

---

**GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS**

---

**DEPARTMENT OF HEALTH**

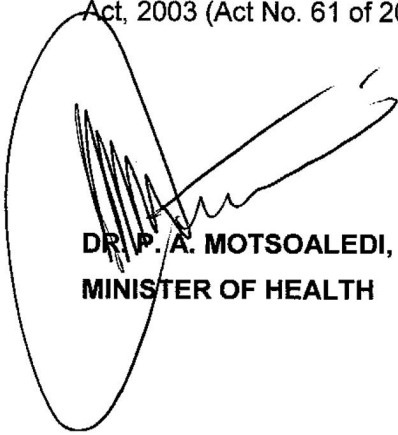
**NO. 1434**

**15 DECEMBER 2017**

**NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)**

**REGULATIONS RELATING TO THE SURVEILLANCE AND THE CONTROL OF  
NOTIFIABLE MEDICAL CONDITIONS**

The Minister of Health has, in terms of section 90(1) (j), (k) and (w) of the National Health Act, 2003 (Act No. 61 of 2003), made the regulations in the Schedule.



**DR. P. A. MOTSOLEDI, MP  
MINISTER OF HEALTH**

**SCHEDULE****ARRANGEMENT OF REGULATIONS**

- |    |             |   |
|----|-------------|---|
| 1. | Definitions | 4 |
|----|-------------|---|

**CHAPTER 1****IMPLEMENTATION PRINCIPLES AND RESPONSIBILITIES IN RELATION TO NOTIFIABLE MEDICAL CONDITIONS**

- |     |   |    |
|-----|---|----|
| 2.  | Implementation principles                                 | 6  |
| 3.  | Responsibilities at national level                        | 7  |
| 4.  | Responsibilities at provincial level                      | 7  |
| 5.  | Responsibilities at health district level                 | 8  |
| 6.  | Responsibilities at health sub-district level             | 9  |
| 7.  | Responsibilities at health establishment level            | 9  |
| 8.  | Responsibilities of health care providers                 | 10 |
| 9.  | Responsibilities of laboratories                          | 10 |
| 10. | Responsibilities of pathologists and laboratory personnel | 11 |
| 11. | Responsibilities of Medical Schemes                       | 11 |

**CHAPTER 2****DECLARATION OF NOTIFIABLE MEDICAL CONDITIONS**

- |     |  |    |
|-----|--|----|
| 12. | Declaration of notifiable medical conditions | 12 |
| 13. | The notification and reporting process       | 12 |

**CHAPTER 3****PREVENTION AND CONTROL OF NOTIFIABLE MEDICAL CONDITIONS**

- |     |   |    |
|-----|---|----|
| 14. | Voluntary medical examination, prophylaxis, treatment, isolation and quarantine | 15 |
|-----|---|----|

<b>15. Mandatory medical examination, prophylaxis, treatment, isolation and quarantine</b>	<b>16</b>
<b>16. Control of the spread of notifiable medical conditions</b>	<b>18</b>

## **CHAPTER 4**

### **GENERAL MATTERS**

<b>17. Representation</b>	<b>19</b>
<b>18. Confidentiality</b>	<b>20</b>
<b>19. Protection of health records</b>	<b>20</b>
<b>20. Offences and penalties</b>	<b>20</b>
<b>21. Repeal</b>	<b>20</b>
<b>22. Short title</b>	<b>21</b>
Annexure A Table 1: List of category 1 notifiable medical conditions	22
Annexure A Table 2: List of category 2 notifiable medical conditions	23
Annexure A Table 3: List of category 3 notifiable medical conditions	24
Annexure A Table 4: List of category 4 notifiable medical conditions	24
Annexure B Table 1: Data elements to be reported by health care providers	25
Annexure B Table 2: Data elements to be reported by private and public health laboratories	26
Annexure B Table 3: Data elements to be reported by medical schemes	27

## Definitions

1. In these regulations, a word or expression to which a meaning has been assigned in the Act bears the meaning so assigned, unless the context indicates otherwise–

**“carrier”** means a person who is confirmed to be infected with a notifiable medical condition through laboratory tests or other medical procedures, but does not show any clinical signs and symptoms of the disease at the time;

**“category 1 notifiable medical condition”** means a condition indicated in Annexure A, Table 1, that requires immediate reporting by the most rapid means available upon clinical or laboratory diagnosis followed by a written or electronic notification to the Department of Health within 24 hours of diagnosis by health care providers, private health laboratories or public health laboratories;

