c) pay the prescribed inspection and evaluation fee,

for purposes of obtaining final approval for that private health establishment in terms of subregulation (4).

(2) The HOD must authorise a duly appointed inspecting officer to conduct an inspection on the private health establishment contemplated in subregulation (1)(a) within 30 days of receipt of the written request in subregulation (1)(a) in order to establish that the private health establishment meets the technical requirements in Schedule 2 and that it was erected in terms of the approved building plans.

(3) The inspecting officer referred to in subregulation (2) must submit his or her inspection report, together with a recommendation, to the HOD within 14 days of carrying out the inspection.

(4) The HOD must, within 30 days of receipt of the inspection report contemplated in subregulation (3), or the as-built plans in terms of subregulation 1(b), whichever is the latest, examine and evaluate the inspection report and the as-built plans with the assistance of any one or more of the members of the advisory committee, to ensure compliance with these Regulations, and if he or she is satisfied that the owner of the private health establishment comply with the provisions of these Regulations, issue the owner of the private health establishment with a final



licence subject to such conditions as he or she may deem appropriate and remove any note in the relevant register which refers to provisional approval.

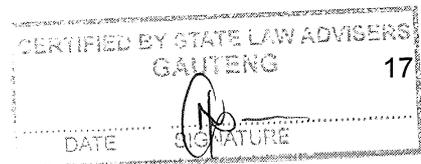
(5) If the private health establishment does not comply with these Regulations, the HOD must inform the owner of that private health establishment or responsible person thereof, and furnish written reasons for such finding and afford the owner an opportunity to rectify the as-built plans, the building or the facilities, and re-submit the as-built plans together with a written motivation why he or she is of the opinion that the private health establishment complies with the requirements for final approval and licensing in terms of these Regulations, within 45 days of receipt of the notice of non-compliance, and pay the re-submission and evaluation fee.

(6) The HOD must re-evaluate the re-submission, and if necessary, cause a further inspection to be carried out and finalise the adjudication process within 30 days of the date of re-submission and inform the owner of the private health establishment or responsible person in writing of his or her decision.

(7) A licence issued in terms of these Regulations must contain the following:

- (a) the name of the owner of the private health establishment;
- (b) the name of the responsible person and his or her contact details;
- (c) the name or trading title of the private health establishment approved by the HOD;
- (d) the physical address of the private health establishment;
- (e) the type of services which the private health establishment is licensed to render;
- (f) where applicable, the number of beds, theatres, procedure rooms and delivery rooms the private health establishment may operate;
- (g) the functional classification of beds permitted in the private health establishment; and
- (h) any condition imposed by the HOD.

(8) The licensee must ensure that the licence, together with a reference to the complaints procedure for unacceptable service delivery in terms of Regulation 28, is easily visible to members of the public, on the premises of the private health establishment.



(9) If final approval of a private health establishment is not obtained within 6 months of the first request in terms of subregulation (1)(a), then the provisional approval will lapse: Provided that the HOD may grant extension of time to comply.

CHAPTER 4 CHANGE IN OWNERSHIP

Application to transfer licence

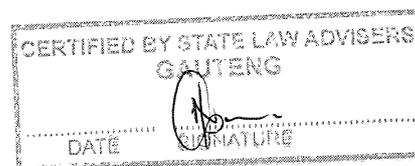
16. (1) A person licensed in terms of these Regulations to operate a private health establishment may transfer that licence to another person who is licensed to operate a private health establishment having regard to the provisions of these Regulations and the application form provided by the Department without having to prove the need for the first establishment.

(2) A person who wishes to purchase or otherwise obtain ownership of a private health establishment must—

- (a) complete an application form provided by the HOD;
- (b) provide the information and documentation required in terms of the application form in paragraph (a);
- (c) pay the transfer fee prescribed in Schedule 1;
- (d) provide such further or additional documentation as may be called for in writing by the HOD.

(3) The HOD must, after having conducted or having caused to be conducted an analysis and evaluation of the transfer of license referred to in subregulation (1), approve or refuse the transfer of the license to the transferee.

(4) The HOD must advise the transferee and the existing licensee of his or her decision in writing with reasons for such decision and, in the event of approving the application, must issue the transferee with a substitute licence to operate the specific private health establishment as registered in the applicable category determine in terms of Regulation 3, read with Schedule 4, with or without conditions.

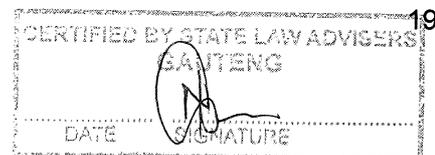
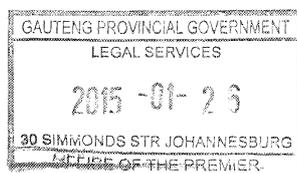


CHAPTER 5 MAINTENANCE OF REGISTERS

Registers

17. The HOD must keep registers—

- (a) for the various categories or sub-categories of private health establishments determined in terms of Regulation 3 in which the HOD must enter—
 - (i) the name and registration or identity number of the owner;
 - (ii) the date of first issue and licence number allocated by the HOD to the licence;
 - (iii) the trading title approved by the HOD;
 - (iv) the particulars of the managing director, the managing member or trustee of the owner;
 - (v) the physical address which appears on the licence from where the private health establishment is or is to be operated;
 - (vi) a postal address within the Province deemed to be the registered address for giving of notices in terms of these Regulations;
 - (vii) a telefax address for the licensee;
 - (viii) an electronic mail address for the licensee;
 - (ix) the particulars of the natural person responsible and accountable for compliance with these Regulations by the private health establishment and liable for non-compliance and his or her contact details;
 - (x) the number of licensed beds and the subcategories into which those beds are divided;
 - (xi) date of last inspection; and
 - (xii) such other information as the HOD may decide;
- (b) for private health establishments that have been exempted in whole or in part from compliance with these Regulations in terms of Regulation 2(2); and
- (c) of closed or cancelled licensed facilities.



