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DEPARTMENT OF HEALTH

NO. 528 **15 June 2021**

REGULATIONS RELATING TO CERTIFICATE OF NEED FOR HEALTH ESTABLISHMENTS AND HEALTH AGENCIES

The Minister of Health intends, in terms of sections 39(1) and 90(4)*(a)* of the National Health Act, 2003 (Act No. 61 of 2003), and after consultation with the National Health Council, to make the Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments on the proposed regulations, or any representations they may wish to make with regard to these regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001, for the attention of the Technical Specialist, Health Economist for NHI Dr Aquina Thulare, Con@health.gov.za, within one month of this Notice.

DR ZWELINI LAWRENCE MKHIZE, MP
MINISTER OF HEALTH
DATE: 04/06/2021

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SCHEDULE

DEFINITION

1. In these Regulations any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, —

"the Act" means the National Health act, 2003 (Act No. 61 of 2003).

APPLICATION FOR CERTIFICATE OF NEED

2. (1) An application for a certificate of need contemplated in section 36(2) of the Act shall—

(a) be made on a form substantially similar to the form contained in Annexure A;

(b) accompanied by the required supporting documentation; and

(c) be accompanied by the application fee and the inspection fee as set out in **Annexure C**.

(2) A certificate of need may not be issued to a health establishment unless-

(a) the premises on which such health establishment is or will be conducted and the equipment which is used or is intended for use in such health establishment are suitable and adequate for the purposes of the said health establishment;

(b) the health establishment is not managed or will not be managed in a manner which will be detrimental to the physical, mental or moral welfare of the patients or staff;

(c) the staff of the health establishment comply with or will comply with accepted standards for the purposes of such health establishment;

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(d) the person in charge of the health establishment—

(i) is or will be registered as a medical practitioner;

(ii) in the case of an exclusively dental service, is or will be registered as a dentist, in terms of the Health Professions Act, 1974 (Act No.56 of 1974); or

(iii) in the case of a general medical nursing service or a midwifery service, is or will be registered in terms of the Nursing Act, 2005 (Act No.33 of 2005), as a registered nurse or midwife, respectively;

(e) a nurse registered in terms of the Nursing Act, 2005 (Act No 33 of 2005), is or will be in charge of the nursing service if the person in charge is a registered medical practitioner or dentist; and

(f) such certificate of need is in the public interest.

(3) The following information must accompany an application contemplated in sub-regulation (1):

(a) Plans of the buildings or proposed buildings which must—

(i) show clearly the nature and construction of the buildings or proposed buildings or the nature of the modifications, as the case may be;

(ii) have been passed by the local authority concerned;

(iii) be drawn to the scale of 1:100; and

(iv) be submitted in duplicate;

(b) a sufficient number of lifts or ramps shall be provided where patients are housed in a multi-storey building: Provided that adequate provision shall be made for lifts suitable for taking a patient bed or trolley and for the separate removal of soiled linen, waste and refuse;

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(c) written proof that neither the Government Departments concerned, nor the local authority concerned has any objection to the health establishment being conducted on the premises concerned;

(d) the population of the sub-district or sub-districts that will be served by the proposed health establishment according to the latest available census information provided by Statistics South Africa (Stats SA);

(e) the relationship between the proposed health establishment and the number and proximity of existing services and facilities such as other health establishment;

(f) The nature and extent of the service that is envisaged to be provided by the proposed health establishment.

(g) the approximate number and location of the population to whom a health establishment service will be provided;

(h) the extent of the provision of services to persons outside the sub-district in which the proposed health establishment is to be situated;

(i) where applicable, any special care needs of the community to be served based on the demographics and/or health status; and

(j) any other relevant information as may be required by the Director-General in order to consider the application.

(4) An applicant must, in the event of any change in information submitted in an application contemplated in sub-regulation (1) or any change in particulars with regard to an existing certificate of need, immediately inform the Director-General in writing of such change.

(5) If the holder of a certificate of need decides not to continue with or intends to close the health establishment or health agency, that holder shall give not less than three months written

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notice of such a decision or intention to the Director-General, the person in charge of a health establishment, patients and staff: Provided that, in exceptional circumstances, the Director-General may authorise a shorter period of notice.

DURATION OF CERTIFICATE OF NEED

3. A certificate of need shall be valid for a period of 20 years from the date of issue unless the Director-General withdraws, in terms of section 36(6) of the Act, the certificate of need.

FEES PAYABLE

4. Fees payable in terms of these Regulations are as set out in **Annexure C**.

REQUIREMENTS FOR ISSUING CERTIFICATE OF NEED FOR A HEALTH ESTABLISHMENT

5. (1) A health establishment for which a certificate of need is required must comply with the following requirements:

(a) Save where otherwise required in these Regulations, all walls of a health establishment—

(i) may not be less than 2,6m high, measured from the floor to the ceiling;

(ii) must be constructed of burnt brick, stone, concrete or some other impervious material and, unless otherwise approved by the municipality; and

(iii) with regard to the external walls, may not be less than 225mm thick and the internal walls may not be less than 89mm thick.

(b) The joint between the walls and the floor must be rounded in operating-theatres, sluice rooms, toilets and shower cubicles.

(c) All corridors taking patient trolleys may not be less than two metres wide.

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(d) All doors giving access to rooms in which patients are to be accommodated may not be less than two meters high and one meter wide.

(e) All rooms must be sufficiently ventilated and lighted and spacious enough to ensure that they are not overcrowded when the maximum number of persons who would normally be in them at any one time is present.

(f) The ceiling of all rooms, corridors and theatres must be provided with a smooth and dustproof surface.