**“category 2 notifiable medical condition”** means a condition indicated in Annexure A, Table 2 that must be notified through a written or electronic notification to the Department of Health within seven days of clinical or laboratory diagnosis by health care providers, private health laboratories or public health laboratories;

**“category 3 notifiable medical condition”** means a condition indicated in Annexure A, Table 3 that must be notified through a written or electronic notification to the Department of Health within 7 days of diagnosis by private or public health laboratories;

**“category 4 notifiable medical condition”** means a condition indicated in Annexure A, Table 4 that must be notified through a written or electronic notification to the Department of Health within 1 month of diagnosis by private and public health laboratories;

**“case”** means a person who is diagnosed with a notifiable medical condition either as a clinical case or a laboratory confirmed case;

**“clinical case”** means a patient that presents with clinical signs and symptoms of a notifiable medical condition;



**“contact”** means a person who has been exposed to a notifiable medical condition but does not show any clinical signs and symptoms of the disease at the time;

**“contamination”** means the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inmate objects, including conveyances, that may constitute a public health risk;

**“focal person”** means a person designated in terms of regulations 4(2) (f), 5(2)(e) and 6(2)(e);

**“IHR”** means the World Health Organization’s International Health Regulations, 2005;

**“ill person”** means an individual suffering from or affected with a physical ailment that may pose a public health risk;

**“isolation”** means the separation of an ill or contaminated person or affected baggage, a container, conveyance, goods or a postal parcel from others in such a manner as to prevent the spread of infection or contamination;

**“laboratory confirmed case”** means a patient with a notifiable medical condition diagnosed through a Department of Health approved laboratory diagnostic method;

**“Medical Scheme”** means a medical scheme registered in terms of section 24 of the Medical Schemes Act, 1998 (Act No. 131 of 1998);

**“national department”** means the national Department of Health;

**“national (IHR) Focal Point”** means the national centre, designated by each State Party, which shall be accessible at all times for communications with World Health Organization’s (WHO) IHR Contact Points under the International Health Regulations;

**“notifiable medical condition”** means a medical condition, disease or infection of public health importance that is classified as notifiable in terms of regulation 12;

**“outbreak”** means the occurrence of more cases of a disease than that which is normally expected, within a specific place or group of people, over a given period of time;

**“provincial department”** means the provincial Department of Health;

**“public health risk”** means a likelihood of an event that may adversely affect the health of human populations, with the emphasis on one which may spread internationally or may present a serious and direct danger;

**“quarantine”** means the restriction of activities and/or separation from others of a suspect person who is not ill or of a suspect baggage, container, conveyance or goods in such a manner as to prevent the possible spread of infection or contamination;

**“surveillance”** means the systematic, ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;

**“suspect”** means “those persons, baggage, cargo, containers, conveyances, goods, or postal parcels considered by the a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;

**“the Act”** means the National Health Act, 2003 (Act No. 61 of 2003); and

**“WHO IHR Contact Point”** means the unit within the WHO which shall be accessible at all time for communications with the National IHR Focal Point.

## CHAPTER 1

### IMPLEMENTATION PRINCIPLES AND RESPONSIBILITIES IN RELATION TO NOTIFIABLE MEDICAL CONDITIONS

#### Implementation principles

2. In implementing these Regulations, the following must be taken into account:
  - (1) the provisions of the Constitution of the Republic of South Africa, 1996;

- (2) full respect for the dignity, confidentiality, human rights and fundamental freedoms of persons; and
- (3) the requirement by the International Health Regulations (IHR), 2005 for countries to develop the capacity to detect, assess, notify and respond promptly and effectively to public health risks.

### **Responsibilities at national level**

3. (1) The Minister has the overall responsibility to oversee the implementation of these Regulations.
- (2) The Director-General must–
  - (a) promote adherence to the use of standard case definitions for all notifiable medical conditions according to the World Health Organization (WHO) International Classification of Diseases as adapted by the national department;
  - (b) promote adherence to the use of national department forms and tools for reporting notifiable medical conditions;
  - (c) promote the adherence to the notification procedures stipulated in these Regulations;
  - (d) ensure that structures, processes and systems are in place for the surveillance and control of notifiable medical conditions as stipulated in national department guidelines;
  - (e) designate and ensure the functioning of the National IHR Focal Point;
  - (f) notify the WHO IHR Contact Point through the National IHR Focal Point within 24 hours of epidemiological assessment, of all events which may constitute a public health emergency of international concern;
  - (g) issue and promote adherence to national department guidelines on the surveillance and control of notifiable medical conditions.

