IARC TECHNICAL PUBLICATIONS

DEVELOPING A LEGAL FRAMEWORK FOR POPULATION-BASED CANCER REGISTRIES: A TOOLKIT

SONDRA DAVOREN, DONALD MAXWELL PARKIN, BIYING LIU, MA-ANNE ROSALES STO. DOMINGO, RACHEL KITONYO-DEVOTSU, HAYLEY JONES, AND FREDDIE BRAY

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McCabe Centre FOR LAW & CANCER

AFCRN

GICR GLOBAL INITIATIVE FOR CANCER REGISTRY DEVELOPMENT · INITIATIVE MONDIALE POUR LE DÉVELOPPEMENT DES REGISTRES DU CANCER · INICIATIVA MUNDIAL PARA EL DESARROLLO DE REGISTROS DE CÁNCER

IACR International Association of Cancer Registries

International Agency for Research on Cancer
World Health Organization

International Agency for Research on Cancer

World Health Organization

GLOBAL INITIATIVE FOR CANCER REGISTRY DEVELOPMENT
INITIATIVE MONDIALE POUR LE DEVELOPPEMENT DES REGISTRES DU CANCER
INICIATIVA MUNDIAL PARA EL DESARROLLO DE REGISTROS DE CÁNCER

AFRICAN CANCER REGISTRY NETWORK
AFCRN
Answers for Cancer Control

IACR
International Association of Cancer Registries

McCabe Centre
FOR LAW & CANCER

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CHAPTER 1.

Introduction and quick start guide

This toolkit, developed by the McCabe Centre for Law and Cancer (Australia), with the support of the International Agency for Research on Cancer (IARC) and the African Cancer Registry Network (AFCRN), is intended to serve as a resource to support countries to establish a legal basis for the mandatory reporting of cancer diagnoses to a population-based cancer registry. The toolkit comprises this report and several online tools to enable a structured approach to drafting a law. It ensures compliance with international best practice while allowing flexibility for local adaptation.

1.1 Orientation

Chapter 2 provides a comprehensive guide to the principles, considerations, and global examples for establishing a legal basis for a cancer registry. It helps users to understand why a legal framework is needed and how to structure it. The chapter reviews the elements of a cancer law and acts as a primer to better understand the key legal and policy issues. It provides guiding questions that help to build registry legislation according to a country's needs.

The toolkit also contains two files that help to build a draft of the law: a fillable legislation template, and a searchable database of existing national laws, the use of which is described below. The template is reproduced as Chapter 3 in this report and contains cross-references to the notes on each element of the law contained within Chapter 2, for ease of reference. Some of the more relevant national laws (from South Africa and the Republic of Korea) are provided as Annexes in this report.

1.2 Quick start guide

The toolkit contains two files, available online on the International Association of Cancer Registries (IACR) website (see https://www.the-iacr.net/standards/law): a fillable legislation template, and a searchable database of existing national laws, the use of which is described below.

***Template.dotx* – a cancer registry law template**

This file:

- is an editable template with placeholders for country-specific details;
- ensures consistency in legal drafting while allowing customization.

How to use:

a. Open the Word template.
b. Fill in the blanks (e.g. country name, responsible authority, reporting requirements).
c. Save as a **new document** with your country's name (e.g. *Cancer Registry Law – [country name].docx*).
d. Review with local lawyers and cancer and health stakeholders.

***Search.xlsm* – a searchable database of existing national laws**

This file:

- is a comparison tool to review existing cancer registry laws from different countries;
- includes a look-up function to search for specific provisions.

How to use:

a. Open the Excel file in Microsoft Excel (enable macros if prompted).
b. Use the look-up function to find relevant legal provisions.

This report is:

- an overview of the key features of existing legal frameworks for cancer registries;
- a guide to the drafting, enactment, and implementation of legislation (or other binding instruments) to establish a cancer registry that meets the needs of the jurisdiction [1]; and
- a tool to support legal and policy coherence – any new or amended cancer registry law will need to be consistent with existing legal frameworks.

Those who use this resource should adopt and adapt the examples as needed, in accordance with national needs, local legal drafting conventions, constitutional requirements, and so on. Detailed matters or implementation are to be determined by national laws and systems [1]. This resource is not legal advice and should not be relied upon as such. Those who use this document do so on the assumption that they will obtain independent legal advice as required.

