

No. R. 1229

31 December 2009

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

REGULATIONS RELATING TO CANCER REGISTRATION

The Minister of Health intends, in terms of section 90(1)(q) of the National Health Act, 2003, (Act No 61 of 2003) to make regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations to the Minister: Health, Private Bag X 828, Pretoria, 0001 (for the attention of the Director: Chronic Diseases, Disability and Geriatrics), within two months of the date of publication of this notice.

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise—

“**cancer**” means all neoplasms and conditions suspected as such, as contained in the international classification of diseases for oncology, latest edition;

“**cancer registration**” means the process of the continuous, systematic collection of a defined data set on the biographical information of all persons diagnosed with cancer, and of the characteristics of the cancer, including its treatment and outcome;

“**committee**” means the National Cancer Registration Advisory Committee established in terms of regulation 2;

“**Director-General**” means the head of the national department;

“**facility based cancer registry**” means a cancer registry that limits its aims to recording the particulars of cancer cases seen in a given health facility or group of health facilities, irrespective of the geographical area of residence of the patients;

“**international agency for research on cancer (IARC)**” means the World

Health Organization (WHO) agency that has its mission to co-ordinate and conduct research on cancer;

"national cancer registry" means a national system used for the recording, collection, storage, analysis and interpretation of data of all persons with cancer on a national basis regardless of age;

"national childhood cancer registry" as a sub-division of the National Cancer Registry means a national system used for the recording, collection, storage, analysis and interpretation of data relating to all cancers in children under the age of 12 years;

"national department" means the national Department of Health

"national health laboratory service" means the Service established in terms of section 3 of the National Health Laboratory Service Act, 2000 (Act No. 37 of 2000);

"population-based cancer registry" means the registration of the details of every cancer that occurs in a defined population, usually in those persons resident within the boundaries of a defined geographical region or country; and

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

CHAPTER 1

NATIONAL CANCER REGISTRATION ADVISORY COMMITTEE

Establishment of the National Cancer Registration Advisory Committee and committees

2. It is hereby established the National Cancer Registration Advisory Committee.

Object of the Committee

3. The object of the Committee is to advise the Director-General on any matter related to cancer registration in the Republic.

Functions of the Committee

4. The Committee must advise the Director-General on any matter relating to cancer registration including: the collection, registration, processing, management and distribution of information relating to cancer.

Composition of the Committee

5. (1) The Committee shall consist of –
 - (a) not more than 4 medical specialists each with at least 10 years experience in oncology, designated by the professional boards of the Health Professional Council of South Africa.

- (b) one pathologist designated by each of the National Pathology Group and the National Health Laboratory Services;
- (c) one medical or clinical epidemiologist;
- (d) one official in the employ of national department dealing with health information technology and policy;
- (e) one official in the employment of the national department dealing with Cancer related policy;
- (f) one representative of the National Health Laboratory Service nominated by the CEO of the National Health Laboratory Service; and
- (g) one person from a non-governmental organization working in the field of cancer.

Appointment of members of the Committee

6. (1) The Director-General appoints members of the Committee.

(2) Whenever it is necessary to appoint a member or members of the Committee, save for the appointment of a person referred to in regulation 5(1)(d) and (e), the Director-General must invite nominations by means of a notice in the Gazette and a notice published in at least two nationally distributed newspapers, specifying a period within which nominations must be submitted.

(3) The Director-General may appoint an alternate member for any member of the Committee; and a replacement for any member who vacates office before the end of the period of such member.

(4) The replacement serves for the remainder of the term of the person he or she replaces.

Conditions of Appointment to the Committee

7. (1) A member of the Committee holds office for a period of three (3) years.

(2) At the expiry of the term of office, a member may be reappointed for another term.

(3) A member of the Committee or an alternate must vacate office if-

- (a) the Director-General at any time terminates his or her membership;
- (b) the member can no longer perform the duties of the Committee;
- (c) the member is convicted of an offence and sentenced to prison without an option of a fine;
- (d) the member is absent from more than two consecutive meetings of the Committee without leave of the Chairperson; or

(e) the member resigns by written notice to the Director-General.

Ad hoc and Sub-Committees

8. (1) The Committee may with the approval of the Director-General establish ad hoc committees and subcommittees, consisting of so many persons, appointed by the Committee, for such period as the Committee may consider necessary.

(2) The Committee must determine and finalize the terms of reference of an ad-hoc or sub-committee contemplated under sub-regulation 1 within one (1) month of such establishment.

Chairperson and vice-chairperson

9. (1) The Committee must at its first meeting and thereafter as often as it may become necessary, elect from among its members a chairperson and a vice-chairperson.

(2) When the chairperson is absent or is unable to perform his or her functions as chairperson or whenever the office of chairperson is vacant, the vice-chairperson shall act as chairperson during such absence or incapacity or until a chairperson is appointed.