### **Responsibilities at provincial level**

4. (1) The Provincial Member of the Executive Council responsible for health must ensure the implementation of these Regulations within the Province.

- (2) The Head of a Provincial Department of Health must–
- (a) ensure adherence to these Regulations within his or her Province;
  - (b) ensure adherence to the use of standard case definitions for all notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (c) ensure adherence to the use of national department forms and tools for reporting notifiable medical conditions;
  - (d) ensure adherence to the notification procedures stipulated in these Regulations;
  - (e) ensure that structures, processes and systems are in place for the surveillance and control of notifiable medical conditions as stipulated in national department guidelines;
  - (f) designate a person responsible for coordinating the surveillance and control of notifiable medical conditions;
  - (g) ensure that national department guidelines on the surveillance and control of notifiable medical conditions are adhered to and implemented.

#### **Responsibilities at health district level**

5. (1) The district health manager must implement these Regulations within his or her district.
- (2) The district health manager must–
- (a) ensure that these Regulations are adhered to in his or her district;
  - (b) ensure adherence to the use of standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (c) ensure adherence to the use of national department forms and tools for reporting notifiable medical conditions;
  - (d) ensure adherence to the notification procedures stipulated in these Regulations;
  - (e) designate a person responsible for coordinating the surveillance and control of notifiable medical conditions;



- (f) ensure that national department guidelines on the surveillance and control of notifiable medical conditions are adhered to and implemented.

#### **Responsibilities at health sub-district level**

- 6. (1) The sub-district health manager must implement these Regulations within his or her health sub-district.
- (2) The sub-district health manager must–
  - (a) ensure that these Regulations are adhered to in his or her sub-district;
  - (b) ensure adherence to the use of standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (c) ensure adherence to the use of national department forms and tools for surveillance of notifiable medical conditions;
  - (d) ensure adherence to the notification procedures stipulated in these Regulations;
  - (e) designate a person responsible for coordinating the surveillance and control of notifiable medical conditions;
  - (f) ensure that national department guidelines on the surveillance and control of notifiable medical conditions are adhered to and implemented.

#### **Responsibilities at health establishment level**

- 7. (1) The health establishment manager must implement these Regulations within his or her health establishment.
- (2) The health establishment manager must–
  - (a) ensure that these Regulations are adhered to in his or her health establishment;
  - (b) ensure adherence to the use of standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (c) ensure adherence to the use of national department forms and tools for reporting notifiable medical conditions;

- (d) ensure adherence to the notification procedures stipulated in these Regulations;
- (e) ensure that national department guidelines on the surveillance and control of notifiable medical conditions are adhered to and implemented.

### **Responsibilities of health care providers**

8. (1) A health care provider must–
- (a) notify the focal person at the health sub-district level of any diagnosed case of a notifiable medical condition through the use of–
    - (i) standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
    - (ii) national department forms and tools for reporting notifiable medical conditions;
    - (iii) notification procedures stipulated in these Regulations;
  - (b) ensure adherence to these Regulations;
  - (c) adhere to national department guidelines on the surveillance and control of notifiable medical conditions.

### **Responsibilities of laboratories**

9. (1) The laboratory manager of a private or a public health laboratory must implement these Regulations within his or her laboratory.
- (2) The laboratory manager must–
- (a) ensure that these Regulations are adhered to in his or her laboratory;
  - (b) ensure adherence to the use of standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (c) ensure adherence to the use of national department forms and tools for reporting notifiable medical conditions;
  - (d) ensure adherence to the notification procedures stipulated in these Regulations;

- (e) ensure that national department guidelines on the surveillance and control of notifiable medical conditions are adhered to and implemented.

### **Responsibilities of pathologists and laboratory personnel**

- 10. (1) A pathologist and laboratory personnel must–
  - (a) notify the focal person at the health sub-district level of any diagnosed case of a notifiable medical condition through the use of–
    - (i) standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
    - (ii) national department forms and tools for reporting notifiable medical conditions;
    - (iii) notification procedures stipulated in these Regulations;
  - (b) ensure adherence to these Regulations;
  - (c) adhere to national department guidelines on the surveillance and control of notifiable medical conditions.