1.3 Cancer registries

This document is guided by key messages from IARC/WHO on the importance and feasibility of implementing cancer registries [2]:

- Population-based cancer registries are the key source of data on cancer incidence and survival through a system of ongoing data collection, storage, validation, analysis, and dissemination. Collection is at the national level (where feasible) or via one or more sentinel population-based cancer registries that combine to be representative of the national population.
- Population-based cancer registries are a critical resource for policymakers, providing the evidence base from which to plan, monitor, and assess the effectiveness of national cancer control programmes.
- The establishment of a cancer registry is always possible, even in low- and middle-income countries, if medical care is available and medical facilities are accessible.
- Improving both the quantity and the quality of population-based cancer registries, particularly in low- and middle-income countries, is critical for assessing progress in cancer control.

1.4 Preliminary issues and environment scan

It is important to consider the starting point for cancer registration in the relevant jurisdiction.
• Is there an existing population-based cancer registry? ◦ If yes, what are some of the limitations of this registry? ◦ If yes, what are some of the barriers to collecting data?
• Which agency is responsible for overseeing and funding the cancer registry?
• Identify and consider any relevant existing legislation [3]; for example: ◦ Are there health information collection laws already? What do they say? ◦ Can a cancer registry be established under existing laws, or is a new law needed? ◦ What privacy and confidentiality laws exist in this jurisdiction, and how will a cancer registry align with or affect these laws?
• What are the likely costs, and who bears these?
• Who is the target for regulation?
• What compliance methods are to be used?
• Who are the regulators? What is their role? Is a new regulator required? What other agencies will they have to work with?

1.5 Steps for developing a cancer registry law

Step 1: Needs assessment
a. Review existing cancer registry provisions and health information and health data laws, and identify gaps.
b. Consult relevant stakeholders (e.g. health ministries, legal drafters, policy-makers).

Step 2: Consult Chapter 2, including the checklist for developing cancer registry legislation
a. Understand the key legal, policy, and contextual elements of a cancer registry.
b. Identify which provisions are most relevant to your country.

Step 3: Draft the law using the template
a. Fill in the required fields with country-specific information.
b. Modify sections to reflect local legal systems and health policies.

Step 4: Review and validate
a. Consult legal and health-care experts for feedback.
b. Ensure alignment with national privacy and health data laws.

Step 5: Finalize and implement
a. Prepare the final draft for government approval.
b. Develop an implementation plan, including funding and regulatory oversight.

1.6 Technical support

For comments or queries, please contact IARC at csu@iarc.who.int.

CHAPTER 2.

Elements of a cancer registry law: notes

The law should, at minimum:
- create a register of information;
- create a mandatory reporting requirement to that register; and
- protect confidentiality and meet privacy requirements.

2.1 Title and commencement

The law should have a **short** title that can clearly identify the instrument. (Details of the purpose or objectives of a law can be stated in a purpose or objectives provision [4].)

The commencement of the law specifies when it comes into force. This may be:
- on a fixed date, stated in the law;
- on a date specified by an authorized entity (according to law-making process in the relevant jurisdiction); or
- contingent upon the occurrence of a specific event.

2.2 Purpose

The purpose and objectives clause should clearly state the intention and scope of the instrument. The core function of the law is to allow for the proper functioning of a population-based cancer registry. This can be expressed in broad terms or specific terms, for example listing functions relating to the use of information, such as to support cancer data reporting and research.

Examples: Title and purpose

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	3. Objectives of the National Cancer Registry: (a) Ensure the collection, recording, validation, storage, management, analysis, interpretation, and reporting of cancer data; (b) Provide information to state organs and the public for education, training, awareness-raising, research, and planning, including the prioritization of cancers and interventions.

*For the original text of the law, see the document in the Instrument column.

2.3 Definitions

Definitions will give standard meaning to words, phrases, or concepts that occur in the Act or that need to be explained [6]. Definitions should align with any other relevant laws, particularly country-specific laws on health data collection and privacy.

2.4 Establishment of the National Cancer Registry

This clause should include the name of the planned registry and reference to a focal point or responsible authority.

Focal point: person or department responsible

This may be a person with an official role or an organization with a specific mandate in relation to cancer, health, or health information. In some cases, a new position or organization may need to be established with responsibility for administering a cancer registry. It may be necessary to consider and define the roles and functions of the focal point, as well as considering whether they have authority (or need authority) to carry out these functions and making provision for this authority.

