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## GOVERNMENT NOTICE

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### DEPARTMENT OF HEALTH

No. R. 380

26 April 2011

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

#### REGULATIONS RELATING TO CANCER REGISTRATION

The Minister of Health has, in terms of section 90(1)(q) of the National Health Act, 2003, (Act No 61 of 2003) after consultation with the National Health Council made the regulations in the Schedule.

#### 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 malignant neoplasms and conditions suspected as such, as contained in the International Classification of Diseases for Oncology, 3<sup>rd</sup> edition (ICD-O-3, 2000);

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

**"International Agency for Research on Cancer (IARC)"** means the World Health Organization (WHO) agency that has as its mission to co-ordinate and conduct research on cancer;

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

**"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).

### **Establishment of the National Cancer Registry**

2. (1) There is hereby established a National Cancer Registry, hereinafter referred to as the NCR, for the collection, validation, recording, management and analysis of all data and information in the Republic relating to cancer as set out in Annexure A.
- (2) A Population Based Cancer Registry, hereinafter referred to as the PBCR, may be implemented incrementally and data submitted for the NCR.
- (3) The NCR is controlled by the Chief Executive Officer, hereinafter referred to as the CEO, of the National Health Laboratory Services, hereinafter referred to as the NHLS.

### **Objectives of the National Cancer Registry**

3. The NCR is established in order to ensure —
  - (a) the collection, recording, validation, storage, management, analysis, interpretation and reporting of data relating to cancer.
  - (b) the provision of information to organs of state and the public—
    - (i) for education and training, awareness raising and research;
    - (ii) for planning, including the prioritization of cancers and interventions.

**Reporting by health establishments**

4. The person in charge of a health establishment, where diagnosis is confirmed, must ensure that Annexure A is completed and submitted to the NCR within 3 months of diagnosis.

**Reporting by laboratories**

5. The head of a laboratory must, on a quarterly basis, ensure that Annexure A as well as the accompanying laboratory report is completed and submitted to the NCR.

**Norms and standards**

6. The CEO of the NHLS must ensure that the NCR conforms to the norms and standards as determined by the International Agency for Research on Cancer.

**Confidentiality**

7. (1) Unless disclosure is made in terms of regulation 9, all personal data or information contemplated in these regulations is confidential.  
  
(2) The NCR must maintain the same standards of confidentiality as customarily apply to doctor-patient confidentiality, and this obligation extends indefinitely, even after the death of the patient.  
  
(3) No person may disclose any information contemplated in sub-regulation 7(1) unless a court order or any law requires such disclosure.

**Protection of data or information**

8. (1) The person in charge of a health establishment must set up control measures to prevent unauthorized access to Annexure A and to the storage facility or system by which the data or information is stored.  
  
(2) As part of compliance with sub-regulation 8(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**

9. (1) The CEO of the NHLS must ensure that accurate, appropriate, adequate and comprehensible data and information is disseminated for epidemiological, public health information and planning purposes and use by the State or relevant authorized organ of State.
- (2) The CEO of the NHLS must, on request, make available a document describing its procedures and criteria for the release of data.
- (3) The CEO of the NHLS or designated person must prepare and submit to the Director-General, an annual report and any information pertaining to the NCR.
- (4) A report to the international agencies shall be signed by the Director-General.

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

10. The Minister may, for the purposes of adapting or maintaining databases, from time to time by notice in the Government Gazette determine the manner and format in which data must be submitted to the NCR.

**Offences and penalties****11. Any person who -**

- (a) is liable to register a condition contemplated in these regulation but fails to do so, or fails 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, connects the personal data of a patient's record with any information of that record that 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 recordkeeping 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 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.

### **Transitional Arrangements & Savings**

12. The NCR, which existed, immediately prior to promulgation of these regulations, is deemed to be established in terms of these regulations.

**DR. A MOTSOLEDI**  
**MINISTER OF HEALTH**

	REPUBLIC OF SOUTH AFRICA DEPARTMENT OF HEALTH <b>CANCER REGISTRATION FORM</b>	To be completed in <b>BLOCK LETTERS</b> . Please mark with <input checked="" type="checkbox"/> the <b>CORRECT</b> box, where required. To be submitted to the National Cancer Register via: e-mail: <a href="mailto:cancer.registry@nhls.ac.za">cancer.registry@nhls.ac.za</a> fax: (011) 489 9151 Post: PO Box 1038, Johannesburg, 2000
<b>A. PARTICULARS OF INDIVIDUAL</b>		
1. Name of health establishment <input type="text"/>		
2. Sumame <input type="text"/>		
3. Full names <input type="text"/>		
4. Date of birth <input type="text"/>		
5. Folder number <input type="text"/>		
6. Sex <input type="checkbox"/> Male <input type="checkbox"/> Female		
7. ID number/Passport number <input type="text"/> Country <input type="text"/>		
8. Race group <input type="checkbox"/> African <input type="checkbox"/> Coloured <input type="checkbox"/> White <input type="checkbox"/> Indian <input type="checkbox"/> Other <input type="text"/>		
9. Area of residence		
9.1 City/town/village <input type="text"/>		
9.2 Postal code <input type="text"/> 9.3 How long at this address? <input type="text"/> years		
Please record place of birth if not the same as current address		
9.4 City/town/village <input type="text"/>		
9.5 Postal code <input type="text"/>		
<b>B. RISK FACTOR PROFILE</b>		
10. Usual occupation of patient <input type="text"/> (if retired, give type of work done for most of working life)		
11. Type of industry/business <input type="text"/> (eg Mining, farming etc)		
12. Did the patient ever smoke tobacco? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
13. Did the patient ever consume alcohol regularly? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (that is, more than once a week)		
14. HIV status <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Unknown		
<b>C. CLINICAL AND LABORATORY DETAILS</b>		
15. Date of diagnosis <input type="text"/>		
16. Cancer diagnosis and Histology <input type="text"/> Please give all information available on the site, laterality, histology and behaviour of the tumour		
17. ICD-10 <input type="text"/>		
18. Grade <input type="checkbox"/> Well differentiated <input type="checkbox"/> Moderately differentiated <input type="checkbox"/> Poorly differentiated <input type="checkbox"/> Unknown/Not applicable		
19. Stage <input type="checkbox"/> Primary/localised <input type="checkbox"/> Metastatic <input type="checkbox"/> Unknown/Not applicable		
20. Invasiveness <input type="checkbox"/> In-situ <input type="checkbox"/> Invasive		
21. Basis of diagnosis <input type="checkbox"/> Clinical <input type="checkbox"/> Clinical with investigation <input type="checkbox"/> Cytology/histopathology <input type="checkbox"/> Molecular <input type="checkbox"/> Death Certificate		
22. Prescribed treatment <input type="checkbox"/> Surgery <input type="checkbox"/> Radiation <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Other <input type="checkbox"/> Palliation <input type="checkbox"/> Alternative <input type="checkbox"/> None		
<b>INFORMANT PARTICULARS</b> Name (Print) <input type="text"/> MP/NC Number <input type="text"/> Signature <input type="text"/> Date <input type="text"/>	<b>OFFICE CODING</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M - <input type="text"/> / <input type="text"/> / <input type="text"/>	