

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 (STANDARDS OF CARE) RULES, 2023

PART 1- PRELIMINARIES

Citation. **1.** This Rules maybe cited as the Cancer Prevention And Control (Standards of Care) Rules, 2023.

Interpretation. **2.** In this Order, unless the context otherwise requires—

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

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

 “cancer centre” includes a medical institution and any other institution designated by the Institute that provides either but not limited to the following cancer care services: advocacy; prevention; diagnosis; treatment; palliative care; survivorship; rehabilitation; oncology training; and research services;

 “Committee” means the Oncology Standards of Care Committee constituted in accordance with rule 3;

 “key sub-committee” means a small ad-hoc committee formed from the Oncology Standards of Care committee to address an emerging issue;

“multi-disciplinary Tumor Board” means the multi-disciplinary team consisting of different cancer experts that manages cancer patients in a consultative approach;

“patient care plan” an individualized documented outline of a patient’s assessed health and social care needs and how they will be managed and supported;

“specialist” means an individual who has completed an approved post-graduate programme in a health science field and who has thereafter gained sufficient experience and demonstrated to the respective regulatory body’s satisfaction, adequate knowledge and skills in the field; and

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

PART II—THE ONCOLOGY STANDARDS OF CARE COMMITTEE

Establishment
of the
Committee.

3. (1) There is established a Committee to be known as the Oncology Standards of Care Committee to be appointed by the Board from the members of staff of the Institute, with the relevant expertise.

(2) Notwithstanding sub-rule (1), where technical expertise is required from outside the Institute, such expertise may be obtained from other entities as may be deemed necessary.

(3) The Committee shall comprise—

- (a) a representative from Standards and Quality Assurance Division who shall be the chair;
- (b) a representative from Diagnostic and Treatment Division who shall be the secretary;
- (c) a representative from the Research and Clinical Trials

Division;

- (d) a representative from the Inspection and Compliance Division;
- (e) a representative from the Oncology Commodities and Technologies Division;
- (f) a representative from the National Cancer Registry Division;
- (g) a representative from Information, Education and Communication; and
- (h) two co-opted persons who shall not be members of the Institute, for the better carrying out of the business of the committee on need basis.

(4) The persons co-opted under sub-rule 3(h) shall not be eligible to vote in any matter before the committee.

(5) Subject to these Rules, the Committee may regulate its own procedure.

Functions of
the
Committee.

4. The functions of the Committee shall be to—

- (a) recommend best practice standards for cancer care across the cancer continuum of care;
- (b) oversight the practices related to cancer management;
- (c) direct and oversight the patient education process;
- (d) guide oncology staff training and competency for cancer clinical care;
- (e) recommend appropriate nutritional and other clinical procedures, protocols and guidelines;

- (f) recommend clinical policies for approval;
- (g) direct and oversight key subcommittees;
- (h) approve criteria for competence in the various patient care settings;
- (i) collaborate with other relevant committees to monitor and improve patient care;
- (j) advise on cancer treatment plans requiring foreign travel and reimbursed by the National Health Insurance Fund; and
- (k) provide technical support to existing and upcoming cancer centers upon request by the centre.

PART III—STANDARDS OF CARE IN THE MANAGEMENT OF CANCER PATIENTS

Cancer
prevention
and
awareness.

5. Every cancer centre shall—

- (a) provide access to cancer information on the risk factors, causes and consequences of cancer;
- (b) provide access to or facilitate risk mitigation measures within the working environment; and
- (c) establish multi-sectoral cancer preventive programs and interventions in the living and working environment.

Cancer
screening and
early
detection.

6. (1) Every cancer centre shall develop and implement a policy that enables or facilitate cancer screening and early detection services.

(2) Every primary health care facility shall establish a gate-

keeping mechanism that enables screening and early detection and has clearly-defined referrals to higher levels of care.

Service norms
of a cancer
centre.

7. Every cancer centre shall be established in accordance with the Guidelines for Establishment of Cancer Centres in Kenya.

Protocols for a
cancer centre.

8. (1) A cancer centre shall adhere to the protocols for diagnosis and treatment of all malignancies approved by the Institute.

(2) A cancer centre shall avail the protocols referred to in sub-rule (1) to the healthcare workers at the centre at all times.

(3) A cancer centre shall keep updated protocols referred to in sub-rule (1) and produce the protocols for inspection when required to do so by the Institute.

Service
delivery.

9. Every cancer centre shall, where relevant—

- (a) formulate and prominently display a service charter;
- (b) provide integrated and multidisciplinary care;
- (c) prioritize coordination and planning for specialists;
- (d) facilitate access by a patient to care at other levels of care;
- (e) facilitate awareness creation, screening, early detection, case management and appropriate referrals;
- (f) be capable of definitive diagnosis or tissue diagnosis within two weeks of tissue collection;
- (g) be capable of initiating appropriate cancer treatment within a month of diagnosis;

- (h) follow evidence-based protocols and guidelines;
- (i) obtain informed consent prior to all procedures including treatments;
- (j) establish clear navigation systems to enable access to services by a patient;
- (k) design a patient-tracking system for patient follow-up throughout the continuum of care; and
- (l) develop standard operating procedures for service offered.

Clinical
management.