Examples: Establishing a cancer registry and person or department responsible

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	2. Establishment of the National Cancer Registry: (a) Established for the collection, validation, recording, management, and analysis of all cancer data in the Republic as per Annexure A; (b) Controlled by the CEO of the National Health Laboratory Services. [Annexure A to the Regulations contains the form for reporting.]
Republic of Korea	Cancer Control Act 2024 [7]	14 (1). Cancer registration statistics services: The Minister of Health and Welfare shall provide services for registration, management, and research (hereinafter referred to as "cancer registration statistics services") to collect statistics on development rates and survival rates of cancer patients, etc. 17 (1). Designation of central cancer registration headquarters and regional cancer registration headquarters: The Minister of Health and Welfare may designate the National Cancer Center or research institutions specialized in cancer which meet the standards for facilities, human resources, equipment, etc. prescribed by Ordinance of the Ministry of Health and Welfare as central cancer registration headquarters to provide services: (a) collection, analysis, and management of data; investigations and research related to cancer registration statistics services; (b) education and training, and international collaboration related to cancer registration statistics services; (c) collection and analysis of cancer registration data for each region, and support for the regional cancer registration headquarters; and (d) other services. 17 (2). The Minister of Health and Welfare may designate a regional cancer centre or an institution from among related specialized institutions that meet the standards for facilities, human resources, equipment, etc. prescribed by Ordinance of the Ministry of Health and Welfare as regional cancer registration headquarters to provide services: collection, analysis, and management of data; investigations and research related to cancer registration statistics services; and other services.

*For the original text of the law, see the document in the Instrument column.

2.5 Mandatory reporting

A mandatory reporting requirement is essential to the effectiveness of a cancer registry.

Mandatory reporting is important for:

a. data quality;
b. waiving of informed consent; and
c. protecting data suppliers from legal action for breach of confidentiality [8].

Reporting entity

Prescribed persons or organizations responsible for reporting must be identified. When identifying who these persons or organizations will be, consider that they may bear the onus of the mandatory reporting requirements, and they may be liable for failure to report, or their employer may be vicariously liable.

Examples: Mandatory reporting and reporting entity

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	4. Reporting by health establishments: The person in charge must complete and submit Annexure A to the National Cancer Registry within 3 months of diagnosis. 5. Reporting by laboratories: The head of a laboratory must complete and submit Annexure A and the accompanying laboratory report to the National Cancer Registry quarterly. 10. Transmission of information: The Minister of Health may determine the manner and format of data submission to the National Cancer Registry by notice in the Government Gazette, for database adaptation or maintenance. [Annexure A to the Regulations contains the form for reporting.]
Republic of Korea	Cancer Control Act 2024 [7]	14 (2). Cancer registration statistics services: The Minister of Health and Welfare may request medical care providers or medical institutions diagnosing and treating cancer patients, the National Health Insurance Corporation and the Health Insurance Review and Assessment Service under the National Health Insurance Act, and any other corporation, institution, or organization conducting cancer-related business to submit data or state opinions necessary for cancer registration statistics services. Persons requested to submit data shall comply with such requests, except in extenuating circumstances.

*For the original text of the law, see the document in the Instrument column.

2.6 Supply of further information

The effectiveness of a mandatory reporting requirement is supported by having an identified or prescribed person responsible for recording and processing data reported to the cancer registry and authorizing requests for additional information.

Examples: Supply of further information

Jurisdiction	Instrument	Provisions*
Singapore	National Registry of Diseases Act 2007 [9]	7. Collection of information: (1) The Registrar or an authorized officer may require the manager of a health-care institution to provide prescribed additional information concerning the person notified under Section 6. (2) The Registrar or an authorized officer may require the manager to: (a) furnish the prescribed additional information to any Registry officer or agent; (b) produce for inspection any medical record, book, or document that contains the prescribed additional information.

*For the original text of the law, see the document in the Instrument column.

2.7 Data privacy, access, use, and confidentiality

This report is guided by the best practice principles for cancer registration and confidentiality, as outlined in:

- the IACR and IARC guidelines on confidentiality for population-based cancer registration [10];
- the European Network of Cancer Registries (ENCR) and IARC guidelines on confidentiality and ethics for population-based cancer registration and linked activities in Europe [8];
- the AFCRN standard procedure manual for population-based cancer registries in sub-Saharan Africa (version 5) [11].