(3) If both the chairperson and the vice-chairperson are absent or unable to perform the functions of the chairperson or whenever both the office of chairperson and the office of vice-chairperson are vacant, the Committee shall elect any other member to act as chairperson during such absence or incapacity or until a chairperson is appointed or a vice-chairperson is elected.

(4) The chairperson must-

(a) cause meetings to be convened; and

(b) ensure the orderly conduct of meetings and that all resolutions are recorded.

Administrative functions

10. (1) The Department must provide administrative or secretarial service to the Committee.

Meetings of the Committee

11. (1) The first meeting of the Committee shall be held within 30 days of its appointment at a time and place to be determined by the Department.

(2) Any subsequent meetings must be held as often as may be necessary for the proper performance of the functions of the Committee, but at least once in every six months, at a time and place determined by the Chairperson.

(3) The Chairperson may at any time convene a special meeting of the Committee, to be held on such a date and at such place as he or she may determine and he or she must, upon a written request by the Director-General or a written request signed by at least two members, convene a special meeting to be held, within thirty days after the date of receipt of the request, on such a date and at such a place as he or she may determine.

(4) The request must clearly state the purpose of the meeting.

(5) Any member who is unable to attend a meeting of the Committee must before the meeting give notice to the chairperson.

(6) The Committee may consult with or receive representations from any person, organization, institution or authority on any matter in order to achieve the objects or to perform the functions of the Committee in terms of this regulation

Quorum and procedure at meetings

12. (1) The majority of the members of the serving members of the Committee shall constitute a quorum at any meeting of the Committee.

(2) A decision of the majority of the members of the Committee present at any meeting shall constitute a decision of the Committee: Provided that in the event of an equality of votes the Chairperson or member presiding shall have a casting vote in addition to a deliberative vote.

(3) No decision taken by the Committee or act performed under the authority of the Committee shall be invalid by reason only of an interim vacancy on the Committee.

CHAPTER 2

CANCER REGISTRATION STRUCTURES AND RESPONSIBILITIES OF HEALTH ESTABLISHMENTS

Establishment of the National Cancer Registry

13. (1) There is hereby established a National Cancer Registry for the collection, recording, management and analysis of all data and information in the Republic relating to Cancer as set out in Annexure A.

(2) The National Cancer Registry may be implemented incrementally.

Establishment of the National Childhood Cancer Registry

14. (1) There is hereby established a National Childhood Cancer Registry as a sub-division of the NCR to which will be recorded cancer pathology reports in the Republic relating to children under the age of twelve (12) years as per Annexure A.

(2) The data or information captured by the National Childhood Cancer Registry must include the information required by the National Cancer Registry.

Establishment of Population Based Cancer Registries,

15. There is hereby established Population Based Registries involving active case finding of address-based cases.

Objectives of the National Cancer Registry

16. The objective of the National Cancer Registry is to –
- (a) store, analyse, verify, evaluate and provide data relating to cancer management; and
 - (b) provide information to organs of state and the public –
 - (i) for education, awareness raising, research and development purposes;
 - (ii) for planning, including the prioritization of regulatory and other initiatives.

Control of the National Cancer Registry

17. The National Cancer Registry is controlled by the Chief Executive Officer of the National Health Laboratory Services.

Reporting by health establishments

18. (1) The person responsible for a health establishment must-
- (a) ensure that a database containing such information as required in terms of this regulations is established, funded and maintained at that health establishment;
 - (b) ensure that all the data or information of all inpatient or outpatients diagnosed, treated or referred for treatment for cancer to the health establishment is recorded on the database;
- (2) The person in charge of a health establishment where a cancer diagnosis is made must designate a person for the specific purpose of managing the database contemplated under sub-regulation (1)(a).
- (3) A health care provider must within an agreed period after diagnosis, submit all required data or information as per Annexure A to the person responsible for the database contemplated under sub-regulation (1)(a).
- (4) The person in charge of such a health establishment must quarterly submit to the National Cancer Registry reports which contain the data and information required in terms of this regulations and as per Annexure A

Reporting by laboratories

19. A head of a laboratory must quarterly submit to the National Cancer Registry and the National Childhood Cancer Registry laboratory reports which contain data or information as set out in Annexure A.

Standards and norms

20. The National Cancer Registry must conform to international norms and standards as determined by the International Agency for Research on Cancer

Confidentiality

21. (1) All data or information contemplated in these regulations is confidential.
- (2) The National Cancer Registry must maintain the same standards of confidentiality as customarily apply to doctor-patient relationship, and this obligation extends indefinitely, even after the death of the patient.
- (3) No person may disclose any information contemplated in sub-regulation (1) unless a court order or any law requires such disclosure;

Protection of data or information

22. (1) The person in charge of such a health establishment must set up control measures to prevent unauthorized access to the database and to the storage facility in which, or system by which, the data or information is kept
- (2) As part of compliance with sub-regulation (1) the person in charge of a health establishment must ensure-
- (a) the data or information contemplated in these regulations is stored in a facility or system which is, designed and located so as to facilitate the safe and secure receipt, storage and dissemination of such data or information;
 - (b) no person discloses or disseminates the data or information without authorization
- (3) Any person working with or coming into contact with the data or information contemplated under these regulations must adhere to all confidentiality and security requirements.

