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?	