These principles include the following.

- Patient anonymity and data minimization:
  - Patient identities are anonymized as much as possible.
  - Cancer registries should collect the minimum amount of personal information as necessary for the effective maintenance of a registry and as authorized by law.
- Transparency:
  - Patients should be informed about how information will be used, stored, and protected (see Section 2.8).
  - Cancer registries should have access controls and restricted use protections.
  - Only authorized personnel should be permitted to access identifiable data. Authorization requirements and expectations of authorized personnel should be guided by a code of practice.
- Data encryption and secure storage:
  - Cancer registries should use trusted encryption techniques to protect data during transfer and storage. Secure physical and digital infrastructures should be in place to prevent unauthorized access, data loss, or data breaches.
- Data retention and destruction policies:
  - Cancer registries should have clear policies and processes for data retention and destruction.

- Compliance with legal and ethical requirements:
  - Cancer registries should comply with national and international legal frameworks and with ethical standards for research involving human data.
  - Cancer registries should review and have oversight of research ethics.

The best approach for confidentiality and privacy will depend on the legal context. In countries where there is a separate law or legal framework governing the collection, use, or disclosure of health information, reference may be made to that law.

In the absence of any health information and/or confidentiality laws, a confidentiality and privacy section should set out the minimum legal protection for health information collected in relation to maintaining a cancer registry [8].

Examples: Data privacy, access, use, and confidentiality

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	7. Confidentiality: (a) All personal data or information is confidential unless disclosed under Regulation 9; (b) The National Cancer Registry must maintain doctor–patient confidentiality standards indefinitely, even after the death of the patient; (c) Disclosure is only allowed if required by court order or law. 8. Protection of data or information: (a) The person in charge of a health establishment must prevent unauthorized access to Annexure A and storage systems; (b) Data must be stored securely, and unauthorized disclosure is prohibited; (c) All personnel must adhere to confidentiality and security requirements. 9. Duty to release data or information: (a) The CEO of the National Health Laboratory Services must ensure that accurate, appropriate, and comprehensible data are disseminated for epidemiological, public health, and planning purposes; (b) Procedures and criteria for data release must be documented and available on request; (c) The CEO must submit annual reports and information to the Director-General; (d) Reports to international agencies must be signed by the Director-General. [Annexure A to the Regulations contains the form for reporting.]
Republic of Korea	Cancer Control Act 2024 [7]	44. Duty to maintain confidentiality: Current or former executive officers or employees of the National Cancer Center are prohibited from disclosing or misappropriating confidential information obtained in the course of duties. 49. Prohibition of use of personal information for purposes other than intended objectives. Persons previously or currently engaged in cancer control services are prohibited from disclosing or misappropriating any personal information obtained in the course of duties for purposes other than the intended objectives, except for cases prescribed in Article 18 (2) of the Personal Information Protection Act.

*For the original text of the law, see the document in the Instrument column.

2.8 Indemnity

Cancer registries are a rare exception to the principle of informed consent [12]. Obtaining informed consent from every individual in a registry is not practicable. Commonly, the right to give consent is waived in the interest of the public good [12], i.e. for the purposes of maintaining an effective, comprehensive cancer registry. This means that privacy, confidentiality, and information use and collection requirements must be carefully defined and stringently regulated to ensure that information retained in a cancer registry is always protected.

An indemnity clause is needed to support this approach. This clause protects people from liability when performing actions permitted by a cancer registry law, such as reporting confidential information to the registry, that would ordinarily be a breach of privacy. It is important that this clause is included, clearly stated, and limited in scope. This acts as protection for those responsible for collecting and reporting information and should foster confidence in the integrity of the registry process.

Examples: Indemnity

Jurisdiction	Instrument	Provisions*
Marshall Islands	Cancer Registry Act 2009 [13]	7. Liability: (a) No action for damages may be maintained against any person or their employer or employee for good faith disclosure of confidential information in cancer registry reporting or studies; (b) No licence of a health-care facility or provider may be denied, suspended, or revoked for such good faith disclosure; (c) This section does not apply to unauthorized disclosure of confidential information due to gross negligence or wilful misconduct.
Singapore	National Registry of Diseases Act 2007 [9]	17. Protection from liability: (1) No legal action against the Government, the Director-General, the Registrar, a Registry officer or agent, an investigation officer, or any person for acts done in good faith under this Act; (2) Notification to the Registrar or providing documents or information for compliance is not liable for breach of confidence or professional conduct; (3) The Registrar or any Registry officer is not liable for errors or omissions in disclosed information if made in good faith.