(g) The floors of all rooms and corridors must be made of material and covered with impervious washable material: Save that where flammable materials are used, kept or stored, the floor of the operating-theatre and the rooms where such flammable materials are used, kept or stored, as well as all floors within a distance of one metre of the doors of the operating-theatre and of such rooms where flammable materials are used, kept or stored, must be covered with antistatic material of a washable impervious type: Provide that where such floors are not in compliance herewith, a conspicuous cautionary notice stating that the floor is not antistatic must be displayed.

(h) Subject to paragraph (i), the surfaces of the walls must be smoothly plastered and be painted with washable paint of a light colour or clad with a washable impervious material.

(i) Sluice rooms, toilets, shower cubicles, operating-theatres, central sterile supply departments or sterilising rooms, the walls up to a height of not less than 2,1m from the floor may be covered with white or light-coloured glazed tiles or other washable, impervious material: Provided that the walls behind all hand-wash basins must, up to a height of 500mm above and 500mm on either side of such wash hand basins, be covered with white or light-coloured glazed tiles or other washable, impervious material.

(j) Properly placed and adequate fire-hydrants, fire-hoses, fire-extinguishers, fire escapes and emergency exits must be provided and constantly maintained.

(k) If the operating-theatre unit is in a multi-storeyed building and not on the ground floor, the building must be equipped with fire-escape stairs and a lift of sufficient size to accommodate a patient stretcher.

(l) A sufficient number of lifts and ramps must be provided where patients are housed in a multi-storey building: Provided that adequate provision must be made for lifts suitable for taking a patient bed or trolley and for the separate removal of soiled linen, waste and refuse.

(m) A constant supply of water to all taps, showers, sluicing apparatus and sanitary conveniences in the operating-theatre unit.

(n) All wastewater from hand-wash basins, sluice rooms, sluice pans and toilet pans must effectively drain into a sewerage system approved by municipality.

(o) An incinerator or other suitable system must be provided for the effective, safe and discreet incineration or disposal of soiled dressings and surgically removed tissues.

REQUIREMENTS FOR RENEWAL OF CERTIFICATE OF NEED

6. (1) An application for the renewal of a certificate of need must—

(a) be made on a form substantially similar to the form contained in **Annexure A**;

(b) be made no less than 90 days before the date of expiry of the validity of such a certificate of need; and

(c) be accompanied by the applicable renewal fee as set out in **Annexure C**.

(2) The regulations applicable to an application for a new certificate of need shall apply equally, with the necessary changes, to an application for the renewal of a certificate of need.

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REQUIREMENTS FOR CERTIFICATE OF NEED FOR EXISTING HEALTH ESTABLISHMENTS AND HEALTH AGENCIES

7. (1) Notwithstanding the provisions of regulation 4, a certificate of need issued to existing health establishments and health agencies shall be valid for a period of three years from date of issue.

(2) The provisions of regulations 1 and 6 shall be applicable to existing health establishments and health agencies.

RE-APPLICATION FOR CERTIFICATE OF NEED

8. Any person who—

(a) has applied for a certificate of need and whose application has been refused;

(b) whose application for renewal of a certificate of need has been refused;

(c) whose certificate of need has been withdrawn in terms of section 36(6) of the Act;

(d) who failed to apply timeously for renewal of a certificate of need and whose certificate of has consequently expired; or

(e) who had failed in an appeal lodged in terms of section 38 of the Act;

may at any time re-apply for a certificate or need or renewal of a certificate of need for the same health establishment: Provided that, if a certificate of need or the renewal of a certificate of need has been refused or withdrawn because of the failure by the applicant to comply with all the conditions and requirements imposed by the Director-General in terms of the Act, such further application may not be made until and unless all such conditions and requirements have been complied with.

REQUIREMENTS FOR CERTIFICATE OF NEED FOR MOBILE HEALTH ESTABLISHMENT

9. (1) A mobile vehicle to be used as a mobile health establishment must be configured in such a way that the patient compartment must conform with the following interior dimensions and other requirements:

(a) Load compartment length (mm) : 4,000 - 5,000

(b) load compartment width (mm) : 1,800 - 2,000

(c) load compartment height (mm) : ≥1,900 (high roof);

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(d) may not have any windows on all sides;
(e) the floor must be 2mmm electro-galvanized;
(f) the walls and roof must be 1.2mmm electro-galvanized;
(g) the double back-door must open vertically to left and right of the outside and must be lockable;
(h) the left rear door must be 850mm wide opening to the outside and must be lockable from inside and outside;

(2) The vehicle contemplated in sub-regulation (1) must have six wheels (double back) and must be fitted with—
(a) a disability ramp;
(b) a steel step for comfortable access to a health establishment;
(c) step holders and an external grip rail;
(d) a tow bar fitted on the rear of the unit; and
(e) a water tank with a submersible pump to supply water to the sink.
(f) air conditioning on the front of the health establishment at least 1200/1800 BTU Unit capable of producing hot and cold air;
(g) a 12 Volts battery capable of providing energy for the lights of the vehicle when its engine is not running;
(h) roll-out shades on the passenger side of the vehicle and should be at least 2,000mm wide and 3,500mm long;
(i) a turbo-diesel charged engine with the output of at least 120 kilo watts;
(j) front and rear mudguards, and rubber deflector flaps behind the wheels
(k) a 2.2m cabinet on the rear wall of the vehicle which must comprise—
(i) a sink with a cold water tap (elbow) which must be supplied with water from a ± 50 litre water tank;
(ii) five drawers; and
(iii) a storage unit;
(l) a 2.5 kg fire extinguisher at the rear end close to the door of the vehicle;
(m) a cabinet for the vaccine fridge in the back right hand side of the vehicle.
(n) four double fluorescent (118cm) lights mounted on the side walls
(o) plug points over the cabinet and plug points for the fridge and air conditioner; and

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(p) external lights.