Duty to release the data or information

23. (1) The National Cancer Registry must-
- (a) ensure that accurate, appropriate, adequate and comprehensible data and information is disseminated to any person that requests the data or information in writing.
 - (b) that a written procedure is prepared, published and implemented relating to the dissemination and publication of the data or information contemplated in these regulations;
- (2) Registries should make available a document describing their procedures and criteria for the release of data, especially identifiable data.
- (3) A report signed by the Director – General will be prepared by the NHLS and the National Department of Health for the purpose of reporting to Intentional Agencies as required.
- (4) The person in charge of the National Cancer Registry-
- (a) must prepare and submit every six months a report to the Director-General and the Heads of Provincial Department of Health in each province; or

(b) must submit any information requested by the Director-General within a reasonable time of such request being made.

Offences and penalties

24. Any person who –

- (a) is liable to register a condition contemplated in these regulation but fails to do so, or fail to comply with any of the provisions of these regulations;
- (b) fails to perform a duty imposed on him or her;
- (c) falsifies any record by adding to, or deleting, or changing any information contained in the record;
- (d) creates, changes or destroys a record without authority to do so;
- (e) provides false information with the intent that it be included in a record;
- (f) without authority, copies any part of the record;
- (g) without authority, connect the personal identification elements of a patient's records with any element of that record concerns that patient's history and/or examination.
- (h) gains unauthorized access to a record or record-keeping system, including intercepting information in transit from one person, or part of a record-keeping system, to another;
- (i) without authority connects any part of a computer or electronic system on which records are kept to-
 - (i) any other computer or electronic system, or
 - (ii) any terminal or other installation connected to or forming part of any other computer or electronic system or;
- (j) without authority, modifies or impairs the operation of-
 - (i) any part of the operating system of a computer or other electronic system on which a patient's records are kept; or any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a patient's records are kept;

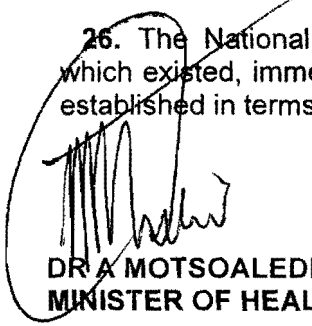
commits an offence and if found guilty, may be liable to a fine.

Transmission of information from source to data system and registries or visa versa

25. The Director-General may, for purposes of adapting or maintaining databases may by notice in the Government Gazette determine the manner and format in which data must be submitted to the National Cancer Registry

Transitional Arrangements & savings

26. The National Cancer Registry and the National Childhood Cancer Registry which existed, immediately prior to promulgation of this regulations, is deemed to be established in terms of these regulations.



DR A MOTOALEDI
MINISTER OF HEALTH



REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

DRAFT CANCER REGISTRATION FORM
[Regulation 2009]

To be completed in duplicate in **BLOCK LETTERS**.
Please mark with the **CORRECT** box, where required.
Original to be submitted to the National Cancer Register and copy to be retained.

1. Name of facility

USE PATIENT STICKER if available

2. Surname

3. Full names

4. Date of birth D D M M Y Y Y Y

5. Folder number

6. Sex Male Female

7. ID number/Passport number

8. Race group African Coloured White Indian Other _____

9. Area of residence
9.1 City/town/village

9.2 Postal code 9.3 How long at this address? years

Please record place of birth if not the same as current address

9.4 City/town/village

9.5 Postal code

B. RISK FACTOR PROFILE

10. Usual occupation of patient
(If retired, give type of work done for most of working life)

11. Type of industry/business
(eg Mining, farming etc)

12. Did the patient ever smoke tobacco? Yes No Unknown

13. Did the patient ever consume alcohol regularly? Yes No Unknown
(that is, more than once a week)

14. HIV status Negative Positive Unknown

C. CLINICAL AND LABORATORY DETAILS

15. Date of diagnosis D D M M Y Y Y Y

16. Cancer diagnosis and Histology _____ 17. ICD-10 .
Please give all information available on the site, laterality, histology and behaviour of the tumour

18. Grade Well differentiated Moderately differentiated Poorly differentiated Unknown/Not applicable

19. Stage Primary/localised Metastatic Unknown/Not applicable

20. Invasiveness In-situ Invasive

21. Basis of diagnosis Clinical Clinical with investigation Cytology/histopathology

22. Prescribed treatment Surgery Radiation Chemotherapy Other systemic Palliation Alternative None

INFORMANT PARTICULARS

Name (Print) _____

MP/NC Number

Signature _____ Date _____

OFFICE CODING

.

M - / /