### **Responsibilities of Medical Schemes**

- 11. A Medical Scheme must–
  - (a) ensure that these Regulations are adhered to within its institution;
  - (b) report any notifiable medical condition for which it has received a claim from a health care provider or laboratory personnel to the national department;
  - (c) ensure adherence to the use of standard case definitions for notifiable medical conditions according to the WHO International Classification of Diseases as adapted by the national department;
  - (d) ensure adherence to the use of national department forms and tools for reporting notifiable medical conditions;
  - (e) ensure adherence to the notification procedures stipulated in these Regulations.



## CHAPTER 2

### Declaration of notifiable medical conditions

12. (1) The medical conditions listed in Annexure A, Tables 1, 2, 3 and 4 are hereby declared to be notifiable medical conditions.
- (2) The Minister, may declare, by Notice in the Government Gazette, a medical condition not listed in Annexure A, as notifiable if in his or her opinion the medical condition—
- (a) poses a public health risk to a population of a particular community, district, municipality, province or the country;
  - (b) may be regarded as a public health risk or has a potential for regional or international spread; and
  - (c) may require immediate, appropriate and specific action to be taken by the national department, one or more provincial departments or one or more municipalities.
- (3) The Minister may determine, by Notice in the Government Gazette, that—
- (a) certain diseases or medical conditions be notifiable in certain provinces, districts or municipalities, for a period specified in the Notice or until the Notice is withdrawn;
  - (b) certain diseases or medical conditions be notifiable by certain categories of health care providers, pathologist or laboratory personnel; and
  - (c) specific diagnostic or laboratory criteria apply to specific diseases or medical conditions.

### Notification and reporting process

- 13 (1) (a) A health care provider who diagnoses a patient with a notifiable medical condition listed in Annexure A, Table 1, must report the medical condition to the focal person at the health sub-district level by the most rapid means available upon diagnosis, even before the case is laboratory confirmed in order to facilitate the implementation of public health measures and response;

- ?
- (b) The report contemplated in sub-regulation (a) must be followed by a written or electronic notification within 24 hours of diagnosis, in order to facilitate the implementation of public health measures and response;
  - (c) A health care provider who diagnoses a patient with a notifiable medical condition listed in Annexure A, Table 2, must notify the focal person at the health sub-district level of the medical condition within seven (7) days of diagnosis, through a written or electronic notification, in order to facilitate the implementation of public health measures and response.
- (2)
- (a) A health care provider who diagnoses or treats a patient with a notifiable medical condition listed in Annexure A, Tables 1 and 2, and the patient subsequently dies as a result of such a condition, must report the death to the focal person at the health sub-district level by the most rapid means available in order to facilitate the implementation of public health measures and response;
  - (b) The report contemplated in sub-regulation (a) must be followed by a written or electronic notification within 24 hours of diagnosis, in order to facilitate the implementation of public health measures and response.
- (3)
- (a) A pathologist or laboratory personnel, who diagnoses a notifiable medical condition listed in Annexure A, Table 1, must, upon diagnosis, report the medical condition to the focal person at the health sub-district level by the most rapid means available in order to facilitate the implementation of public health measures and response;
  - (b) The report contemplated in sub-regulation (a) must be followed by a written or electronic notification within 24 hours of diagnosis, to facilitate the implementation of public health measures and response;
  - (c) A pathologist or laboratory personnel, who diagnoses a notifiable medical condition listed in Annexure A, Table 2, must notify the focal person at the health sub-district level of the medical condition within seven (7) days of diagnosis, through a written or electronic notification in order to facilitate the implementation of public health measures and response;
  - (d) A pathologist or laboratory personnel, who diagnoses a notifiable medical condition listed in Annexure A, Table 3, must notify the focal person at the health sub-district level of the medical condition within 7 days of diagnosis,