*For the original text of the law, see the document in the Instrument column.

2.9 Offences

Offence or penalty clauses serve an important role in the effectiveness of a legal framework for cancer registries. They promote compliance with the requirements of the law and help to protect patient privacy, ensure the ethical use of health information, and ensure the integrity of the data.

Offences are commonly subject to civil law penalties, such as a fine. They may also give rise to a cause of action for professional misconduct, in the case of registered health professionals.

Examples: Offences

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	11. Offences and penalties: Any person who fails to register a condition, fails to comply with regulations, fails to perform duties, falsifies records, creates, changes, or destroys records without authority, provides false information, copies records without authority, connects personal data without authority, gains unauthorized access to records, connects computer systems without authority, or modifies or impairs computer systems without authority commits an offence and may be liable to a fine.
Singapore	National Registry of Diseases Act 2007 [9]	6. Duty to notify the Registrar of reportable disease: Failure to notify the Registrar of a reportable disease or providing false information – Fine of up to $2000. 7. Collection of information: Failure to provide prescribed additional information or providing false information when required by the Registrar – Fine of up to $2000. 8. Confidentiality: Unauthorized disclosure of individually identifiable information – Fine of up to $10 000, imprisonment for up to 12 months, or both.

*For the original text of the law, see the document in the Instrument column.

2.10 Regulations

Both an Act and Regulations may be needed to facilitate a cancer registry. Acts are legislation passed by legislature and often changed only through amendatory Acts of legislature, which can be a slow process. Regulations are made under Acts and typically provide further detail about how the overarching requirements of the relevant Act will apply. Regulations are often passed administratively or ministerially, and they do not have to go through the same process as for passing Acts of legislature. Regulations are suitable for providing operational requirements for cancer registries that may need to be adjusted as needed.

Examples: Regulations and administrative issuances

Jurisdiction	Instrument	Provisions*
Republic of Korea	Cancer Control Act 2024 [7]	18-2 (3). Designation of national cancer data centre: Matters necessary for the designation, operation, etc. of the national cancer data centre shall be prescribed by Ordinance of the Ministry of Health and Welfare.

*For the original text of the law, see the document in the Instrument column.

2.11 Transitional and miscellaneous provisions

Schedules are a way to include information that is highly detailed. Schedules to cancer registry laws commonly include:

- the type of information to be held in the registry;
- the form of the report; and
- the time for reporting.

Examples: Other provisions

Jurisdiction	Instrument	Provisions*
South Africa	Regulations Relating to Cancer Registration 2011 [5]	6. Norms and standards: The CEO of the National Health Laboratory Services must ensure that the National Cancer Registry conforms to the norms and standards as determined by the International Agency for Research on Cancer.

*For the original text of the law, see the document in the Instrument column.

2.12 Checklist for developing cancer registry legislation

Preliminary considerations	
Conducted an environment scan to determine whether a new law is required?	
Identified the responsible agency or authority for overseeing the registry?	
Reviewed relevant existing legislation?	
Considered funding sources and ongoing sustainability?	
Consulted key stakeholders, including health officials, legal experts, and data protection authorities?	
Legal framework and governance	
Does the law establish a national population-based cancer registry with a clear legal mandate?	
Is there a designated focal point responsible for registry operations and compliance?	
Are the roles and responsibilities of different agencies and reporting entities clear?	
Data collection and reporting requirements	
Does the law create a mandatory reporting obligation for the reporting entity?	
Are provisions about data to be reported, form of reporting, and time for reporting clear?	
Are there clear guidelines on who must report information to the registry?	
Data privacy and confidentiality	
Are data protection and privacy measures aligned with best practice principles for cancer registries and confidentiality?	
Are access controls clear?	
Are there safeguards for secure storage and data retention?	
Does the law include penalties for unauthorized disclosure of registry data?	
Compliance and enforcement	
Are there defined penalties for non-compliance with the law?	
Does the law indemnify information providers from legal liability when reporting in accordance with the law?	

CHAPTER 3.