(3) The paint of the vehicle must be anti-rust primer and the final coat must be white poly-ethylene.

(4) The sign writing on the vehicle must comply with specifications of the Department of Health.

(5) (a) The base of the vehicle must be reinforced for gravel roads and the chassis and under-body must be treated with an anti-corrosive material.

(b) The fuel tank of the vehicle must have a capacity sufficient for 500km range at 90km/h travelling speed and must be lockable.

(c) The fuel tank filler cap and neck must be completely recessed in the bodywork and siphon-proof.

(6) The vehicle must be supplied with a toolbox which must contain at least the following:

(a) A set of Allen keys;

(b) a set of six common spanners;

(c) a pliers;

(d) a set of screwdrivers;

(e) a hydraulic jack; and

(f) a special wheel spanner.

(7) The vehicle must be assembled in the Republic of South Africa.

(8) The interior of the walls of the mobile health establishment must be covered with a special light wood board which will also act as insulation.

(9) The floor of the vehicle must be covered in hospital type vinyl covering with rounded skirting.

(10) The electrical main board must be mounted in the corner of the vehicle for on-board power supply.

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(11) The vehicle must operate from a 20m extension cord or generator.

(12) A generator of 5kva-5.5kva must be provided as part of the mobile unit vehicle and be stored into a concealed box underneath.

(13) A minimum of 25m of water pipe should be supplied with a quick connector to the tank and to the tap contemplated in paragraph (k).

ROOMS REQUIRED FOR GENERAL HEALTH ESTABLISHMENTS

10. A health establishment must be conducted in accommodation in which provisions are made for-

(a) an operating-theatre with adjoining sterilising room and recovery area and ward accommodation so planned or conducted that male and female patients shall be effectively separated: Provided that if such recovery area is so arranged as to provide adequate substitute ward accommodation, no such separate ward accommodation is required;

(b) a scrubbing-up area outside the operating-theatre: Provided that if in the operating theatre is sufficiently spacious for the purpose, such scrubbing-up area may be provided at a suitable place within the operating-theatre; and

(c) a sluice room, sluicing facilities, nurses' duty-room facilities, a linen room or cupboard for clean linen, storage space for flammable material, adequate change room and toilet facilities for staff and patients separately (toilets, independent from change-rooms may be provided, for males and females separately), a waiting-room for patients and their visitors, office space and, where applicable, a consulting room.

ACCOMMODATION

11. The rooms referred to in Regulation 14 shall comply with the following requirements:

(a) The waiting-room must have a floor area of not less than 12 square metres, with a minimum wall length of 3 metres: Provided that if the office space is to be provided inside the waiting-

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room the floor of the waiting-room must have an area of not less than18 square metres and a minimum wall length of 3,6 metres.

(b) The office space must—

(i) have a floor area of not less than 6m2 if a portion of the waiting-room is set aside for this purpose; or

(ii) be provided in the form of a separate room, with a floor area of not less than 10 square metres and a minimum wall length of 2,4metres.

(c) The consulting room, if provided, must be outside the operating-theatre area and musthave a floor area of not less than 12 square metres and a minimum wall length of three metres and be fitted with at least one hand-wash basin with sufficient hot and coldwater laid on.

(d) The operating-theatre must have a floor area of not less than 20 square metres, and a minimum wall length of 3,6 metres. The walls must not be less than 2,6 metres high, measured from the floor to the ceiling, and must have a continuous, smooth surface and be painted with hard glossy epoxy resin or a similar paint or covered with any other suitable washable impervious material; the ceiling must be painted with a light-coloured enamel paint.

(e) The walls, the floor and the ceiling must be capable of withstanding repeated cleansing and disinfection.

(f) In the scrubbing-up area, hot and cold water must be laid on to elbow-operated taps over two hand-wash basins or troughs.

(g) The operating-theatre should be sufficiently ventilated and lighted: Provided that windows, if any, are dustproof.

(h) The minimum requirement for air conditioning is the installation of an office type conditioning unit with a 10micron dust filter.

(i) The operating-theatre is provided with electric power to at least three flashproof wall plugs, a suitable electric operating-theatre lamp suspended from the ceiling or cantilevered from the wall, approved facilities for emergency lighting in the event of a power failure and an approved operating table capable of placing the patient at least in the Trendelenburg position and, where applicable, in other positions as well, depending on the operations to be carried out.

(j) The operating-theatre is provided with suitable suction apparatus (for use by the surgeon and the anaesthetist separately) with at least two suction points capable of effectively removing blood and mucus simultaneously and provision is also be made for emergency facilities of this kind, which can be used if the apparatus that is normally used fails.

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(k) The operating-theatre is provided with suitable piping for conducting oxygen and nitrous oxide from a gas bank, unless such gases are supplied in cylinders- A Boyle's apparatus or other suitable type of anaesthetic apparatus with all the necessary connections for the patient's airways is be provided.

(l) The sterilising room has a floor area of not less than 9 square metres and a minimum wall length of 3metres. Save that where an unattached operating-theatre unit was conducted on the same premises prior to the promulgation of these Regulations and a sterilising room with a smaller floor area was used for this purpose, such room may continue to be so used.