Maintenance of registers

18. (1) Any entry into a register which is proved to the satisfaction of the HOD to have been made in error, through misrepresentation or in circumstances not authorised by these Regulations may be removed from the register: Provided that the licensee in respect of whose entry a removal is contemplated is notified and given an opportunity to furnish written reasons within 10 days why he or she or its name should not be removed from the register.

(2) The licence of a licensee removed from a register in terms of subregulation (1) must be deemed to be cancelled as from the date on which notice has so been given.

(3) The owner of the private health establishment or responsible person, managing director or manager licensed to carry on the business of operating a private health establishment must, within 30 days—

- (a) after the forwarding by the HOD of a written inquiry by registered mail to the licensee's registered address requesting information relating to—
 - (i) the occupancy rate of licensed beds with reference to the sub-categories referred to in the licence;
 - (ii) a change in the numbers of the sub-categories of medical-, surgical-, and specialised beds; and
 - (iii) the ownership or any direct or indirect beneficial interest in the licensee or the private health establishment,

furnish the HOD with such information and acceptable documentary evidence in support thereof, and any other information relevant to the business of the licensee or to the private health establishment which the HOD might request;

- (b) after the occurrence of any of the following, notify the HOD in writing of:
 - (i) a change in the numbers of the sub-categories of licensed beds;
 - (ii) the closure of a private health establishment;
 - (iii) a change of beneficial interest in shares or members' interest or trust unit or benefit in the ownership of the private health establishment, for which purpose a change in the effective control of a company, close corporation or business trust or partnership must be deemed to be an unauthorised change in ownership of that private health establishment, unless approved in terms of Chapter 4: Provided that



this provision may not apply to the holding company of a licensee or a licensee listed on a recognised stock exchange in the Republic;

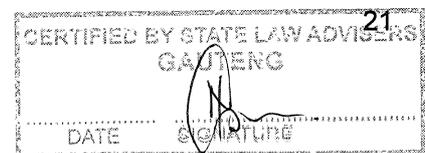
- (iv) a change in—
 - (aa) the shareholders or directors of a company entitled to carry on the business of operating a private health establishment;
 - (bb) the members of a close corporation entitled to carry on the business of a private health establishment;
 - (cc) the trustees or beneficiaries of a business trust;
 - (dd) re-constitution of a partnership;
- (v) a change of the responsible person;

and if necessary file an application in terms of Chapters 3 or 4;

- (c) of the forwarding by the HOD of a written enquiry by registered mail requesting information which is reasonably necessary or which may be regarded as reasonably necessary for the performance or exercising of the functions or powers of the Department or the HOD in terms of these Regulations, answer such enquiry in writing and furnish the HOD with all the necessary documentary and other proof in support of the furnished information.

(4) The responsible person must within 7 days of the date of the designation of a new responsible person—

- (a) submit to the HOD—
 - (i) a duly completed application for the registration of the new responsible person on a form approved and provided by the Department;
 - (ii) a copy of the letter:
 - (aa) addressed to the person who is to be registered as the responsible person;
 - (bb) from the responsible person so appointed, accepting the appointment; and
- (b) pay the fee prescribed in Schedule 1.



Bi-annual and Annual Returns

19. The responsible person must on or before the 31st day of January and July of each year furnish the HOD with schedules, certified as correct by auditors or the accounting officer of the licensee, of the —

- (a) directors and shareholders;
- (b) members or owners;
- (c) trustees and beneficiaries; or
- (d) partners or natural persons,

as the case may be, of the private health establishment and such other information as may be required by the HOD.

Renewal of licence

20. A person licensed in terms of these Regulations to operate a private health establishment must before 31 January of every year, renew the licence annually by completing the form provided by the HOD and paying the prescribed annual fees in Schedule 1,.

Amendment of licence

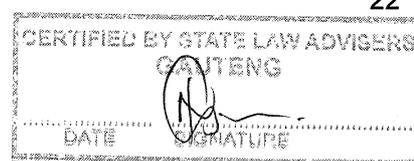
21. (1) If a licensee has successfully applied for the extension or alteration of a private health establishment or the extension, alteration or reduction of the services rendered in that establishment, and the relevant extension or alteration has been approved, the licensee must submit the original licence to the HOD with a request to issue an amended licence: Provided that the licensee complies with the requirements of Chapter 3.

(2) The provisions of Regulation 9 apply with the necessary changes in the event of a change of the type and number of licensed beds or the name or trading title of the private health establishment.

Removal from the register and cancellation of licence

22. The HOD may direct that a private health establishment and the name of a licensee be removed from the relevant register if—

- (a) the private health establishment or licensee does not comply with any one of the conditions of licensing applicable to that private health establishment;



- (b) the responsible person fails to perform the duties prescribed in terms of these Regulations;
- (c) the private health establishment fails to pay its annual fees:

Provided that —

- (i) the licensee has been given notice in the manner prescribed in Regulation 33 of the intention to remove the private health establishment from the relevant register and to close the private health establishment,
- (ii) the licensee has been afforded an opportunity to furnish the HOD with written reasons, within 14 days after the date upon which the notice is deemed to have been received in terms of Regulation 33;
- (iii) the licensee has failed to furnish acceptable reasons why his or her or its name, and the name of the private health establishment should not be removed from the relevant register, and why the private health establishment should not, as a result of the removal, be closed; and
- (iv) the HOD is of the opinion that in the interest of the public, he or she may dispense with the required notice.

Restoration to the register

23. (1) The licensee whose licence has been cancelled and whose name has been removed from the relevant register in terms of Regulation 22 may have the name of the private health establishment restored to the relevant register by—

- (a) submitting to the HOD—
 - (i) a duly completed application for restoration of the name of the private health establishment on a form approved and provided by the HOD; and
 - (ii) acceptable documentary evidence that the private health establishment again complies with the conditions of its licence issued in terms of these Regulations;
- (b) paying the restoration fee prescribed in Schedule 1; and
- (c) furnishing proof to the HOD that the responsible person is a fit and proper person to manage the business of the private health establishment;



- (2) If the HOD is not satisfied that the name of the private health establishment should be restored to the relevant register, the HOD must submit the application to the appeal committee for a decision.