Template for elements of a cancer registry law

How to use this template

The template reproduced below is available as a fillable legislation template online on the IACR website (see https://www.the-iacr.net/standards/law). To use it, follow these instructions:

1. Open the Word template file (*dotx* file) containing the cancer registry legislation template.
2. If there is a yellow banner at the top that says "Protected View", click "Enable Editing" to allow changes.

The document contains fillable form fields to input country-specific details.

3. Click inside a fillable field (e.g. "[Enter Country Name]") and type the required information.

Once the necessary details have been completed:

4. Click "File → Save As".
5. Name the file (e.g. "Cancer Registry Law - [country name].docx").
6. Click "Save".

Note: This template is modelled on common law jurisdictions but can also be used as a basis for civil law jurisdictions, with modifications as needed to align with relevant legal systems.

For further guidance, the boxes below cross-reference the notes on each element in Chapter 2.

See 2.1.

3.1 Title and commencement

a. This Act may be cited as the Click or tap here to enter text..
b. This Act shall come into force on Click or tap to enter a date..

See 2.2. Definitions should align with country-specific laws on health data, privacy, and any relevant medical standards.

3.2 Purpose

The purpose of this Act is to allow for the proper functioning of a population-based National Cancer Registry.

See 2.3.

3.3 Definitions

For the purposes of this Act:

a. "Cancer" as defined by [IARC].
b. "Cancer Registry" means the national population-based cancer registry established under this Act.
c. "Health Authority" means the designated government agency responsible for managing the Cancer Registry.
d. "Reporting Entity" refers to the entity responsible for providing the data collected and managed by the Cancer Registry.
e. [Other definitions based on jurisdiction]

See 2.4.

3.4 Establishment of the National Cancer Registry

A National Cancer Registry is established under the Click or tap here to enter text..

See 2.5. Prescribed form, time, and information should be included in Schedules standards.

3.5 Mandatory reporting

a. If an individual is diagnosed with cancer of a prescribed type, the reporting entity must report the diagnosis to the Cancer Registry.
b. For the purposes of this Act, diagnosis of cancer includes a diagnosis of a recurrence of a cancer or a precursor of a prescribed type.
c. The report of a diagnosis of cancer or a precursor must:
   - include the prescribed information; and
   - be in the prescribed form; and
   - be made within the prescribed time.

See 2.6. The person responsible for authorizing requests for additional information should be identified.

3.6 Supply of further information

The Click or tap here to enter text. may direct a person or organization to provide further information in relation to a person who has been diagnosed with cancer or a precursor of a prescribed type.

See 2.7 and the IACR and IARC guidelines on confidentiality for population-based cancer registration.

3.7 Data privacy, access, use, and confidentiality

a. All data collected pursuant to this Act are confidential.
b. Information collected pursuant to this Act must be stored and protected in accordance with the measures noted in Click or tap here to enter text..
c. The Click or tap here to enter text. may use and disclose data collected under this Act for the purpose of performing its functions under this Act.
d. Identifiable data shall not be disclosed except in accordance with Click or tap here to enter text..

See 2.8.

3.8 Indemnity

The provision of information in accordance with this Act —
a. does not for any purpose constitute unprofessional conduct or a breach of professional ethics on the part of the person or organization; and
b. does not make the person or organization subject to any liability in respect of it; and
c. does not constitute a contravention of any other Act or law.

See 2.9.

3.9 Offences

Every person commits an offence and is liable on conviction to Click or tap here to enter text. who:
a. fails, without reasonable excuse, to comply with the requirements of this Act;
b. knowingly supplies information that is false or misleading in purported compliance with this Act.

See 2.10.

3.10 Regulations

The Click or tap here to enter text. may issue regulations for the effective implementation of this Act.

See 2.11. Any other transitional provisions that may be necessary, such as phased implementation of requirements.

3.11 Transitional and miscellaneous provisions

References

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ANNEX 1.

National law from South Africa

National Health Act, 2003 (Act No. 61 of 2003). Regulations Relating to Cancer Registration. Republic of South Africa. 26 April 2011. Government Gazette No. 34248, Vol. 550 No. 9527.

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, 3rd 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 prioritisation 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 three 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 subregulation 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 unauthorised 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 subregulation 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 authorisation.

(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.