(m) The instruments, basins, dressings, dressing drums or packs, containers and water, must be sterilised in the sterilising room in an approved sterilising apparatus which may use one or more of the following methods:

(i) Steam under pressure;

(ii) boiling water;

(iii) dry heat;

(iv) a sterilising gas;

(v) any other approved method:

Provided that if a steam autoclave is used, the apparatus are mounted in an adequately ventilated machine room outside but immediately next to the sterilising room, with the autoclave facing into the sterilising room: Provided further that if the process used involves the production of steam, water vapour or other gases, a suitable apparatus for the effective removal thereof is provided.

(n) Instead of built-in sterilising apparatus, suitable arrangements may be made for an approved central sterile supply department to provide sufficient sterile dressings, towels, bowls, basins, instruments, syringes and sterile water for all operations.

(p) The recovery room or area is in the demarcated area and has a floor area of not less than 12 square metres and a minimum wall length of three metres, the room or area is fitted with at least one hand-wash basin to which hot and coldwater are laid on to elbow-operated taps over the hand-wash basin; at least one flash proof wall plug; a portable lamp that can be taken to every bed; a suction apparatus which can effectively draw off blood and mucus and can reach every bed; a supply of oxygen so laid on that oxygen can be supplied to every bed; and suitable resuscitation apparatus, in addition, facilities are be provided for the screening-off of patients if necessary.

(q) A slop hopper and sink are provided in a suitable area.

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(r) The change room has a floor area of not less than seven square metres and a minimum wall length of 2,1metres and is fitted with flashproof wall plugs and at least one wash-hand basin to which hot and cold water is laid on.

(s) Flush toilets are provided in each change room on the basis of one for every eight persons, and such flush toilets are partitioned off from the rest of the change room.

(t) The change room must have adequate facilities where clothes and clean and soiled theatre clothing may be kept separately.

(u) The change room must have one door which opens inside the demarcated area and a separate entrance from outside the demarcated area.

(v) The ward shall have a floor area of not less than eight square metres for every bed and must be fitted with at least one flashproof wall plug and a wash-hand basin to which hot and cold water is laid on to elbow-operated taps.

(w) The sluice room has a floor area of not less than 5 square metres and a minimum wall length of 2,1metre.

(x) Sufficient cold water must be laid on to a sluice pan.

(y) The sluice room must be fitted with suitable shelves of impervious material for clean and disinfected bed pans and urine containers, as well as receptacles of impervious material, with tight-fitting lids, for soiled linen.

(z) (i) The storage area for flammable material has a floor covered with a washable, impervious material;

(ii) a suitable linen room or cupboard for clean 1: linen is be provided; and

(iii) facilities for sterile storage are be provided.

(s) The duty room must have a floor area of not less than 10 square metres and a minimum wall length of 2,4 metres and must be next to the recovery room or area and between the latter and the ward, if any, with a window in the wall between the duty room and the recovery room or area and one in the wall between the duty room and the ward.

(aa) The duty room must be equipped with hot and cold water laid on to elbow-operated taps over a wash-hand basin and a table with a top of impervious material, and, unless provided elsewhere in the building, a flush toilet and sufficient shelves and lockers for keeping clothes, shoes and soiled gowns separately: Provided that instead of a duty room, a duty station may be provided for the nurse within the recovery room or area or the ward, and such station is equipped with such facilities as may be necessary for this purpose. An alarm system is installed to alert all staff of any emergency cases.

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FURNITURE AND EQUIPMENT

12. (1) The following facilities must be provided in addition to the furniture and equipment in an accommodation in which a health establishment is being conducted:

(a) Facilities for the administration of intravenous fluids and blood;
(b) sphygmomanometers;
(c) a stethoscope;
(d) syringes and needles;
(f) a separate lockable cupboard for Schedule 7 substances;
(g) a separate lockable cupboard for all other Schedule 1-6 unscheduled medicines;
(h) a separate lockable cupboard for hazardous substances; and
(i) an instrument cupboard for the operating-theatre.

(2) The operating-theatre unit must contain sufficient suitable apparatus and instruments, including not less than two laryngoscopes, McGill forceps for adults and children, suitable endoctracheal tubes with the necessary connections, tongue forceps, airways, a tracheostomy set, a cardiac massage set and defibrillator, as well as the means to ventilate a patient if the oxygen supply fails, and other equipment and materials that may be required for emergencies.

PRIVATE HOSPITALS

ACCOMMODATION AND FACILITIES

13. A private hospital must be conducted on premises where adequate and satisfactory provision is made for -

(a) one or more nursing units, including-
(i) beds in wards or rooms for the treatment of patients;
(ii) a duty room or duty station for nurses so placed that physical access to any patient requiring care is not impeded or delayed:
(iii) bathing and toilet facilities for patients;
(iv) a treatment or dressing room;
(v) separate storage space for linen, pharmaceuticals, ward equipment,

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patients' belongings and such sundry items as may be necessary for the management of the nursing unit;

(vi) a sluice room;

(vii) facilities for the cleansing and storage of cleaning equipment and materials;

(viii) a ward kitchen; and

(ix) connecting corridors;

(b) a room or rooms, adequate for administrative control, enquiries, admission of patients and. storage of records, which shall be separate from the duty room of a nursing unit and accessible to the staff without their having to pass through the patient areas;

(c) a main kitchen;

(d) store-rooms for bulk storage;

(e) a rest-room and toilet facilities for staff;

(f) a waiting area and toilet facilities for visitors;

(g) sterile supplies;

(h) facilities for the immediate supply of all necessary pharmaceutical products;

(i) a laundry or a supply of clean linen;

(j) a mortuary or for the immediate removal of any dead body; and

(k) an approved incinerator or other suitable system for the effective and innocuous disposal of soiled dressings and surgically removed tissues.

