

**LEGAL NOTICE NO. ....**

**THE CANCER PREVENTION AND CONTROL ACT, 2012**

*(No. 15 of 2012)*

**IN EXERCISE** of the powers conferred by section 36 of the Cancer Prevention and Control Act, 2012, the Cabinet Secretary for Health, on the recommendation of the National Cancer Institute, makes the following Rules—

**THE CANCER PREVENTION AND CONTROL (CANCER REGISTRIES) RULES, 2023**

**PART I—PRELIMINARIES**

Citation.                    **1.** These rules may be cited as the Cancer Prevention and Control (Cancer Registry) Rules, 2023.

Interpretation.           **2.** In these Rules, unless the context otherwise requires—

No. 15 of 2012.              “Act” means the Cancer Prevention and Control Act, 2012;

                                 “Board” means the Board of Management established by section 6 of the Act;

                                 “county level user” means a person who has the rights of access to the national cancer registry specified in rule 7;

                                 “facility cancer registrar” means a person who is trained in Cancer Registration and Notification by the Institute or its authorised entity and who has the rights of access to the National Cancer Registry specified in rule 7;

                                 “facility other user” means a person who has the rights of access to the national cancer registry specified in rule 7;

                                 “sub-county level user” means a person who has the rights of access to the national cancer registry specified in rule 7;

“National Cancer Registrar” means a person who has the rights of access to the national cancer registry specified in rule 7;

“system administrator” means a person who has the rights of access to the National Cancer Registry specified in rule 7;

“line list” means a listing of patient level information generated from the National Cancer Registry System;

“Institute” means the National Cancer Institute of Kenya established by section 4 of the Act;

“medical institution” has the meaning assigned to it by the Act;

“registry” means the National Cancer Registry of Kenya where the National Cancer Register is maintained;

“system” means the National Cancer Registry of Kenya System which is the electronic version of the cancer notification where cancer patient notification records are uploaded;

“notification” means submission of information to the Institute in the form set out in the First Schedule;

“sub-county level user” means a person who has the rights of access to the national cancer registry specified in rule 7;

“system admin” means a person who manages the operations of the system and has the rights of access to the national cancer registry specified in rule 7.

Purpose.

**3.** These rules shall be to provide for—

- (a) criteria for submission of notifications
- (b) criteria and scope of access to the Registry; and

- (c) the management of the registry.

## **PART II—SUBMISSION OF NOTIFICATIONS**

Submission of  
notifications.

**4.** A medical institution shall submit a notification to the Institute in Form I set out in the First Schedule within sixty days of a patient being diagnosed with cancer.

## **PART III—NATIONAL CANCER REGISTRY**

The National  
Cancer  
Registry  
System.

**5.** (1) There is established a system which shall contain the particulars specified under sec. 5(f) and 20 (2) of the Act.

(2) The system shall provide for—

- (a) electronic notification of cancer cases;
- (b) interoperability of cancer data and electronic systems;
- (c) collection, aggregation and analysis of cancer data;  
and
- (d) dissemination of cancer data

Facility  
cancer  
registry.

**6.** (1) There shall be a facility cancer registry which shall be headed by the facility cancer registrar whose functions shall be to —

- (a) registration and activation of cancer patient records;
- (b) filing and retrieval of cancer patients' records;
- (c) abstraction of cancer data for notification;
- (d) coding and indexing of cancer diagnosis;
- (e) tracing of cancer patient records;

- (f) uploading of cancer data to the system.
- (g) generating facility level aggregate cancer reports;
- (h) disseminating cancer aggregate reports
- (i) conducting or participating in the conduct of cancer research
- (j) complying with the standard operating procedures of cancer registry; and
- (k) preparing for cancer clinics

(2) The national cancer registrar shall maintain a web-based repository and information system within the national cancer registry.

(3) The information system referred to in sub-rule (2) shall—

- (a) collect and store cancer patient level data;
- (b) manage data on persons who play a critical role in cancer surveillance; and
- (c) generate data on the burden of cancer in the country.

Access to the national cancer registry.

7. (1) Access to the national cancer registry shall be granted to a—

- (a) county level user;
- (b) facility cancer registrar;
- (c) facility other user;
- (d) sub-county level user;
- (e) national cancer registrar; and

(f) system administrator.

(2) A county level user shall—

- (a) be capable of generating, viewing and downloading aggregate facility reports of their respective county; and
- (b) not be capable of viewing, generating or sharing any cancer patient level data from the system.