CHAPTER 6 INSPECTIONS AND ENFORCEMENT

Appointment of inspecting officers and their powers

24. (1) The HOD may appoint one or more officers as defined in section 1(1) of the Public Service Act, 1994(Proclamation No. 103 of 1994), as an inspecting officer or inspecting officers for the enforcement of these Regulations and may delegate any duty imposed or power conferred on him or her in terms of these Regulations to the inspecting officer or inspecting officers.

(2) The HOD must issue every officer appointed as an inspecting officer in terms of subregulation (1) with a certificate of appointment containing the following information—

- (a) the full names and identity number of the inspecting officer;
- (b) a recent colour photo of the inspecting officer;
- (c) a reference to the empowering provision of his or her appointment; and
- (d) a reference to the duties, functions and authority of the inspecting officer listed in subregulation (3).

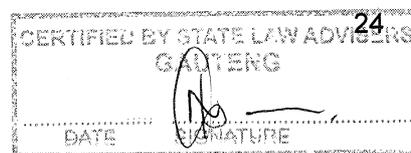
(3) An inspecting officer may, at all reasonable times—

- (a) enter upon the premises which is licensed in terms of these Regulations to operate as a private health establishment; or
- (b) enter upon the premises which is not licensed in terms of these Regulations to operate as a private health establishment, but so conduct a business of operating as a private health establishment,

and inspect the premises, facilities, data base or records, of that establishment.

(4) If the inspecting officer suspects on reasonable grounds that—

- (a) an offence in terms of these Regulations has been or is being committed thereon; or
- (b) an attempt has been made or is being made to commit an offence thereon; or
- (c) one or more of these Regulations are being violated:



Provided that the inspecting officer is in possession of a warrant issued in terms of subregulation (6) or the inspecting officer acts in terms of subregulation (7), the inspecting officer may—

- (aa) inspect any data base, book, record or document in printed or electronic format if the inspecting officer on reasonable grounds believes that such premises, data base, book, record or document contains any information relevant to the administration or enforcement of these Regulations; or
- (bb) seize any sample, data base, book, record, documents in printed or electronic format or make copies thereof or take samples as he or she may consider necessary for the purpose of testing, examination or analysis in terms of these Regulations:

Provided further that the inspecting officer prepares an inventory of anything seized on site and obtains the signature of the person ostensibly in charge of the premises thereon and hands him or her a copy thereof and confirms under oath that it has been done.

(5) An inspecting officer must apply to a magistrate court for a warrant to enter upon any premises whether licensed or not in terms of these Regulations or to seize any data base, book, record or document, or take a sample in terms of these Regulations.

(6) The Court may, if it appears from information on oath that there are reasonable grounds to believe that—

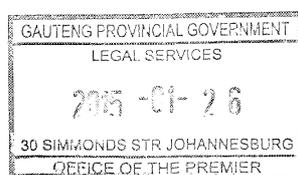
- (a) reasons for entry described in subregulation (4)(a),(b) or (c) exist in relation to unlicensed premises;
- (b) entry into unlicensed premises is necessary for any purpose relating to the administration or enforcement of these Regulations or to protect the public,

issue a warrant authorising the inspecting officer named therein to enter the premises recorded in the warrant subject to such conditions as may be specified in the warrant.

(7) If an inspecting officer believes on reasonable grounds that—

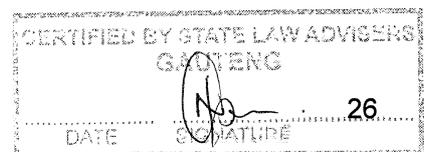
- (a) a warrant would be issued to him or her under subregulation (6) if he or she applies for such a warrant; and
- (b) a delay in obtaining that warrant would defeat the object of the entry, search and seizure,

he or she may without a warrant enter and search any premises for purposes of establishing whether a health service which requires licensing in terms of these Regulations is being provided



at such premises or whether it is being provided in compliance with these Regulations and seize any data base, book, record or document in printed or electronic format relevant to the administration or enforcement of these Regulations, or take samples as contemplated in subregulation (4)(c)(ii), and the inspecting officer must immediately obtain a warrant after having searched, entered premises and seized property thereon.

- (8) Any sample taken in terms of subregulation (4)(c)(ii) or (7)(b) must be—
 - (a) taken in accordance with the generally accepted methods in the health or pharmaceutical industry and in the presence of the person who is in charge of the premises where the sample is taken or where the object from which the sample is taken is kept, or if there is no such person, or if he or she is absent for any reason or refuses to co-operate, then to take such sample in the presence of any other witness, and must pack, seal and suitably label or mark the sample in a manner its nature may permit; and
 - (b) transmitted to a qualified and skilled analyst together with a certificate as may be made available by the HOD for this purpose and sign it, and hand a copy of the certificate to, or transmit it by registered post to the owner of the private health establishment or responsible person, or the owner of the premises at which the services which require licensing in terms of these Regulations were being provided.
- (9) The analyst to whom a sample has been transmitted in terms of subregulation (8) must as soon as possible test, examine or analyse the sample delivered to him or her, and the result of the test, examination or analysis must be recorded in a certificate issued and signed by the analyst and will constitute *prima facie* proof of the facts recorded therein and be admissible as evidence in any proceedings instituted in terms of these Regulations.
- (10) The owner of the sample or other item lawfully seized in terms of this Regulation cannot have any claim for compensation against the Department.



Pre- and post-licensing inspections

25. (1) The HOD must, at least once in a calendar year, inspect or cause to be inspected by a duly appointed inspecting officer, every private health establishment licensed in terms of these Regulations.

(2) Subject to patients' rights to privacy and confidentiality, the owner of a private health establishment, the responsible person or the person who is in charge of the nursing services in the establishment must provide the inspecting officer with information that the officer may require.

(3) The inspecting officer may, if authorised by the HOD to do so, call for any other information to ensure compliance with these Regulations or to enable the Department to discharge its duties in terms of these Regulations.

(4) Subject to patients' rights to privacy and confidentiality, and any serious risk to health, a person may not obstruct an inspecting officer from carrying out his or her duties or refuse to furnish any information lawfully requested by the officer or to allow him or her entry into any part of the premises or to show him or her any apparatus or place or thing or to unlock any cupboard, or room.