ADDITIONAL FACILITIES

14. Depending on the requirements of the patients admitted or treated at a health establishment, any or all of the following facilities may be provided, in accordance with these Regulations, and, where deemed indispensable or required by the Director-General, shall be thus provided:

(a) An operating-theatre unit;

(b) a separate maternity unit;

(c) reception and treatment facilities for out-patients and/or casualties;

(d) central sterilising facilities;

(e) accommodation and facilities for employees;

(f) facilities for-

(i) radiology and allied diagnostic purposes;

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(ii) physiotherapy;
(iii) occupational therapy;
(iv) electro-convulsive treatment;
(v) psychotherapy;
(vi) any special investigation or treatment;
(vii) the training of nurses, medical practitioners and members of supplementary health service professions;
(viii) the medical examination of employees; and
(ix) the training of employees in first aid; and

(g) any other approved facilities.

GENERAL STRUCTURAL REQUIREMENTS

15. Save where otherwise required in these Regulations, the following structural requirements apply to all health establishments:

(a) The walls of the operating-theatre unit and of the labour unit shall be not less than 2,6 metres high, measured from the floor to the ceiling and shall be constructed of approved impervious material.

(b) In the operating-theatre unit, the labour unit, all toilets, bathrooms and sluice rooms, and wherever else necessary, the joint between the floor and the walls shall be so rounded as to permit effective cleaning.

(c) Each corridor or passageway used for patients may not be less than two metres wide and where patients are moved within the operating-theatre unit or labour unit the corridor shall be at least 2,5 metres wide.

(d) All rooms shall be sufficiently lighted and ventilated.

(e) Dustproof ceilings of smooth, impervious material, painted with a white or light coloured suitable washable paint, shall be provided throughout all patient accommodation and treatment areas.

(f) The floors of all rooms and corridors shall be constructed of concrete or a similar impervious material brought to a smooth finish and, except where otherwise provided in these Regulations, shall be covered with a washable, impervious material.

(g) All interior wall surfaces shall be given a smooth, hard plaster finish with rounded corners, painted with a light-coloured durable washable paint or alternatively

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satisfactorily covered with a similar washable, impervious material: Provided that, where walls have been painted, the walls behind wash-handbasins shall be specially clad to a height of at least 500 millimetres above, and to a distance of at least 500 millimetres beyond the sides of such wash-handbasins in glazed tiling or a special washable, impervious material so as to form an impervious finish continuous with the paintwork.

(h) Effectively placed and adequate fire-hydrants, fire-hoses, fire-extinguishers, fire escapes and emergency exits shall be provided and satisfactorily maintained.

(i) Wash-hand basins shall be provided in the immediate vicinity of all toilets, urinals and sluices.

(j) An air-conditioning system is installed in the room provided for the storage of medicine in order to ensure a constant room temperature.

PATIENT ACCOMMODATION.

16. (1) In this Regulation any fixture is, for purposes of determining minimum measurements, regarded as a wall or part of a wall of a room in which a patient is accommodated.

(2) No patient may be accommodated in any room with a floor area of less than10 square metres or in a single room where there is not a minimum space of -

(a) 0,9 metres between any side of any bed and the nearest wall on that side; and

(b) 1,2 metres between the foot of any bed and the opposite wall.

(3) No patient may be accommodated in a room with more than one bed unless provision is made for a minimum space of -

(a) 0,75 metres between any side of any bed and the nearest wall:

(b) 0,9 metres between the sides of any adjacent beds; and

(c) 1,2 metres between the foot of any bed and the opposite wall or a minimum of 1,5 metres between the foot of any bed and the opposite bed.

(4) No infant may be accommodated in a nursery unless there is a minimum space of-

(a) 0,75 metres between adjacent cots;

(b) 0,6 metres in between any side of any cot and the nearest wall; and

(c) 0,9 metres between the foot of any cot and the opposite wall.

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(5) No patient room may be used for the accommodation of both male and female patients, except when all patients are children not older than 10 years: Provided that a patient room may be used for the simultaneous accommodation of a husband and wife.

(6) Except in the case of a mother and child, children and adults, shall always be accommodated in separate rooms: Provided that, where separate accommodation for adults and children under the age of 10 years is impractical for reasons of treatment, proper screening facilities shall be made available.

PATIENT ROOMS

17. (1) Each patient room in a private hospital must communicate directly with a corridor or passageway.

(2) Doors giving access to rooms in which patients are or are to be accommodated must be at least 1,2 metres wide.

(3) Each patient room shall have a hand-wash basin fitted with elbow operated taps to which hot and cold water is laid on.

(4) Each patient room must be identified by displaying at the entrance -

(a) the number of the patient room; and

(b) the approved number of beds in such room.

ANCILLARY FACILITIES

18. (1) (a) Where several patient rooms share toilet facilities or where a patient room with its own facilities contains more than eight beds, the following shall be provided:

(i) At least one bath or shower per 12 patients or part of such number: Provided that the proportion of baths to showers shall correspond to the function of the nursing unit;

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(ii) at least one toilet per eight patients or part of such number, but wards for male patients a urinal may be substituted for every third toilet; and

(iii) at least one wash-hand basin per eight patients or part of such number.

(b) Adequate special bathing facilities for babies shall be provided in direct conjunction with nurseries.

(2) (a) The size and equipment of the ward kitchen shall be adequate for the size and function of the nursing unit and for the system of supplying food.