(3) A facility cancer registrar shall —

- (a) be capable of inputting and viewing facility patient level data;
- (b) be capable of generating their facility aggregate reports;
- (c) be accountable for the accuracy, security and safety of data entered in the system at the facility level;
- (d) not be capable of generating or sharing any cancer patient level data from the system; and

(4) A facility other user shall—

- (a) be capable of generating, viewing and downloading aggregate reports of the respective facility; and
- (b) not be capable of viewing, generating or sharing any cancer patient level data from the system.

(5) A sub-county level user shall—

- (a) be capable of generating, viewing and downloading aggregate facility and sub-county reports of their respective sub-county; and
- (b) not be capable of viewing, generating or sharing any cancer patient level data from the system

(6) A Registrar shall—

- (a) be responsible for the deployment, maintenance and management of the system;
- (b) be capable of viewing all cancer patient level data and authorising a facility registrar to edit the data;
- (c) be capable of generating patient level line lists and aggregate reports for any facility in the country;
- (d) be responsible for authorizing and assigning user roles; and
- (e) be responsible for authorising, assigning and withdrawal of user access rights.

(7) A system administrator shall, with the authorization of the registrar—

- (a) provide technical support to the National Cancer Registrar;
- (b) view all cancer patient level data;
- (c) generate line lists and reports for any medical institution in the country;
- (d) assign user access rights to the National Cancer Registry System users;
- (e) withdraw user rights;
- (f) maintain the system; and
- (g) not be capable of sharing any cancer patient level or aggregate data from the system.

Other users.

**8.** Any other user shall—

- (a) be capable of viewing standard reports from the system;  
and
- (b) make a formal request to the registrar for any other report.

Cancer  
registrars  
register

**9.** The Institute shall maintain a register of all cancer registrars.

Training,  
certification  
and  
registration of  
cancer  
registrars

**10.** (1) A person qualifies to be trained as a cancer registrar if the person is —

- (a) a holder of a diploma or degree in health records and information management from a recognized institution;  
and
- (b) a member of a relevant professional body in good standing.

(2) A person referred to under sub-rule 10 (1) shall undergo training in cancer registration and notification for a period not less than one week by the Institute or an approved training institution.

(3) A person who meets the requirements in sub-rule (1) and (2) shall be issued with a certificate and registered in the cancer registrars register.

Requirements  
for medical  
institutions.

**11.** (1) A medical institution shall employ at least one certified cancer registrar.

(2) The person employed under sub-rule (1) shall be stationed at the cancer registry.

Obligation of  
a cancer

**12.** A cancer registrar shall—

registrar.

- (a) be the custodian of the medical records of cancer patients and shall be held responsible for breach of confidentiality for data in their custody;
- (b) adopt a recognized filing and tracing system for the medical records of cancer patients; and
- (c) maintain copies of the cancer notification forms submitted under section 4 of the Act in a secure storage.

#### **PART IV—OPERATIONS OF CANCER REGISTRIES**

Tracing and  
sharing of  
cancer  
patients  
records.

**13.** (1) All medical records of cancer patients in a cancer registry shall be traced through a file tracing system which shall—

- (a) track the movement of the medical records of cancer patients;
- (b) identify the member of staff of the medical institution who collects a medical record from the filing area or releases the record;
- (c) indicate where the medical record is to be delivered or transmitted;
- (d) identify the unique number of the medical record;
- (e) indicate the reason for which the medical record was collected;
- (f) indicate the date on which the medical record was collected and the date when the medical record was returned to the cancer registry; and
- (g) document the signature of the person who collected, transmitted and returned the medical record.

(2) The system referred to in sub-rule (1) may be a manual

or an electronic system.

(3) A cancer registrar may share the cancer medical records of a cancer patient for patient management purposes, research purposes or medico-legal purposes.

(4) A cancer registrar shall designate a specific part of the cancer registry for the storage of all the medical records of cancer patients.

(5) Where the designated storage referred to in sub-rule (4) provides for a manual filing system, the cancer registrar shall use the terminal digit or straight numerical filing system.

(6) Where the designated storage referred to in sub-rule (5) provides for an electronic filing system, the cancer registrar shall establish a system that—

- (a) can generate a notification form;
- (b) has an audit trailing functionality;
- (c) is interoperable to communicate with the national cancer registry system; and
- (d) can uniquely and easily identify cancer patient records.