Duly 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 authorised 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 vice 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 unauthorised 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 MOTSOALEDI
MINISTER OF HEALTH

CANCER REGISTRATION FORM

GW

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

CANCER REGISTRATION FORM

To be completed in duplicate in **BLOCK LETTERS**.
Please mark with ☑ the CORRECT box, where required.
To be submitted to the National Cancer Register via:
e-mail: cancer.registry@nhls.ac.za

A. PARTICULARS OF INDIVIDUAL

1. Name of facility

2. Surname

3. Full names

4. Date of birth Age

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? (that is, more than once a week) ☐ Yes ☐ No ☐ Unknown

14. HIV status ☐ Negative ☐ Positive ☐ Unknown

C. CLINICAL AND LABORATORY DETAILS

15. Date of diagnosis

16. Cancer diagnosis and Histology 17. ICD-10 ☐☐.☐

Please give all information available on the site, laterality, histology and behaviour of the tumour

Site: **Laterality:**

Type / Stage:

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 ☐ Molecular ☐ Death Certificate

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

INFORMANT PARTICULARS

Name (Print)

MP/NC Number

Signature Date

CODING:

Top ☐☐.☐

M - ☐☐☐ / ☐☐ / ☐☐

ANNEX 2.

National law from the Republic of Korea

Government of the Republic of Korea (2024). Excerpts (Section 2: Cancer Research Projects and Section 3: Central Cancer Registration Headquarters, Regional Cancer Registration Headquarters, National Cancer Data Center, and Regional Cancer Centers) from the Cancer Control Act. Enforcement Date 20 September 2024. Act No. 20379, 19 March 2024.

Article 14 (Cancer Registration Statistics Services)

(1) The Minister of Health and Welfare shall provide services for registration, management and research (hereinafter referred to as "cancer registration statistics services") to collect statistics on cancer incidence rates and survival rates of cancer patients, etc. through the continuous and systematic collection and analysis of data on risk factors of the development of cancer and the development and cure of cancer. In such cases, the Statistics Act shall apply mutatis mutandis to the collection of statistical data and the compilation of statistics, etc., and any personal information processed to collect statistics shall be deemed personal information to which the Personal Information Protection Act shall not apply, pursuant to Article 58 (1) of that Act. <Amended on Mar. 29, 2011>

(2) The Minister of Health and Welfare may request medical care providers or medical institutions diagnosing and treating cancer patients, the National Health Insurance Corporation and the Health Insurance Review and Assessment Service under the National Health Insurance Act, Ministry of the Interior and Safety, the Statistics Korea, statistics service agencies under the Statistics Act, and any other corporation, institution or organization conducting cancer-related business to submit data or state opinions necessary for cancer registration statistics services, as prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, a person requested to submit data shall comply with such request, except in extenuating circumstances. <Amended on Apr. 7, 2020>

(3) Where the Minister of Health and Welfare manages personally identifiable information in connection with cancer registration statistics services, he or she shall take measures necessary to ensure its safety, such as encrypting such information, in order to protect personal information, as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted on Dec. 29, 2015>

Article 15 (Cancer Information Services)

(1) The Minister of Health and Welfare shall provide services (hereinafter referred to as "cancer information services") gathering information on cancer continuously and systematically and providing such information to citizens efficiently.

(2) The Minister of Health and Welfare may have the National Cancer Center to provide cancer information services in order to efficiently promote cancer information services.

(3) Cancer information services pursuant to paragraph (1) shall be as follows: <Amended on Apr. 7, 2020>
1. Production, collection, and management of various information on cancer;
2. Provision of information on cancer to citizens and consultation with them thereabout;
3. Development of educational materials on cancer, and education and publicity thereon;
4. Other services the Minister of Health and Welfare deems necessary for the implementation of the cancer information services.