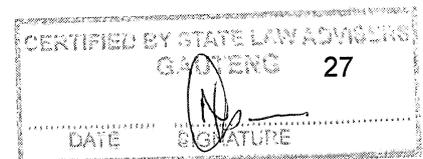
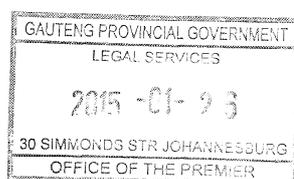
(5) A inspecting officer must, within 30 days of completing an inspection, submit a written report on his or her findings to the HOD and to the licensee;

(6) Depending on the nature of the findings referred to in subregulation (5), the licensee of the private health establishment or person responsible must, within 30 days of receipt of the report or findings, respond in writing to the findings and the report must be kept in the Department's file related to the private health establishment concerned.

Voluntary or compulsory temporary closure

26. (1) The owner of a licensed private health establishment may provide to the HOD 90 days' a notice of the intended closure of that establishment, which complies with Regulation 33: Provided that the HOD may in exceptional circumstances accept a shorter period of notice.

(2) The HOD may, if he or she has received a complaint constituting *prima facie* evidence of a contravention of these Regulations which is deemed to constitute a risk to public health and safety —



- (a) apply to the court in which the person or establishment provides the licensed services, or carries on the business of a private health establishment whilst being unlicensed; and
- (b) upon good cause being shown, obtain a warrant authorising a duly appointed inspecting officer in terms of subregulation (1) to—
 - (i) either alone, or
 - (ii) with the assistance of the South African Police Services,

for a period not exceeding 90 days close a private health establishment pending an investigation in terms of Regulation 27.

Appointment of Committee of Inquiry

27. (1) The MEC must appoint a committee of inquiry to investigate complaints regarding unacceptable service delivery or contravention of these Regulations, or a condition of the licence issued to a private health establishment.

(2) The MEC may appoint up to 3 persons who are not employees of the Department or members of the advisory committee to serve as a committee of inquiry to investigate a complaint in terms of regulation 28(1).

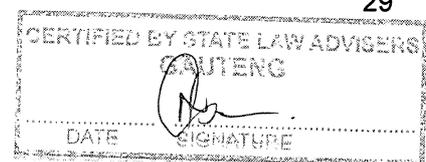
(3) Subject to the provisions contained in this Regulation, the committee of inquiry must consist of –

- (a) one person appointed on account of his or her knowledge of the law, and without limiting the foregoing, knowledge of the fundamental rights in the Bills of Rights in Chapter 2, and national legislation required and enacted in terms of Chapter 2 of the Constitution of the Republic of South Africa; 1996;
- (b) one person appointed on account of his or her knowledge of the private health establishment industry in South Africa; and
- (c) one person appointed on account of his or her knowledge of the technical requirements prescribed in Schedule 2.

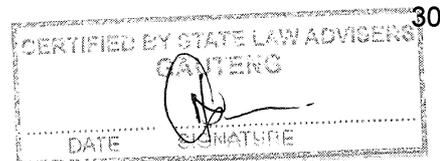
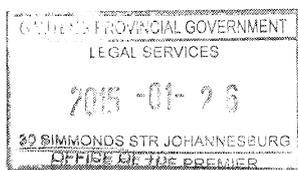


Inquiry into complaint of unacceptable service delivery or contravention of these Regulations

28. (1) The HOD may, if he has received a complaint from any person regarding alleged unacceptable service delivery, or a contravention of these Regulations, or a condition of the licence issued to a private health establishment—
- (a) consult with or seek further information regarding the complaint from any person, including the respondent;
 - (b) call on any person whom he or she on reasonable grounds believes to be in possession of a document, photograph, computer record, contract, book relevant to the complaint, in order to make same available to the HOD before the date determined by the HOD in the notice, for the purpose of investigating the complaint in terms of these Regulations;
 - (c) apply to the Court of the district in which the respondent carries on business, to obtain a warrant, which must substantially correspond with Schedule 6 to these Regulations, authorising an inspecting officer appointed in terms of Regulation 26—
 - (i) to enter, either alone or with the assistance of the South African Police Service, the business premises of the respondent or any other premises where business records or stock belonging to the respondent are kept, identified in the warrant;
 - (ii) to search such premises for statutory records and other documents required to be kept in terms of these Regulations or any other statutory provision applicable to the business of the respondent, that are relevant to the complaint; and
 - (iii) to seize and remove from the business or other premises identified in the warrant stock, records or documents after having compiled a complete inventory of the stock, records or documents and verified the inventory with a person over the age of 16 years apparently in control of such business or other premises
 - (iv) to leave, when applicable and practicable, copies of the records or documents seized and to be removed with that person;
 - (d) seek legal or other advice regarding the complaint.



- (2) If the HOD is of the opinion that the complaint constitutes *prima facie* proof of unacceptable service delivery, he or she must—
- (a) inform the respondent in writing of the nature of the complaint and furnish such particulars regarding the complaint as are available;
 - (b) request the respondent to respond, before a date determined by the HOD, in writing to such complaint, and give reasons why he or she is of the opinion that the complaint does not constitute unacceptable service delivery; and
 - (c) warn the respondent that his or her written response and reasons may be used as evidence at any subsequent inquiry.
- (3) The HOD, after having investigated the complaint and considered the recommendation of the inspecting officer referred to in subregulation (1)(c), and whether or not a response was received from the respondent as contemplated in subregulation (2), must—
- (a) if he or she is of the opinion that a further inquiry in terms of these Regulations would not be appropriate, inform the complainant and the respondent accordingly and furnish reasons for the decision;
 - (b) if he or she is of the opinion that it would be appropriate to hold an inquiry—
 - (i) appoint a pro forma complainant;
 - (ii) request the pro forma complainant to prepare a notice in a format substantially corresponding with Schedule 7A to these Regulations, notifying the respondent to attend an inquiry at a time, on a date and at a venue indicated by the pro forma complainant in the notice, or to sign the consent order and pay the admission of guilt fine; and
 - (iii) make a written request to the committee of inquiry to hold an inquiry at the time, on the date and at the venue indicated by the pro forma complainant in the notice referred to in subregulation (ii).
- (4) In deciding whether or not an inquiry would be appropriate, the HOD must take into account —
- (a) the nature of the complaint;
 - (b) the consequences of the alleged unacceptable service delivery of the respondent for the complainant, the general public, or any other interested parties;