Alteration of  
the national  
cancer  
register.

**14.** (1) A cancer registrar shall verify medical records of cancer patients for accuracy and completeness.

(2) Where a cancer registrar identifies an error on medical records of cancer patients that has already been submitted to the Institute, the registrar shall submit a request in writing to the Institute for rectification.

(3) A request submitted under sub-rule (2) shall indicate—

(a) the name of the medical institution;

(b) a description of the error made; and

(c) the correction to be made.

(4) The Institute shall review the request submitted under sub-rule (2), conduct investigations and within thirty days issue a notice to the person who submitted the request indicating the decision of the Institute.

(5) Where the request submitted under sub-rule (2) is approved, the Institute shall authorise the error to be rectified.

(6) Where the Institute identifies an error, the national cancer registrar shall issue a notice to the medical institution to which the error relates.

(7) The Institute shall then conduct investigations and authorise rectification of the error.

(8) A person who maliciously enters fraudulent information in the register commits an offense and shall be liable to a fine not exceeding two hundred thousand shillings or to imprisonment for a term, not exceeding two years or to both.

Access to  
information  
by persons.

**15.** An application to access information in the registry shall be made to the registrar in the prescribed form accompanied by the necessary fees.

NCI-K/MER/001



**National Cancer  
Institute of Kenya**  
NCI - KENYA

### NATIONAL CANCER NOTIFICATION FORM

FILL THIS FORM IN BLOCK LETTERS

PATIENT UNIQUE ID: \_\_\_\_\_

|                                                                                                                                                                                                                 |  |                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------|
| <b>(I) FACILITY DETAILS</b>                                                                                                                                                                                     |  | KMFL Code: _____            |
| Facility Name: _____                                                                                                                                                                                            |  | Sub County: _____           |
| County: _____                                                                                                                                                                                                   |  | Ward: _____                 |
| Constituency: _____                                                                                                                                                                                             |  |                             |
| Ownership: <input type="checkbox"/> Public <input type="checkbox"/> Private <input type="checkbox"/> Faith based <input type="checkbox"/> CBO                                                                   |  |                             |
| Licensed by: <input type="checkbox"/> Not Licensed                                                                                                                                                              |  |                             |
| <input type="checkbox"/> Kenya Medical Practitioners and Dentists Council                                                                                                                                       |  |                             |
| <input type="checkbox"/> Kenya Medical Laboratory Technicians and Technologists Board                                                                                                                           |  |                             |
| <input type="checkbox"/> Kenya Nuclear Regulatory Authority                                                                                                                                                     |  |                             |
| <input type="checkbox"/> Nursing Council of Kenya                                                                                                                                                               |  |                             |
| <input type="checkbox"/> Others, Specify _____                                                                                                                                                                  |  |                             |
| NCI - K Designation: <input type="checkbox"/> Not designated <input type="checkbox"/> Basic <input type="checkbox"/> Middle <input type="checkbox"/> Comprehensive                                              |  |                             |
| NCI - K Registration/License No: _____ Status: <input type="checkbox"/> Functional/Operating <input type="checkbox"/> Not Functional/Operating <input type="checkbox"/> Being Established                       |  |                             |
| Services Provided: <input type="checkbox"/> Prevention <input type="checkbox"/> Screening <input type="checkbox"/> Treatment (Surgical Oncology, Chemotherapy or Radiotherapy)                                  |  |                             |
| Cancer Registration <input type="checkbox"/> Palliative <input type="checkbox"/> Care <input type="checkbox"/> Survivorship <input type="checkbox"/> Cancer Research <input type="checkbox"/> Oncology Training |  |                             |
| Date of Notification: ____/____/____ (DD/MM/YYYY)                                                                                                                                                               |  | Hospital Patient No.: _____ |
| <b>(II) PATIENTS DETAILS (Please <input checked="" type="checkbox"/> tick appropriate box where applicable)</b>                                                                                                 |  |                             |