Article 16 (Epidemiological Investigations)

(1) The Commissioner of the Korea Disease Control and Prevention Agency or the Mayor/Do Governor may conduct an epidemiological investigation, if he or she deems it necessary for finding causes of the development of cancer. <Amended on Apr. 7, 2020; Aug. 11, 2020>

(2) The Commissioner of the Korea Centers for Disease Control and Prevention or the Mayor/Do Governor shall each establish an epidemiological investigation team to conduct an epidemiological investigation. <Amended on Apr. 7, 2020; Aug. 11, 2020>

(3) In order to efficiently conduct the epidemiological investigation under paragraph (1), the Commissioner of the Korea Disease Control and Prevention Agency or the Mayor/Do Governor may request the head of a relevant administrative agency or the head of an institution or organization prescribed by Presidential Decree to submit data necessary for the epidemiological investigation. In such cases, the head of the institution who has been requested to submit data shall comply therewith, unless there is a compelling reason not to do so. <Newly Inserted on Apr. 7, 2020; Aug. 11, 2020>

(4) In the epidemiological investigation conducted by the Commissioner of the Korea Disease Control and Prevention Agency or the Mayor/ Do Governor, no one shall engage in any of the following acts: <Newly Inserted on Apr. 7, 2020; Aug. 11, 2020>
1. Refusing, obstructing, or avoiding the epidemiological investigation without good cause;
2. Making false statements or submitting false data;
3. Intentionally omitting or concealing facts.

(5) Matters necessary for the content, time, and method of the epidemiological investigation under paragraph (1) and the composition, mission, etc. of the epidemiological investigation team under paragraph (2) shall be prescribed by Presidential Decree. <Newly Inserted on Apr. 7, 2020>

Article 17 (Designation of Central Cancer Registration Headquarters and Regional Cancer Registration Headquarters)

(1) The Minister of Health and Welfare may designate the National Cancer Center or research institutions specialized in cancer, which meet the standards for facilities, human resources, equipment, etc. prescribed by Ordinance of the Ministry of Health and Welfare as Central Cancer Registration Headquarters in order to provide the following services: <Amended on Apr. 7, 2020>
1. Collection, analysis, and management of data for calculating cancer statistics such as cancer incidence and survival rates;
2. Investigations and research related to cancer registration statistics services;
3. Education and training, and international collaboration related to cancer registration statistics services;
4. Collection and analysis of cancer registration data for each region and support for the regional cancer registration headquarters;
5. Other services the Minister of Health and Welfare deems necessary in connection with cancer registration statistics services.

(2) The Minister of Health and Welfare may designate a regional cancer center pursuant to Article 19 or an institution from among related specialized institutions meeting the standards for facilities, human resources, equipment, etc. prescribed by Ordinance of the Ministry of Health and Welfare as regional cancer registration headquarters of the Special Metropolitan City, a Metropolitan City, Special Self-Governing City, Do, or Special Self-Governing Province (hereinafter referred to as "City/Do"), in order to provide the following services: <Amended on Dec. 29, 2015; Apr. 7, 2020>
1. Collection, analysis and management of data to collect statistics on cancer, such as a cancer incidence rate, survival rate of cancer patients, etc. of the relevant area;
2. Investigations and research related to cancer registration statistics services of the relevant area;
3. Other services the Minister of Health and Welfare or the head of Central Cancer Registration Headquarters deems necessary in connection with cancer registration statistics services.

(3) Where the Central Cancer Registration Headquarters or a regional cancer registration headquarters falls under any of the following subparagraphs, the Minister of Health and Welfare may cancel designation thereof:
1. Where it fails to provide a service pursuant to paragraph (1) or (2), or to follow the direction and supervision pursuant to Article 18;
2. Where it fails to meet the standards for designation pursuant to paragraph (1) or (2);
3. Where it falls under other grounds prescribed by Presidential Decree.

(4) Necessary matters concerning procedures for designation of the Central Cancer Registration Headquarters or a regional cancer registration headquarters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 18 (Direction and Supervision of Central Cancer Registration Headquarters and Regional Cancer Registration Headquarters)

(1) The head of the Central Cancer Registration Headquarters shall formulate a plan for cancer registration statistics services every year and notify regional cancer registration headquarters, medical care providers or the heads of medical institutions diagnosing and treating cancer patients of details of, standards, etc. for statistical data on cancer registration.

(2) The head of Central Cancer Registration Headquarters shall integrate and analyze the results of cancer registration statistics services of the preceding year and report the same to the Minister of Health and Welfare by the end of February of the following year and then publish the same every year.

(3) Where the head of a regional cancer registration headquarters intends to publish the results of cancer registration statistics services, he or she shall consult with the head of the Central Cancer Registration Headquarters in advance.

(4) The Minister of Health and Welfare may have the head of the Central Cancer Registration Headquarters and the head of a regional cancer registration headquarters report the situation concerning the provision of related services, if necessary in connection with cancer registration statistics services.