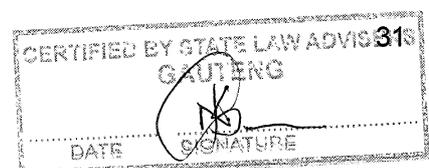


- (c) the penalty which in the opinion of the HOD could be imposed by the committee of inquiry, if the respondent is found to have rendered unacceptable service delivery.
- (5) The pro forma complainant appointed in terms of subregulation (3)(b)(i) must—
- (a) serve the notice contemplated on the respondent by registered post addressed to the registered address of the respondent, together with any applicable documents not previously furnished to the respondent; and
 - (b) furnish the members of the committee of inquiry with a copy of the notice and copies of all the applicable documents.
- (6) The respondent may—
- (a) if he, she or it agrees with the contents of the proposed consent order, which forms part of the notice referred to in subregulation (3)(b)(i), complete and sign it before a commissioner of oaths and return it to the pro forma complainant before the date set for the inquiry, in which case the committee of inquiry will, on the date scheduled for such inquiry, make the proposed consent order, a final consent order; or
 - (b) if he, she or it disagrees with the contents of the proposed consent order, which forms part of the notice referred to in subregulation (4)(b)(ii), and prefers to present his, her or its case to the committee of inquiry-
 - (i) complete a form substantially corresponding with Schedule 7B to these Regulations and sign and return it to the committee of inquiry before the date on which the inquiry is scheduled to take place; and
 - (ii) appear in person or with legal representation at the inquiry to—
 - (aa) hand in written submissions to the committee of inquiry; or
 - (bb) lead oral evidence; or
 - (cc) present argument;

in order to prove that he or she is not guilty of unacceptable service delivery.

Procedure for inquiries

29. (1) At the inquiry the following procedure must be followed—



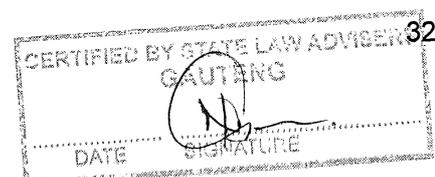
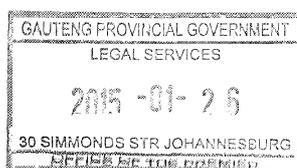
- (a) The pro forma complainant must read out the notice addressed to the respondent, unless the respondent is absent or the respondent or his or her legal representative indicates that it is not required;
- (b) If the respondent is present or represented by a legal representative, the chairperson must ask the respondent or his or her legal representative to plead guilty or not guilty to the complaint of unacceptable service delivery, and record the plea;
- (c) If the respondent, or his or her legal representatives, refuses or fails to plead directly to the complaint, the chairperson of the committee of inquiry must record a plea of not guilty on behalf of the respondent and a plea so recorded has the same effect as if it had actually been pleaded;
- (d) If the respondent, or his or her legal representative, is not present at the formal inquiry, the committee of inquiry must proceed in the respondent's absence and record a plea of not guilty, unless the respondent has, in writing, pleaded guilty to the complaint, in which case the chairperson of the committee must record same as the respondent's plea; and
- (e) If the respondent is neither present nor represented, the written defence, statement(s) or explanations made by him, her or it on his, her or its behalf before the formal inquiry, if any, constitute his, her or its defence and must be submitted by the pro forma complainant to the committee of formal inquiry.

(2) If a plea of guilty is entered and the committee of inquiry is of the opinion that further information is required for purposes of making a finding as to whether the complaint constitutes unacceptable service delivery on the part of the respondent, it may call any witness summoned on behalf of the pro forma complainant or the respondent or call its own witnesses to give oral evidence under oath or affirmation and may accept such documentary evidence relevant to the complaint as it deems necessary, before making a finding.

(3) If a respondent pleads not guilty, first the pro forma complainant and then the respondent may lead evidence in support of the complaint and the defense, respectively.

(4) After a witness has testified, the other party may cross-examine the witness.

(5) The chairperson of the committee of formal inquiry-



- (a) may put questions to any witness called on behalf of or by the pro forma complainant or the respondent and allow other members of the committee of inquiry to put questions to such a witness;
- (b) must, before re-examination of the witness by the party who called that witness, allow further cross-examination arising from questions put by the chairperson and other members; and
- (c) must, after the cross-examination referred to in subregulation (4)(b), allow the party who called the witness an opportunity to re-examine the witness on matters raised in cross-examination or with regard to questions put to that witness by the chairperson or other members of the committee of inquiry.
- (6) The committee of inquiry may, after parties have closed their cases—
- (a) allow further evidence to be led;
- (b) recall any witness who has testified.
- (7) The respondent and the pro forma complainant, or their legal representatives, may cross-examine any witness who has testified as contemplated in subregulation (1).
- (8) After all evidence has been led—
- (a) the pro forma complainant may address the committee of inquiry on the evidence and the legal position;
- (b) the respondent or his, her or its legal representative may thereafter address the committee of inquiry; and
- (c) the pro forma complainant may reply to the arguments raised by or on behalf of the respondent.
- (9) All oral evidence must be taken under oath or affirmation by the chairperson of the committee of inquiry.
- (10) Evidence by way of affidavit must be admissible in terms of the Civil Proceedings Evidence Act, 1965 (Act No. 25 of 1965), or any common-law principle applicable to civil litigation.
- (11) The record or any part thereof, of a lawfully constituted court, inquest or statutory body will be *prima facie* evidence if it has been certified to be a true copy; provided that if it is practicable and appears just, the committee of inquiry may call a witness whose evidence appears in such record to give evidence at the inquiry.