- through a written or electronic notification, in order to facilitate the implementation of public health measures and response.
- (e) A pathologist or laboratory personnel, who diagnoses a notifiable medical condition listed in Annexure A, Table 4, must notify the focal person at the health sub-district level of the medical condition within 1 month of diagnosis, through a written or electronic notification, in order to facilitate the implementation of public health measures and response.
- (4) A Medical Scheme must report a notifiable medical condition listed in Annexure A, Tables 1, 2, 3 and 4, for which it has received a claim from a health care provider, a pathologist or laboratory personnel, to the national department on a monthly basis in order to facilitate the implementation of public health measures and response.
- (5) (a) A health care provider, pathologist or laboratory personnel who has knowledge of an outbreak or an unusual incidence of–
- (i) a notifiable medical condition listed in Annexure A, Tables 1, 2, 3 and 4;
  - (ii) a medical condition deemed to be notifiable by the Minister;
- or
- (iii) any other unusual case or cluster of disease not listed in Annexure A,
- must immediately report the outbreak or unusual incidence to the focal person at the health sub-district level, in order to facilitate the implementation of public health measures and response;
- (b) The report contemplated in sub-regulation (a) must be followed by a written or electronic notification within 24 hours of diagnosis, in order to facilitate the implementation of public health measures and response.
- (6) (a) A health care provider, must report data elements for notifiable medical conditions listed in Annexure A, Tables 1 and 2 as detailed in Annexure B, Table 1;
- (b) A pathologist and laboratory personnel, must report data elements for notifiable medical conditions listed in Annexure A, Tables 1, 2, 3 and 4 as detailed in Annexure B, Table 2;

- (c) A Medical Scheme must report data elements for notifiable medical conditions listed in Annexure A, Tables 1, 2, 3 and 4 as detailed in Annexure B, Table 3.

### CHAPTER 3

#### PREVENTION AND CONTROL OF NOTIFIABLE MEDICAL CONDITIONS

##### Voluntary medical examination, prophylaxis, treatment, isolation and quarantine

14. (1) The disease-specific guidelines on how to diagnose, manage and prevent the spread of notifiable medical conditions issued by the national department must be followed in implementing the appropriate medical examination, prophylaxis, counselling, treatment, isolation or quarantine measures.
- (2) (a) A case or carrier of a notifiable medical condition listed in Annexure A, Tables 1, 2, 3 and 4 or a medical condition deemed to be notifiable by the Minister, must subject himself or herself to further medical examination;
- (b) The medical examination referred to in sub-regulation (a) may include but is not limited to a clinical examination followed by the taking of biological specimens necessary for laboratory confirmation.
- (3) A person who has been in contact with a case or carrier of a notifiable medical condition must also subject himself or herself to the medical examination referred to in sub-regulation (2) (a).
- (4) Following the medical examination, the health care provider may prescribe prophylaxis, treatment or implement isolation or quarantine procedures, if deemed necessary.
- (5) The need, nature and extent of the intervention must be assessed, based on the nature of the public health risk and the particular circumstances of the individual.



- (6) (a) The case or carrier referred to in sub-regulation (2)(a) must comply, to the best extent possible, with all infection control measures given, including but not limited to prophylaxis, treatment, isolation or quarantine measures;
- (b) The case or carrier must also provide all information required to enable physical or virtual monitoring during the disease or pathogen incubation period.
- (7) The likelihood of a carrier or contact becoming a case, based on the extent and duration of exposure to a known case, must be considered in determining and implementing appropriate isolation or quarantine measures.
- (8) The carrier or contact must provide all information required to enable physical or virtual monitoring during the disease or pathogen incubation period.
- (9) The following conditions must be fulfilled before voluntary prophylaxis, treatment, isolation or quarantine may be taken-
  - (a) the notifiable medical condition must pose a public health risk; and
  - (b) the person who is a case, carrier or contact of a notifiable medical condition has been offered and encouraged to accept counselling services in order to assist him or her to understand the nature of the voluntary measures, the personal health risk and the public health risk.

#### **Mandatory medical examination, prophylaxis, treatment, isolation and quarantine**

- 15.** (1) The required mandatory medical examination, prophylaxis, treatment, isolation or quarantine procedures must be determined on a case by case basis and tailored depending on the public health risk and individual circumstances of the person in question.
- (2) The head of a provincial department must apply to the High Court for an appropriate court order, if a person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition listed in Annexure A, Tables 1, 2, 3 and 4 or a medical condition deemed notifiable by the Minister, refuses to consent to-