|                                                                                                                                                                                                                                                                |                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Patient Identification <input type="checkbox"/> National ID: _____ <input type="checkbox"/> Passport No: _____ <input type="checkbox"/> Birth certificate No: _____                                                                                            |                                                                                                       |
| Date of Birth: ____/____/____                                                                                                                                                                                                                                  | Age: _____ Years _____ Months                                                                         |
| Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female                                                                                                                                                                                             | <input type="checkbox"/> Other, Specify _____                                                         |
| Marital Status: <input type="checkbox"/> Single <input type="checkbox"/> Married                                                                                                                                                                               | <input type="checkbox"/> Divorced <input type="checkbox"/> Separated <input type="checkbox"/> Widowed |
| Telephone Number: _____                                                                                                                                                                                                                                        |                                                                                                       |
| Nationality: _____                                                                                                                                                                                                                                             | Ethnicity: _____                                                                                      |
| Religion: <input type="checkbox"/> None <input type="checkbox"/> Christian/Muslim                                                                                                                                                                              | <input type="checkbox"/> Hindu <input type="checkbox"/> Other _____                                   |
| Level of education: <input type="checkbox"/> None <input type="checkbox"/> Primary                                                                                                                                                                             | <input type="checkbox"/> Secondary <input type="checkbox"/> Post-secondary                            |
| Usual Residence: County: _____ Sub county: _____                                                                                                                                                                                                               | Constituency: _____                                                                                   |
| Ward: _____ Estate/Village: _____                                                                                                                                                                                                                              |                                                                                                       |
| Insurance Cover: <input type="checkbox"/> None <input type="checkbox"/> NHIF                                                                                                                                                                                   | <input type="checkbox"/> Others, Specify _____                                                        |
| Name of Caregiver: _____                                                                                                                                                                                                                                       | Care giver's Tel Number: _____                                                                        |
| Relationship to the patient: _____                                                                                                                                                                                                                             |                                                                                                       |
| <b>(III) CANCER INFORMATION (Please <input checked="" type="checkbox"/> tick appropriate box where applicable)</b>                                                                                                                                             |                                                                                                       |
| Place of diagnosis: <input type="checkbox"/> Current facility <input type="checkbox"/> Other specify: _____                                                                                                                                                    |                                                                                                       |
| Definitive Diagnosis done? <input type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                                                            |                                                                                                       |
| Basis of definitive Diagnosis: <input type="checkbox"/> Laboratory investigation <input type="checkbox"/> Cytology/Histology (Primary) <input type="checkbox"/> MRI <input type="checkbox"/> Endoscopy <input type="checkbox"/> PET Scan                       |                                                                                                       |
| <input type="checkbox"/> CT Scan <input type="checkbox"/> Cytology/Histology (Metastasis)                                                                                                                                                                      |                                                                                                       |
| Date of Sample collection: ____/____/____                                                                                                                                                                                                                      | Date of reporting: ____/____/____                                                                     |
| Topography (Primary site): _____                                                                                                                                                                                                                               | ICD Code: C _____                                                                                     |
| Histology Type: _____                                                                                                                                                                                                                                          | Morphology Code M _____                                                                               |
| Stage: <input type="checkbox"/> Uncertain <input type="checkbox"/> In situ <input type="checkbox"/> Stage I <input type="checkbox"/> Stage II <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IV                                             |                                                                                                       |
| Risk Stratification: <input type="checkbox"/> Low <input type="checkbox"/> Intermediate <input type="checkbox"/> High                                                                                                                                          |                                                                                                       |
| Referral: <input type="checkbox"/> Not Referred <input type="checkbox"/> To: _____                                                                                                                                                                             | From: _____                                                                                           |
| <b>(IV) TREATMENT (Please <input checked="" type="checkbox"/> tick all that apply)</b>                                                                                                                                                                         |                                                                                                       |
| <input type="checkbox"/> No Treatment                                                                                                                                                                                                                          |                                                                                                       |
| <input type="checkbox"/> Surgery                                                                                                                                                                                                                               | Date of Surgery: ____/____/____                                                                       |
| <input type="checkbox"/> Radiotherapy                                                                                                                                                                                                                          | Number of Sessions prescribed: _____ Number of Sessions received: _____ Start date: ____/____/____    |
| <input type="checkbox"/> Chemotherapy                                                                                                                                                                                                                          | Number of cycles prescribed: _____ Number of cycles received: _____ Start date: ____/____/____        |
| <input type="checkbox"/> Hormonal Therapy                                                                                                                                                                                                                      | Start date: ____/____/____                                                                            |
| <input type="checkbox"/> Immunotherapy                                                                                                                                                                                                                         | Start date: ____/____/____                                                                            |
| <input type="checkbox"/> Other, specify: _____                                                                                                                                                                                                                 | Start date: ____/____/____                                                                            |
| Purpose for treatment: <input type="checkbox"/> Neoadjuvant <input type="checkbox"/> Adjuvant <input type="checkbox"/> Concurrent <input type="checkbox"/> Radical/Definitive <input type="checkbox"/> Palliative <input type="checkbox"/> Other Specify _____ |                                                                                                       |
| <b>(V) COMORBIDITIES (Please <input checked="" type="checkbox"/> tick all that apply)</b>                                                                                                                                                                      |                                                                                                       |
| <input type="checkbox"/> None <input type="checkbox"/> HIV <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Cardiovascular disease                                                                             |                                                                                                       |
| <input type="checkbox"/> Renal disease <input type="checkbox"/> Sickle cell <input type="checkbox"/> Autoimmune disease <input type="checkbox"/> Other, specify _____                                                                                          |                                                                                                       |
| <b>(VI) PATIENT STATUS (Please <input checked="" type="checkbox"/> tick appropriate box where applicable)</b>                                                                                                                                                  |                                                                                                       |
| Patient status: <input type="checkbox"/> Alive <input type="checkbox"/> Dead                                                                                                                                                                                   |                                                                                                       |
| If Dead, Underlying Cause of death: _____                                                                                                                                                                                                                      | <input type="checkbox"/> Unknown Date of Death: _____                                                 |
| <b>FORM COMPLETED BY:</b>                                                                                                                                                                                                                                      |                                                                                                       |
| Name: _____                                                                                                                                                                                                                                                    | Telephone: _____ Designation: _____                                                                   |
| Email Address: _____                                                                                                                                                                                                                                           | Signature: _____                                                                                      |