(b) The ward kitchen shall be so placed that it does not cause a nuisance.

(3) (a) Depending on the system of supplying food, adequate provision shall be made for-

(i) facilities for taking delivery of, storing and preparing hot and cold food, and serving such food to patients and staff;

(ii) facilities for the removal, washing-up and storage of crockery and cutlery; and

(iii) facilities for the effective extraction of steam, smoke, vapour and heat.

(b) Adequate and suitable provisions shall be made for-

(i) garbage bins which can be properly emptied and cleaned, and which are provided with closefitting lids; and

(ii) wash-band basins for kitchen staff.

(4) Suitable, change room, rest room and toilet facilities for employees shall be provided and such facilities shall be of the standard laid down in the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

(5) Suitable and adequate waiting rooms, toilets and wash-hand basins shall be provided for visitors.

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OPERATING-THEATRE UNIT IN A PRIVATE HOSPITAL

GENERAL REQUIREMENTS

19. An operating-theatre unit must include the following:

(a) One or more operating-theatres with access only through a room, area, passageway or corridor which is clearly within the demarcated area and shall be planned and equipped in such a way that adequate control can be exercised over all persons and materials which enter such room, area, passageway or corridor; and

(b) further within the demarcated area -

(i) an adequate sterile pack and setting rooms;

(ii) a scrubbing-up area outside but adjacent to the operating-theatre, with satisfactory access to such operating-theatre: Provided that, subject to the recommendation of the Director-General with regard to any special services offered in the operating-theatre, the Director-General may permit such scrubbing-up area to be situated within the operating-theatre;

(iii) a recovery room or area where patients can be adequately accommodated for post-operative nursing surveillance, which is immediately accessible to a medical practitioner and which has sufficient resuscitation and emergency facilities;

(iv) a sterile supply unit: Provided that a portion of the facilities of such unit may be screened off so as to fall outside the demarcated area;

(v) a sluice room to serve the operating-theatre or operating-theatres only: Provided that, where a special corridor is provided from which cleaning of the operating-theatre or operating-theatres can be effected such sluice room shall not be situated within the demarcated area, but shall be so situated as to have an access door from such corridor only;

(vi) suitable change-room facilities, with direct access to the demarcated area, for medical practitioners, nursing and domestic staff: Provided that additional change-room facilities shall be provided for patients not utilising ward accommodation;

(vii) a transfer area, for the transfer of patients from ward trolleys to theatre trolleys, across the demarcated area;

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(viii) a nurses' duty room or duty station which is so situated, constructed and equipped that it is possible for the nursing staff to observe patients directly and render assistance to patients where necessary;

(ix) if light refreshments are to be served, suitable facilities for storing, preparing and serving such refreshments;

(x) cleaners' facilities: and

(xi) separate store-rooms, or sufficient suitable storage cupboards in lieu thereof, for the storage of clean linen, medicines, equipment and sundry items.

DIMENSIONS

20. Any operating-theatre shall have-

(a) a floor are-a of not less than 30 square metres;

(b) a wall height of not less than 3metres;

(c) a width of not less than 5,1metres; and

(d) an instrument setting area immediately off the operating-theatre.

FLOOR

21. (1) The floor of any operating-theatre shall be of impervious material, laid without open interstices and with jointing filled in so as to provide a continuous impervious covering, and so finished that the wall covering and the floor covering are joined in a continuous smooth surface without interstices.

(2) In an operating-theatre, unless anti-static flooring has been laid and maintained inconformity with the specifications of the South African Bureau of Standards, there shall be affixed and prominently displayed at the entrance to such theatre a cautionary notice to the effect that the floor of such theatre is not anti-static and that explosive anaesthetic agents, gases or cleaning agents are not to be used inside such theatre.

INSTALLATIONS

22. Every operating theatre shall be provided with the following: -

(a) An adequate piped gas supply of oxygen and nitrous oxide;

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(b) an adequate lighting system;

(c) an air-conditioning system fitted with filters effective for five micron particles and with sufficient capacity to maintain a temperature of at least 10° C and a relative humidity of at least 45 per cent;

(d) an adequate and satisfactory mechanical suction system with at least two suction points;

(e) adequate facilities for an emergency supply of oxygen and nitrous oxide, emergency lighting and emergency suction in the event of mechanical, electrical or other failure during an operation;

(f) electric power to at least three flash-proof wall plugs with an earth leakage device at a minimum height of 1,5 metres; and

(g) an approved operating table on which the patient can be positioned according to the requirements of the operation to be performed.

CORRIDORS WITHIN OPERATING-THEATRE UNITS

23. An unobstructed width of not less than 2,5 metres must be maintained for patient trolleys in corridors and passageways within any operating-theatre unit.

SCRUBBING-UP AREAS WITHIN OPERATING-THEATRE UNITS

24. (1) Any scrubbing-up area must have a width of not less than 2,1metres and must be so equipped so as to permit both unhindered and simultaneous scrubbing-up by at least two persons under hot and cold running water from elbow-operating taps over splash-limiting basins or a drainage trough, and gowning prior to entering the operating-theatre.

(2) Where the use of the operating-theatre is limited to specific procedures, satisfactory provision for simultaneous separate scrubbing-up, by two persons only shall be deemed sufficient for the purposes of this regulation.

RECOVERY AREAS WITHIN OPERATING-THEATRE UNITS

25. (1) The recovery room or area must be inside the demarcated area and must have a floor area of not less than 12 square metres and a wall length of not less than three metres, and must

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provide sufficient space for at least one patient from each operating-theatre which it serves, calculated on the basis of 9square metres of unobstructed floor area per patient.