- (a) a medical examination, including but not limited to the taking of any biological specimen;
  - (b) being admitted at a health establishment; or
  - (c) mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission.
- (3) The health care provider should with the assistance of law enforcement agencies, subject a person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition to prophylaxis, treatment or implement isolation or quarantine procedures whilst awaiting the court order anticipated in sub-regulation (2) in order to prevent transmission.
- (4) The head of a provincial department must apply to a High Court for an order to conduct an autopsy on the body of a patient who has presumably died of a notifiable medical condition, in order to ascertain the exact cause of death, and only where this is in the interest of public health and is on special request by an interested person.
- (5) The following conditions must be fulfilled before mandatory prophylaxis, treatment, isolation or quarantine may be taken-
- (a) the notifiable medical condition must pose a public health risk;
  - (b) the person must have expressly, impliedly or by conduct refused voluntary measures to protect public health;
  - (c) consent in terms of section 7 of the Act could not be obtained; and
  - (d) the person who is a case, carrier or contact of a notifiable medical condition has been offered and encouraged to accept counselling services in order to assist him or her to understand the nature of the voluntary measures, the personal health risk, the public health risk and the procedure that will be followed should he or she refuse voluntary measures.
- (6) The head of a provincial department is required-
- (a) to revise the decision to apply for a court order when the conditions of mandatory action change;

- (b) where a court order has been issued, to approach a court to amend a court order as conditions of the mandatory action change.

### **Control of spread of notifiable medical conditions**

16. (1) The district health manager must ensure that health care providers, the case, contact or carrier comply with the specified disease prevention, management and control measures stipulated in the national department guidelines.
- (2) Where animal and environmental control is required, the district health manager must ensure that the necessary stakeholders are informed of, and involved in, the prevention and control of such a notifiable medical condition in line with the national department guidelines and procedures.
- (3) The head of an institution, including but not limited to a training or education institution, a care or residential institution, a correctional services institution, who is aware or reasonably suspects that a person at the institution—
- (a) is a case or carrier of a notifiable medical condition listed in Annexure A, Tables 1 and 2 or a medical condition deemed to be notifiable by the Minister; or
- (b) was in contact with a carrier or case of a notifiable medical condition listed in Annexure A, Tables 1 and 2 or a medical condition deemed to be notifiable by the Minister,
- must immediately report this to the health care provider within the institution or to the nearest health establishment who must notify the notifiable medical condition as stipulated in Annexure A, Tables 1 and 2.
- (4) The head of a provincial department must ensure the implementation of public health measures and response in order to prevent transmission, including closure of the institution should circumstances require.
- (5) Any member of the community, including community health workers, local leaders, traditional or religious leaders, who is aware or reasonably suspects that a person in the community—



- (a) is a case or carrier of a notifiable medical condition listed in Annexure A, Tables 1 and 2 or a medical condition deemed to be notifiable by the Minister; or
- (b) was in contact with a carrier or case of a notifiable medical condition listed in Annexure A, Tables 1 and 2 or a medical condition deemed to be notifiable by the Minister,

must immediately report this to the nearest health establishment who must notify the notifiable medical condition as stipulated in Annexure A, Tables 1 and 2.

## CHAPTER 4

### GENERAL MATTERS

#### Representation

17. (1) A person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition and who refuses–
- (a) to voluntarily consent to a medical examination by a qualified health care provider including the taking of any biological specimen;
  - (b) to be admitted at a health establishment; or
  - (c) mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission,
- is entitled to legal representation.
- (2) An indigent person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition and who refuses–
- (a) to voluntarily consent to a medical examination by a qualified health care provider including the taking of any biological specimen;
  - (b) to be admitted at a health establishment; or
  - (c) mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission,
- is entitled to legal aid provided by the State in respect of any proceedings instituted or conducted in terms of the Act, subject to the provisions of the Legal Aid South Africa Act, 2014 (Act No. 39 of 2014).

**Confidentiality**

18. (1) Information concerning a case, contact or a carrier of a notifiable medical condition, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.
- (2) No person may disclose information contemplated in sub-regulation 18 (1) unless–
- (a) the disclosure is for the purposes of public health surveillance, investigations and interventions; or
  - (b) a court order or any law requires that disclosure.

**Protection of health records**

19. The health records of a case, contact or carrier of a notifiable medical condition must be protected as provided for in section 17 (1) of the Act.

**Offences and penalties**

20. Any person who–
- (a) fails to comply with a provision of these Regulations; or
  - (b) has a duty to notify and fails to notify a condition contemplated in Tables 1, 2, 3 and 4 of Annexure A,
- is guilty of an offence and is on conviction liable to a term of imprisonment not exceeding 10 years, or imprisonment and such fine as determined by a court of law.