Edition: Apr, 2021

No: This form should be filled in duplicate for every newly diagnosed cancer patient within 60 days of diagnosis for notification purposes (Cancer Prevention and Control Act, No 15 of 2012)  
 Original (White): To be filed separately using the hospital patient No.  
 Copy (Pink): To be retained in patient file.

**FORM 2****(r. 6(1))****Application for Registration as Medical Institution**

|    |                                                                      |                    |
|----|----------------------------------------------------------------------|--------------------|
| 1. | Name of medical institution.                                         |                    |
| 2. | County                                                               |                    |
| 3. | Sub County                                                           |                    |
| 4. | Ward                                                                 |                    |
| 5. | Ownership                                                            | Public/Private/FBO |
| 6. | Physical Address                                                     |                    |
| 7. | Is the organisation/ association registered                          | Yes/ No            |
|    | (a) If Yes registered under which umbrella body or government entity |                    |
|    | (b) Registration Number                                              |                    |
| 8. | Services Provided                                                    | Yes/ No            |
|    | (a) Prevention                                                       |                    |
|    | (b) Cancer awareness                                                 |                    |
|    | (c) Screening                                                        |                    |
|    | (d) Palliative Care                                                  |                    |
|    | (e) Survivorship                                                     |                    |
|    | (f) Cancer Research                                                  |                    |
|    | (g) Oncology Training                                                |                    |
|    | (h) Nutrition                                                        |                    |

|    |                                                                                                |  |
|----|------------------------------------------------------------------------------------------------|--|
|    | (i) Counselling                                                                                |  |
|    | (j) Rehabilitation services                                                                    |  |
|    | (k) Prosthesis provision                                                                       |  |
|    | (l) Herbal supplements                                                                         |  |
|    | (m)Community outreaches – screening,<br>awareness creation, empowerment of<br>cancer survivors |  |
| 9. | Status                                                                                         |  |

## SECOND SCHEDULE

### FEES

#### FEES FOR COPIES OF NATIONAL CANCER REGISTER

(r. 16)

| Reason for Request/Use                  | Charges             |                      |
|-----------------------------------------|---------------------|----------------------|
|                                         | Aggregate/Processed | Individual/Line list |
| Conference/ Presentation                | 20,000              | 50,000               |
| Capacity building/Training              | 5,000               | 10,000               |
| Grant application                       | 100,000             |                      |
| Media                                   | 20,000              |                      |
| Research/Academic project(s)            |                     |                      |
| Diploma                                 | 2,000               | 5,000                |
| Bachelors' degree/Post-graduate diploma | 5,000               | 10,000               |
| Masters' degree                         | 10,000              | 20,000               |
| Doctorate Degree                        | 20,000              | 50,000               |

Made on the ....., 2023.

**SUSAN NAKHUMICHA ,**  
*Cabinet Secretary for Health*