(2) The recovery room or area must be fitted with -

(a a hand-wash basin to which hot and cold water is laid on to elbow operated taps;

(b) a sufficient supply of oxygen for each patient to be accommodated;

(c) a sufficiently adjustable fixed or portable lamp for every recovery bed or trolley;

(d) an adequate and satisfactory mechanical suction system with one suction point for every recovery bed or trolley;

(e) two flash-proof electric power outlets for every recovery bed or trolley; and

(f) facilities for screening of patients.

STERILE SUPPLY UNIT

26. (1) A sterile supply unit must have a floor area of not less than 12 square metres, a wall length of not less than three metres and adequate free floor space.

(2) The sterile supply unit must be adequately equipped separately to receive, clean, pack, sterile and store instruments, materials, dressings, basins, containers, water and sundry items used in connection with the treatment provided.

(3) If a steam autoclave is used, it must be mounted an adequately ventilated and accessible machine room outside and immediately adjacent to the sterilising area, with the autoclave opening into such area: Provided that, if any sterilising process used involves the production of steam, water vapour or any other gases, a suitable means for the effective removal thereof shall be provided.

(4) The provisions of this regulation do not preclude any proprietor from establishing and maintaining, with the consent of the Head of Department, and subject to such conditions as the Head of Department may impose, an approved central sterile supply department in order to

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provide adequate sterile supplies to all patient accommodation and treatment areas of the hospital.

DUTY ROOMS WITHIN OPERATING-THEATRE UNITS

27. (1) A theatre duty room must have a floor area of not less than 10 square metres and a minimum wall length of 2,4 metres and shall be so situated and constructed so as to make effective patient surveillance possible: Provided that an adequate duty station may be provided instead of a duty room.

(2) The theatre duty room or station shall be equipped with such facilities that are necessary for the purpose for which such theatre duty room or station is used.

SLUICE ROOMS OF OPERATING-THEATRE UNITS

28. A theatre sluice room must have a floor area of not less than five square metres and a minimum wall length of 2,1 metres and shall be fitted with -

(a) a sluice pan;
(b) adequate shelving for storing clean containers;
(c) a stainless steel wash-up basin to which hot and cold water is laid on; and
(d) a wash-hand basin to which hot and cold water is laid on.

CHANGE ROOMS OF OPERATING-THEATRE UNITS

29. A change room of an operating-theatre unit must be of adequate size and shall have a floor area of not less than nine square metres and a minimum wall length of 2,1 metres and shall be provided with -

(a) a wash-hand basin to which hot and cold water is laid on;
(b) suitably partitioned off toilets on the basis of one toilet for every seven members of the theatre staff or part of such number;
(c) adequate facilities for the separate storage of personal clothing and effects, clean and used theatre clothing; and
(d) a shower cubicle with a dry change area.

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MATERNITY UNIT

GENERAL REQUIREMENTS

30. A maternity unit shall include -

(a) one or more nursing units, in accordance with these regulations;

(b) adequate nursery facilities which may include -

(i) a separate room where facilities for special care must be provided, including-

(aa) at least one incubator;

(bb) resuscitation equipment with suction and oxygen; and

(cc) oxygen and suction supply in the: main nursery;

(ii) resuscitation equipment in the delivery room shall include-

(aa) a table of a suitable height; with overhead heating; and

(bb) oxygen and suction supply;

(c) a milk kitchen, if more than 15 mother beds are provided;

(d) a patients' preparation room, if more than 15 mother beds are provided;

(e) a labour unit consisting of-

(i) a delivery room or rooms on the basis of one delivery room for every 10 mother beds. or one delivery room plus a room for patients in the first stage of labour for every 15 mother beds;

(ii) ancillary services, including-

(aa) a sluice room with provision for storing, examining and disposing of placentas; and

(bb) separate storage facilities for sterile packs and instruments, linen, medicines and sundry equipment;

(f) where more than 15 mother beds are provided and no operating-theatre facilities are readily available, provision shall be made for an operating-theatre unit with sufficient suitable theatre facilities.

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DELIVERY ROOMS

31. (1) Each delivery room must have a floor area of not less than 16 square metres and a minimum width of 3,7 metres.

(2) Each delivery room must also contain -

(a) adequate scrubbing-up facilities;

(b) a suitable adjustable lamp, fixed or mobile;

(c) an anti-static floor if explosive anaesthetic gases are used:

(d) adequate provision for oxygen; and

(e) adequate baby resuscitation facilities.

MODIFICATIONS

32. (1) No building of any health establishment or any portion of such building may be extended, demolished or modified or otherwise structurally or functionally altered without the written approval of the Director-General.

(2) Any person wishing to obtain such approval must apply in writing and every such application must -

(a) be accompanied by detailed plans and specifications; and

(b) set out in full the reasons for the proposed extension, demolition modification or alteration.

DISPLAYING OF CERTIFICATE OF NEED

33. The certificate of need issued in respect of a health establishment or health agency must be displayed in a conspicuous place on the premises of the health establishment or health agency.

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INSPECTIONS

34. (1) The Director-General may request the Office to inspect a health establishment or health agency applying for a certificate of need in terms of this Regulations in order to ensure compliance with necessary standard requirements set out in this Regulations.

(2) The person in charge for the management and control of the health establishment and health agency and nursing services must render to the inspecting officer in terms of these Regulations all information, the said officer may require in regard to the organisation and management of such health establishment and health agency and the accommodation, nursing and treatment of the patients.

(3) All registers, clinical records and any other records in connection with patients and staff shall also be available for inspection.