**Repeal**

21. The Regulations published under Government Notice No. R2438 of 30 October 1987, No. 328 of 22 February 1991, No. 716 of 22 April 1994, No. 1307 of 3 October 1997, No. R485 of 23 April 1999, are hereby repealed.

**Short title**

- 22.** These Regulations are called Regulations Relating to the Surveillance and the Control of Notifiable Medical Conditions, 2017.

**ANNEXURE A**

**Table 1:** Category 1 notifiable medical conditions that require immediate reporting by the most rapid means available upon diagnosis followed by a written or electronic notification to the Department of Health within 24 hours of diagnosis by health care providers, private health laboratories or public health laboratories

	<b>Notifiable medical condition</b>
1.	Acute flaccid paralysis
2.	Acute rheumatic fever
3.	Anthrax
4.	Botulism
5.	Cholera
6.	Diphtheria
7.	Enteric fever (typhoid or paratyphoid fever)
8.	Food-borne disease outbreak*
9.	Haemolytic uraemic syndrome (HUS)
10.	Listeriosis
11.	Malaria
12.	Measles
13.	Meningococcal disease
14.	Pertussis
15.	Plague
16.	Poliomyelitis
17.	Rabies (human)
18.	Respiratory disease caused by a novel respiratory pathogen**
19.	Rift valley fever (human)
20.	Smallpox
21.	Viral haemorrhagic fever diseases***
22.	Yellow fever

\* Food-borne disease outbreak is the occurrence of two or more cases of a similar food-borne disease resulting from the ingestion of a common food.

\*\*Examples of novel respiratory pathogens include novel influenza A virus and MERS coronavirus.

\*\*\* Viral haemorrhagic fever diseases include Ebola or Marburg viruses, Lassa virus, Lujo virus, new world arena viruses, Crimean-Congo haemorrhagic fever or other newly identified viruses causing haemorrhagic fever.

**Table 2:** Category 2 notifiable medical conditions to be notified through a written or electronic notification to the Department of Health within seven (7) days of clinical or laboratory diagnosis by health care providers, private health laboratories or public health laboratories

	<b>Notifiable medical condition</b>
1.	Agricultural or stock remedy poisoning
2.	Bilharzia (schistosomiasis)
3.	Brucellosis
4.	Congenital rubella syndrome
5.	Congenital syphilis
6.	<i>Haemophilus influenzae</i> type B
7.	Hepatitis A
8.	Hepatitis B
9.	Hepatitis C
10.	Hepatitis E
11.	Lead poisoning
12.	Legionellosis
13.	Leprosy
14.	Maternal death (pregnancy, childbirth and puerperium)
15.	Mercury poisoning
16.	Soil transmitted helminths ( <i>Ascaris Lumbricoides</i> , <i>Trichuris trichiuria</i> , <i>Ancylostoma duodenale</i> , <i>Necator americanus</i> )
17.	Tetanus
18.	Tuberculosis: pulmonary
19.	Tuberculosis: extra-pulmonary
20.	Tuberculosis: multidrug-resistant (MDR-TB)
21.	Tuberculosis: extensively drug-resistant (XDR-TB)

**Table 3:** Category 3 notifiable medical conditions to be notified through a written or electronic notification to the Department of Health within 7 days of diagnosis by private and public health laboratories

	<b>Notifiable medical condition</b>	<b>Pathogen/s to notify</b>
1.	Gonorrhoea	Ceftriaxone-resistant <i>Neisseria gonorrhoea</i>
2.	Endemic arboviral diseases	West Nile virus, Sindbis virus, Chikungunya virus
3.	Non-endemic arboviral diseases	Dengue fever virus, other imported arboviruses of medical importance
4.	Non-typhoidal Salmonellosis	<i>Salmonella</i> spp. other than <i>S. Typhi</i> and <i>S. Paratyphi</i>
5.	Rubella	Rubella virus
6.	Shiga toxin-producing <i>Escherichia coli</i>	Shiga toxin-producing <i>Escherichia coli</i>
7.	Shigellosis	<i>Shigella</i> spp.