(12) Any decision by the committee of inquiry with regard to any point arising in connection with, or in the course of, an inquiry must be communicated to the persons concerned during that inquiry.

(13) Upon the conclusion of the inquiry, the committee of inquiry must deliberate *in camera* on a finding.

(14) If a respondent is found not guilty of the complaint lodged against him, her or it, the respondent must be informed accordingly forthwith and the committee of inquiry must report its finding to the HOD.

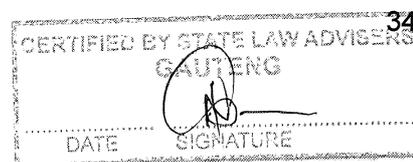
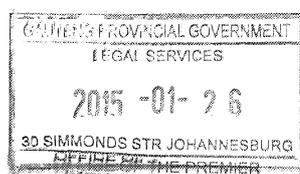
(15) If the committee of inquiry determines that sufficient facts were presented during the formal inquiry to prove the complaint on a balance of probabilities, it must decide whether the complaint as proved constitutes unacceptable service delivery and it must report its finding the HOD.

(16) If a respondent is found guilty by the committee of inquiry, the pro forma complainant must adduce evidence of previous adverse findings of unacceptable service delivery, including any consent order made in terms of these Regulations, if such findings have been recorded against the name of the respondent in the relevant register kept by the Department; provided that notice of the intention to do so was given to the respondent by the pro forma complainant prior to the commencement of the inquiry.

(17) Evidence of previous adverse findings referred to in subregulation (16) must be adduced by means of a certificate under the hand of the HOD indicating the nature of the complaint against the respondent at the time, the finding, the date of such finding and the penalty imposed.

(18) The respondent may challenge the correctness of a certificate referred to in subregulation (17), in which case a copy of the relevant record in the possession of the HOD and the record of proceedings of the committee of inquiry at which the finding was made and the penalty imposed or must be produced, after which the fact of adverse finding must be regarded as conclusively proved.

(19) The respondent may, after proof of previous adverse findings by the pro forma complainant, if any, address the committee of inquiry or adduce evidence, either orally or in writing, in mitigation of the penalty to be imposed.



(20) Any witnesses called in mitigation may be questioned by the members of the committee of inquiry and the pro forma complainant.

(21) The pro forma complainant may, after the respondent has addressed the committee of inquiry or adduced evidence in mitigation of the penalty to be imposed, make representations to the committee of inquiry or lead evidence, orally or in writing, regarding a suitable penalty to be imposed.

(22) If the respondent is neither present nor represented, any written representation, statement or explanation made by him, her or it on his, her or its behalf, that has a bearing on a suitable penalty, must be taken into account by the committee of inquiry.

(23) The committee of inquiry must deliberate *in camera* on the penalty to be imposed as contemplated in regulation 28 of these Regulations, to be made, and a cost order.

(24) The chairperson of the committee of inquiry must announce the finding, the penalty imposed and the cost order made, if applicable, at an open meeting.

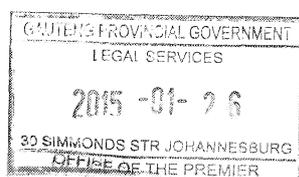
(25) The committee of inquiry must report its finding, the penalty imposed and the cost order made, if any, to the Department.

(26) The HOD must arrange for the publication, in any one of the official languages of Gauteng in the Provincial *Gazette* and in the Department's annual report, of the name of the respondent, a summary of the facts on which the finding of unacceptable service delivery is based, and the penalty which has been imposed.

(27) The committee of inquiry may appoint and remunerate a person with experience in the administration of justice to be present at any inquiry—

- (a) as an assessor; or
- (b) to advise the committee of inquiry on matters of law, procedure and evidence.

(28) The committee of inquiry may, of its own accord, or at the request of the pro forma complainant, or of the respondent, or his, her or its legal representative, adjourn any inquiry being held in terms of these Regulations to be resumed on such date and at such time and place as the committee of inquiry may determine or as the chairperson may by registered post communicate to the parties concerned.



Imposition and recovery of penalties and cost orders

30. (1) A licensee who, after an inquiry in terms of Regulation 28 has been found guilty of unacceptable service delivery, or a contravention of a provision of these Regulations, or a condition of the licence, may be liable to one or more of the following penalties:

- (a) a reprimand and a caution;
- (b) a fine not exceeding the amount determined by the MEC from time to time in Schedule 5 by notice in the Provincial *Gazette*;
- (c) suspension from conducting business as a private health establishment for a specified period;
- (d) removal of the name of the licensee from the relevant register;
- (e) a refusal to renew a licence in terms of Regulation 20.

(2) When the committee of inquiry has imposed one or other of the penalties referred to in subregulation (1), the HOD must cause to be published in the Provincial *Gazette* the name of the person concerned, the finding and the penalty imposed.

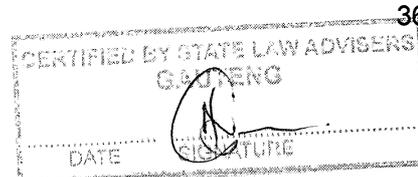
(3) Where the committee of inquiry finds a person referred to in sub regulation (1) guilty of conduct referred to therein, it may:

- (a) postpone, for such period and on such conditions as it may determine, the imposition of a penalty; or
- (b) impose any penalty mentioned in sub regulation (1) but order the execution of such penalty to be suspended for such period and on such conditions as it may determine.

(4) If at the end of the period for which the imposition of a penalty has been postponed in terms of subregulation (3)(a), the HOD is satisfied that the person concerned has observed all the relevant conditions, the HOD must inform such person that no penalty will be imposed.

(5) If the execution of a penalty has been suspended in terms of subregulation (3)(b), and the HOD is satisfied that the person concerned has observed all relevant conditions throughout the period of suspension, the HOD must inform such person that such penalty will not be executed.

(6) If the execution of a penalty has been suspended in terms of subregulation (3)(b) and the person concerned fails to observe any of the conditions of suspension, the HOD must put such penalty into operation unless such person satisfies the HOD that the non-observance of the condition in question was due to circumstances beyond his or her or its control.