(4) No person may in any way obstruct any inspecting officer carrying out his inspection or refuse to furnish to the best of his or her knowledge any information requested by such officer or to show any apparatus or place or item, or to unlock any cupboard.

SHORT TITLE

35. These Regulations are called the Regulations Relating to the Certification of Need, 2020.

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ANNEXURE A

Department of Health

Application for a Certificate of Need

The Director-General: Health
Private Bag X828
PRETORIA
0001

Application is hereby made for the certification of need for the following health establishment and health agencies, details of which are supplied below.

1. Name of health establishment:.....

.....

2. Situation of premises (street, locality, town): .....

.....

3. Name and postal address of registered owner of the property (premises): .....

.....

4. Name and address of proprietor (in the case of a company or association, its nominee) who will be conducting the health establishment:.....

.....

5. Name and address of the medical practitioner or registered nurse and midwife who will be in charge: .....

6. If a medical practitioner will be in charge, name and qualifications of the registered nurse and midwife who will be in charge of the nursing services:.....

.....

7. Name and allocation of beds available for patients (see notes below).....

.....

General Maternity

Adults Children Mothers Babies

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Infectious diseases

Others

(specify)

Total

8. Number of:

(a) Operating theatres:.....

(b) Delivery rooms:.....

9. Changes in the patient accommodation/beds available during the current year, if any

(specify): .....

10. Numbers of registered staff *employed at date of application/to be employed at date of new registration applied for:

Practitioners Nurses

Medical Dental Registered Student

Full-time.....

Part-time....

11. Number of full-time enrolled nurses *employed at the date of application / to be employed at date of new registration applied for:

Enrolled

nurses

Enrolled

student nurse

Enrolled nursing

assistants

Enrolled pupil

nursing assistants

Full-time.....

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12. Other full-time registered staff employed (if any) (specify) .....

.....

13. Other part-time registered staff employed (if any) (specify) .....

.....

14. If the hospital is recognised by the South African Nursing Council as an approved training school for nurses, midwives or enrolled nurses or enrolled nursing assistants:

(a) General nurses Midwives Enrolled nurses Enrolled nursing assistants

(b) If the hospital is recognised as an approved training school for one or more of the categories of nursing staff referred to in subsection (a), the following information should also be given:

Category Number of registration or enrolment Date of issue certificate issued by the S.A.N.C.

(i) Student general nurses....

(ii) Student midwives.....

(iii) Pupil nurses.....

(iv) Pupil nursing assistants....

Registration with the SA Nursing Council (specify):

Number of original Annual registration certificate

Date of issue

Receipt number Date

General.....

Midwifery.....

Other.....

(c) Other trained staff, excluding person in control:

(i) Registered nurses/midwives:

31

Name Qualifications Number of original Annual registration certificate

Date of issue

Receipt number

Date

(ii) Enrolled nurses .....

Total..... .....

(iii) Enrolled nursing assistant.....

Total..... .....

15. Arrangements for the training and teaching of each of the following categories, as applicable:

(i) Student nurses.....

(ii) Student midwives.....

(iii) Pupil nurses.....

(iv) Pupil nursing assistants.....

I hereby certify that the above particulars are true and correct

Place.....

Date..... .....

Signature of proprietor

N.B.-If available space is insufficient, attached separate schedule.

Notes:

(a) *Words designated by an asterisk to be deleted if not applicable

(b) This form is to be used for the first and every subsequent application for registration.

(c) Item 7: The numbers of beds, cribs/cots actually available for accommodating patients are to be stated, but these exclude -

- all trolleys;
- all waiting, preparation, first stage and labour room beds and cots in maternity

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units;

• the recovery trolleys and recovery beds of an operating-theatre unit of a health establishment.

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ANNEXURE B

CERTIFICATE OF NEED

Certificate No……..

Reference No……..

DEPARTMENT OF HEALTH

CERTIFICATE OF NEED

It is hereby certified that the ……..

……

situated at ……

is granted a Certificate of Need as a health establishment in terms of these Regulations relating to Certificate of Need for Health Establishments and Health Agencies

for a period of 20 years, ending……..

Name of proprietor or managing body……

Address of proprietor or managing body……

……

Name of person in charge……

Maximum number of patients who may be accommodated at the same time:

Maximum Patients that can be accommodated simultaneously number accommodated

* Medical and surgical:

(a) Adults……

(b) Children……..

* Maternity:

(a) Mothers……

(b) Babies……

Infectious diseases……

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Other (specify).....

With the exception of the above-mentioned activities, the activities of the above-mentioned health establishment are restricted as follows .....

.....

Signed at ..... this .....day

of .....20.....

.....

Director-General

This certificate is not transferable and must be renewed annually

* Delete if not applicable

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ANNEXURE C

FEES

ITEM AS PER REGULATION AND STANDARDS (AS APPLICABLE)	SERVICE	FEE
a) Application Fees for the establishment, construction, modification or acquiring of a health establishment		R000.00
b) Application Fees for the increase of the number of beds in a health establishment		R000.00
c) Application Fees for the establishment or acquiring of a health agency		R0 000.0
d) Application Fees for the acquiring of a health technology in a health establishment		R000.00
e) Inspection Fees for the establishment, construction, modification or acquiring of a health establishment		R000.00
f) Inspection Fees for the increase of the number of beds in a health establishment		R000.00
g) Inspection Fees for the establishment, or acquiring of a health agency		
h) Inspection Fees for the acquiring of a health technology in a health establishment		R000.00
i) Renewal Fees for health establishment		R000.00
j) Renewal Fees for the health agency		R000.00
k)		

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