**Table 4:** Category 4 notifiable medical conditions to be notified through a written or electronic notification to the Department of Health within 1 month of diagnosis by private and public health laboratories

	<b>Notifiable medical condition</b>	<b>Pathogen/s to notify</b>
1	Health care-associated infections or multi drug-resistant organisms of public health importance*	<ul style="list-style-type: none"> <li>• Carbapenemase-producing Enterobacteriaceae</li> <li>• Vancomycin-resistant enterococci</li> <li>• <i>Staphylococcus aureus</i>: hGISA and GISA</li> <li>• Colistin-resistant <i>Pseudomonas aeruginosa</i></li> <li>• Colistin-resistant <i>Acinetobacter baumannii</i></li> <li>• <i>Clostridium difficile</i></li> </ul>

\*Health care-associated infection means an infection occurring in a patient during the process of care in a health establishment which was not present or incubating at the time of admission.



**ANNEXURE B****Table 1:** Data elements to be reported by health care providers for Category 1 and Category 2 notifiable medical conditions

First names
Surname
Gender (M/F)
Pregnant (yes/no)
Citizenship
ID number
Passport number (if applicable)
Other ID number (if applicable)
Date of birth
Age
Patient HPRS-PRN
Patient File/Folder #
Hospital number (if applicable)
Ward name (if hospitalised)
Residential address
Telephone number
Name and address of employer, school or other institution where patient spends much of the day
Telephone number of employer, school or other institution where patient spends much of the day
Notifiable medical condition diagnosed
Method of diagnosis (clinical, lab, x-ray, other)
ICD10 code
Clinical symptoms
Date of onset of symptoms
Date of diagnosis
Vaccination status
Treatment given
History of possible exposure in the last 60 days (yes/no/unknown)
Specimens collected (yes or no)
Specimen type
Date of specimen collection
Specimen laboratory barcode/number
Patient vital status (alive/deceased)
Date of death
Patient admission status (inpatient/ outpatient/discharged)
Transferred to another facility (yes/no)
Name of health establishment if transferred
Places travelled to in the last 60 days (country, province, locality)
Dates travelled to and from the place of travel
Health care provider first name
Health care provider surname
Health care provider practice number
Health care provider mobile number
Health establishment name
Health establishment registration number
Sub-district
District/ Municipality
Province
Health establishment contact number
Date of notification

**Additional information may be requested as and when necessary**



**Table 2: Data elements to be reported by private and public health laboratories for Category 1, 2, 3 and 4 notifiable medical conditions**

First names	
Surname	
Sex (M/F)	
Citizenship	
ID number	
Passport number (if applicable)	
Other ID number (if applicable)	
Date of birth	
Age	
Hospital number (if applicable)	
Ward name (if hospitalised)	
Residential address	
Telephone number	
Specimen type	
Date of specimen collection	
Date of specimen receipt into laboratory	
Laboratory test performed	
Pathogens isolated	1.
	2.
	3.
	4.
Final laboratory test result	
Date final result authorised and reported to health care provider	
Health care provider name	
Health care provider practice number	
Health care provider contact number	
Health establishment name	
Health establishment registration number	
Sub-district	
District/ Municipality	
Province	
Health establishment contact number	
Laboratory name	
Laboratory practice number	
Pathologist or laboratory personnel name	
Laboratory contact number	

**Additional information may be requested as and when necessary**

**Table 3:** Data elements to be reported by medical schemes for Category 1, 2, 3 and 4 notifiable medical conditions

First names	
Surname	
Sex (M/F)	
Citizenship	
ID number	
Passport number (if applicable)	
Other ID number (if applicable)	
Date of birth	
Age	
Hospital number (if applicable)	
Ward name (if hospitalised)	
Residential address	
Telephone number	
Method of diagnosis (clinical, lab, x-ray, etc)	
Notifiable medical condition diagnosed	
ICD10 code	
Clinical symptoms	
Date of onset	
Date of presentation to health establishment	
Treatment given	
Specimen type	
Date of specimen collection	
Date of specimen receipt into laboratory	
Laboratory test performed	
Pathogens isolated	1.
	2.
	3.
	4.
Final laboratory test result	
Date final result authorised and reported to health care provider	
Health care provider name	
Health care provider practice number	
Health care provider contact number	
Health establishment name	
Health establishment registration number	
Sub-district	
District/ Municipality	
Province	
Health establishment contact number	
Laboratory name	
Laboratory practice number	
Pathologist or laboratory personnel name	
Laboratory contact number	

**Additional information may be requested as and when necessary**