(7) Any fine imposed in terms of these Regulations must, unless an appeal has been noted against such penalty in terms of Regulation 31, be paid to the Department within 14 days after the imposition thereof, or within such extended period and in such instalments as the HOD may in his or her discretion determine.

(8) Any cost order made in terms of Regulation 30 must be paid within 14 days after the amount thereof has been fixed.

(9) The imposition of a fine or the making of a cost order in terms of these Regulations must have the effect of a judgment in civil proceedings in the magistrate's court of the district in which the person liable to pay such fine has his, her or its registered address or main place of business.

Appeals and procedures

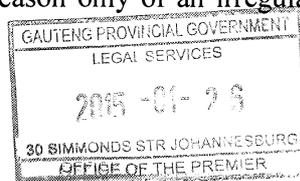
31. (1) The MEC must appoint up to three persons who are not employees of the Department or members of the advisory or inquiry committees to serve as an appeal committee to hear any appeal in terms of subregulation (3).

(2) The appeal committee must consist of—

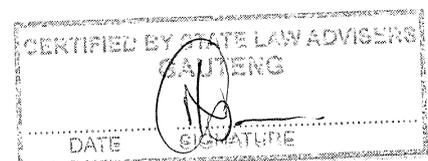
- (a) a chairperson appointed on account of his or her knowledge of the law;
- (b) one person appointed on account of his or her knowledge of the technical requirements prescribed in Schedule 2; and
- (c) one additional person.

(3) A person—

- (a) whose rights may be adversely affected by any decision of the HOD regarding the licensing, suspension or cancellation or refusal to transfer the licence of a private health establishment, may appeal against such decision to the appeal committee in the manner set out hereafter; or
- (b) aggrieved by a finding of or penalty imposed by the committee of inquiry in terms of Regulation 30, may, after notice to the HOD and within a period of two months after the date of such finding or the imposition of the penalty, appeal to the appeal committee in terms of Regulation 31; provided that no finding of or penalty imposed by the committee of inquiry may be set aside by reason only of an irregularity which did not embarrass or prejudice the



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appellant in answering the complaint or charge or in the conduct of his or her or its defence.

(4) The appellant must lodge his, her or its appeal within 30 days after notice of such decision in writing is deemed to have come to the attention of the appellant in terms of Regulation 35.

(5) The notice of appeal must be in writing and under oath, stating in full the decision against which the appeal is lodged, the grounds on which such appeal is lodged, and must nominate a physical address, where the appellant will accept delivery of all documents relevant to the appeal.

- (6) The notice of appeal must be lodged with the appeal committee together with—
- (a) payment of the fee prescribed in of Schedule 1; and
 - (b) 4 copies of the record of appeal consisting of the decision appealed against, the written reasons for such decision and all relevant documents, duly indexed and paginated, after having served a copy thereof on all interested parties, who are hereafter referred to as the respondents.

(7) The appeal committee clerk must upon receipt of the notice of appeal, allocate a case number and notify the appellant, and all the respondents thereof.

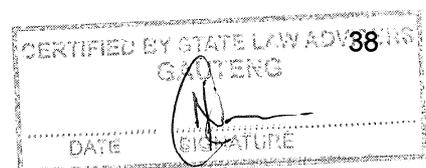
(8) The respondents may within 30 days of delivery to them of the notice of appeal, deliver answering affidavits to the committee clerk, and must serve copies thereof on the appellant and all other respondents.

(9) The appellant may within 14 days of delivery to him, her or it of the answering affidavits, deliver a replying affidavit.

(10) The committee clerk must on the expiry of the period referred to in subregulation (9) arrange a date and venue for the hearing of the appeal with the chairperson of the appeal committee and the other members and furnish them with copies of the appeal record and the affidavits delivered by the appellant and the respondents.

(11) The committee clerk must advise the appellant and all respondents, of the date of and the venue for the hearing, whereupon the appeal is set down for hearing accordingly.

(12) Not less than 10 days before the appeal is to be heard the appellant must deliver to the appeal committee, and all respondents, one copy of a concise and succinct statement of the



main points which he, she or it intends to argue on appeal, and provide a list of the authorities to be used in support of each point.

(13) The respondents in an appeal must deliver a statement similar to the one contemplated in subregulation (12) to the appeal committee and the appellant five days prior to the date of the hearing.

(14) If an appeal has been noted, the decision appealed against and any execution thereof must be suspended pending the outcome of the appeal, unless the appeal committee, upon the urgent motion of the HOD, is on the strength of *prima facie* proof, of the opinion that it is in the public interest that a temporary closure order in terms of Regulation 26 should be granted and imposed pending the outcome of the appeal.

(15) The appeal committee may –

- (a) dismiss an appeal or, if it is of the opinion that the Head of Department, or a delegated officer, has not acted in accordance with the provisions of these Regulations, or that the decision constitutes an unjustified and unreasonable breach of the appellant's fundamental rights in terms of Chapter 2 of the Constitution of the Republic of South Africa, 1996;
- (b) make an order reversing or modifying the decision appealed against and uplift the temporary suspension if applicable; and
- (c) remit the matter to the Head of Department or delegated officer for further consideration, or make such other order, including an order as to costs, as it may deem appropriate.

(16) An appeal must be finally adjudicated within 120 days of the date on which the appeal is noted in terms of subregulation (4).

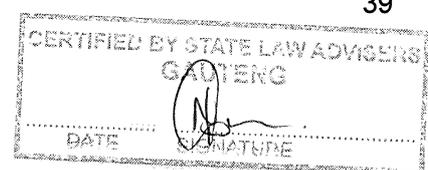
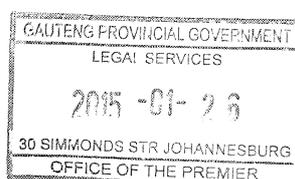
CHAPTER 7 GENERAL PROVISIONS

Fees and Fines

32. (1) The MEC may —

- (a) on recommendation of the HOD, prescribe and amend or add to the fees payable in terms of these Regulations: Provided that the MEC publishes

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those fees as Schedule 1 to these Regulations in the Provincial *Gazette*, specifying the date from which those fees become applicable;

- (b) prescribe the maximum fines which may be imposed in terms of these Regulations: Provided that the MEC publishes those fines as Schedule 5 to these Regulations in the Provincial *Gazette*, specifying the date from which those fines may be applicable.

(2) The fees or fines payable in terms of these Regulations must be paid to the Department and the Department must deposit those fees or fines into the Provincial Revenue Fund or an account approved by the National Treasury and which account may be used for purposes of administering these Regulations and to defray any expenses incurred in pursuit thereof, subject to the statutory requirements regarding auditing of public funds.

(3) The HOD is the responsible accounting officer for purposes of collecting the fees or fines and authorising the payment of and paying any expenses in terms of these Regulations from the account referred to in subregulation (2).

Contraventions and remedies

33. (1) If a licensed private health establishment does not comply with any provision of these Regulations or any condition of its licence, the HOD must issue a written notice to that establishment advising it —

- (a) of the nature and extent of the alleged non-compliance and affording it an opportunity to furnish written reasons for non-compliance or to rectify the non-compliance within the time specified in the notice; and
- (b) that failure to furnish reasons or rectify the non-compliance within the time provided will result in the cancellation and withdrawal of his, her or its licence and removal of his, her or its name from the relevant register of private health establishments.

(2) In the event that no satisfactory response or proof that the cause of the complaint has been removed or rectified is received within the time provided, the HOD may —

- (a) cancel and withdraw the licence and remove the name of the private health establishment from the relevant register of private health establishments and in writing inform the owner of such private health establishment or



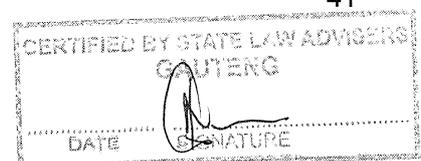
- responsible person that his, her or its licence has been cancelled and withdrawn and that his, her or its name has been removed from the relevant register of private health establishments and that he, she or it is no longer entitled to operate as a private health establishment or provide the services which he, she or it was previously licensed to do;
- (b) temporarily close that private health establishment in terms of Regulation 26;
 - (c) impose a fine not exceeding the maximum fine prescribed by the MEC in Schedule 5 for every day of non-compliance; and
 - (d) refuse to renew the licence of that private health establishment.
- (3) If an unlicensed private health establishment does not comply with any provision of these Regulations or condition of registration, the HOD must issue a written notice to that establishment advising it—
- (a) of closure of that private establishment in terms of Regulation 26; and
 - (b) of the fine imposed not exceeding the maximum fine prescribed by the MEC in Schedule 5 for every day of non-compliance.

Delegations

34. The HOD may delegate any power conferred or function imposed upon her or him in terms of these Regulations to a specialised unit within the Department or any officer or official employed by the Department, except the power to approve an application in terms of these Regulations.

Notices

35. Any notice to be given in terms of these Regulations—
- (1) must be in writing and addressed to and may be sent by registered mail to the registered address, or may be delivered by hand to the physical address, or may be sent by telefax to the telefax address, or may be forwarded by electronic mail to the relevant address, recorded by the HOD in terms of Regulation 17(1)(a)(vi), (vii) or (viii); and
 - (2) must be deemed to have been properly given and to have been received and to have come to the notice of the addressee—



- (a) within 10 days after the day on which the notice or document was sent by pre-paid registered post, if posted;
- (b) within one day after the date and at the time (if any) which appears on the acknowledgement of receipt of the notice or document, if delivered by hand;
- (c) within three days after the date appearing on the telefax control sheet of the sender, if sent by telefax;
- (d) within three days after the date appearing on the electronic mail message, if sent by electronic mail.

(3) The HOD must publish the withdrawal of any licence or approval granted or the temporary closure of a private health establishment in terms of these Regulations in the Provincial *Gazette*, and must give notice thereof to all other relevant organs of state or statutory organisations or private institutions exercising a public power or performing a public function or discharging a public duty related to the health care industry in terms of any legislation.

Repeal of Regulations Governing Private Hospitals and Unattached Operating Theatre Units, 1980

36. The Regulations Governing Private Hospitals and Unattached Operating Theatre Units, 1980, published in Government *Gazette* No. 6832, Notice No. R.158, of 1 February 1980, are hereby repealed, in so far as they apply or relate to private hospitals and unattached operating-theatre units in the Gauteng Province.

Transitional provisions

37. (1) Subject to subregulation (2) and (3), a private health establishment which, at the commencement of these Regulations, was registered in terms of the Regulations Governing Private Hospitals and Unattached Operating Theatre Units 1980, published in Government *Gazette* No. 6832, Notice No. R.158, of 1 February 1980, must be deemed to be licenced in terms of these Regulations, and the certificate of registration or license applicable to that establishment is effective for the remainder of the portion of the said period as may be specified in the certificate of registration, where after the licensee has to apply for a renewal of the licence in terms of these Regulations.



(2) A private health establishment contemplated in subregulation (1) must be subject to all other provisions of these Regulations for its continued licensing: Provided that the licensee is given sufficient time to comply with the technical requirements prescribed in Schedule 2.

(3) Alterations to a private health establishment referred to in subregulation (1), or the services which the licensee is licensed to render therein, must be applied for in terms of Regulation 9(2).

(4) An owner of a private health establishment who is not registered in terms of the regulations referred to in subregulation (1), has six months from the date of commencement of these Regulations in which to comply with the technical requirements prescribed in Schedule 2 to these Regulations and to lodge an application for a licence in terms of Regulation 9(1).

Savings

38. Any notice, order, decision, approval, permission, authority, information or document issued, made, granted or furnished and any other action taken under any provision of the Regulations Governing Private Hospitals and Unattached Operating Theatre Units, 1980, published in Government *Gazette* No. 6832, Notice No. R.158, of 1 February 1980, if not inconsistent with the provisions of these Regulations, is deemed to have been issued, made, granted, furnished or taken under the corresponding provisions of these Regulations.

Short title

39. These Regulations are called the Regulations Governing Private Health Establishments, 2015.