10. Every cancer centre shall, where relevant—

- (a) provide holistic and patient-centred cancer management;
- (b) clearly define and communicate the goals of care to the patient in accordance with the patient care plan;
- (c) provide detailed information to a patient on the condition, treatment options, clinical trials, side effects, expected outcome and prognosis of the disease;
- (d) inform a patient the right to seek a second or additional opinion before consenting to treatment;
- (e) document, store and easily retrieve all aspects of cancer management;
- (f) allow access by patients to all their medical records;
- (g) comprehensively document patient history;
- (h) train members of staff on chemo safety; and

(i) be well prepared and equipped to manage oncological emergencies.

Multi-disciplinary
Tumor Board.

11. (1) Every cancer centre shall where necessary appoint Multi-disciplinary Tumor Board which shall be responsible for the management of cancer patients in a consultative approach.

(2) The team appointed under sub-rule (1) shall be drawn from—

- (a) medical oncologists;
- (b) radiation oncologists;
- (c) surgeons;
- (d) pathologists;
- (e) palliative experts;
- (f) oncology pharmacists;
- (g) oncology nurses;
- (h) nutritionists;
- (i) medical social workers;
- (j) cancer registrars;
- (k) interventional radiologists;
- (l) hematologists;
- (m) medical physicists;
- (n) medical dosimetrists;
- (o) radiation therapists;

- (p) medical laboratory technologists with oncology specialization;
- (q) oncology clinical officer; and
- (r) others.

(3) The team appointed under sub-rule (1) shall meet at least once every week.

(4) The meetings of the team appointed under sub-rule (1) shall be attended by the representatives of all relevant disciplines depending on the cancer case and the level of care.

(5) The team appointed under sub-rule (1) shall deliberate on all relevant cancer cases.

(6) The team appointed under sub-rule (1) shall appoint a coordinator from among the members who shall be responsible for organizing the meetings, keep records of the meetings and provide reports upon request by the Institute on the management of cancer patients.

Diagnostic
imaging.

12. Every cancer centre shall, where applicable—

- (a) incorporate clinical findings when conducting diagnostic imaging;
- (b) consider image-guided diagnostics where applicable;
- (c) use a standard protocol for conducting imaging procedures as provided by Kenya Nuclear Regulatory Authority;
- (d) use the recognized standards and guidelines for the safe installation recognised by the International Atomic Energy Agency and the Kenya Nuclear Regulatory Authority, operation and use of imaging equipment;

- (e) use a standard imaging diagnostic reporting protocol prescribed by the Ministry of Health; and
- (f) provide access to imaging diagnostic facility that has been accredited by the Kenya Nuclear Regulatory Authority.

Pathology and laboratory diagnosis.

13. Every cancer centre shall, where applicable—

- (a) have access to a comprehensive pathology and medical laboratory that is registered and licensed by Kenya Medical Laboratory Technicians and Technologists Board;
- (b) develop a functional specimen referral and consultation mechanism;
- (c) notify the Institute using the National Cancer Registry System;
- (d) avail tissue blocks to the patient upon request; and
- (e) provide the most precise diagnostic data as per best practice and using novel and advanced techniques which are regulated, validated and approved by the relevant regulatory bodies.

Nuclear medicine and radiation oncology.

14. Every cancer centre shall, where applicable—

- (a) provide nuclear medicine and radiation oncology services in adherence to International Atomic Energy Agency and Kenya Nuclear Regulatory Authority;
- (b) maintain records on all ionizing radiation therapeutic applications;
- (c) maintain records of treatment planning simulations, isodose distribution plans, dosimetry, brachytherapy

and physics documentation;

- (d) deliver novel and advanced technologies available for nuclear medicine and radiation oncology;
- (e) provide technologies available for nuclear medicine and radiation oncology that are cost-effective, efficient, upgradable and practical;
- (f) adequately inform a patient receiving radioactive therapy on procedures conducted;
- (g) use radiopharmaceuticals that are sourced from an International Atomic Energy Agency accredited source;
- (h) have a reliable and uninterrupted source of positron emitting radiotracers;
- (i) have a valid commercial radionuclide distribution license;
- (j) use radiopharmaceuticals are manufactured according to the basic principles of good manufacturing practice and management as prescribed by the relevant regulatory bodies; and
- (k) ensure continuous quality control is conducted, this will be done retrospectively.

Surgical
considerations

15. Every cancer centre shall, where applicable—

- (a) enable access by a patient to surgical diagnosis and treatment for solid malignancies in accordance with the recommendations of the multi-disciplinary team made under rule 11;
- (b) where tissue is obtained for histological examination, ensure that the responsible surgeon observes the

standard operating procedure for histology specimen handling, storage and transport; and

- (c) provide surgical treatment in accordance with the surgical guidelines and evidence-based surgical-oncological practices.

Nursing.

16. Every cancer centre shall, where applicable—

- (a) provide oncology and palliative nursing care for the entire continuum of care of a cancer patient;
- (b) appoint oncology nurses who have at least a higher diploma in oncology and are registered with the Nursing Council of Kenya;
- (c) coordinate the oncology and palliative care teams;
- (d) support community linkage for cancer patients;
- (e) provide personal protective equipment for the nurses working in proximity to cytotoxic medication; and
- (f) provide chemotherapy safety training (chemo safe) certification for the nurses in every two years.

Chemotherapy

17. Every cancer centre shall, where applicable—

- (a) ensure that chemotherapy and biotherapy are only initiated under the supervision of a qualified oncologists;
- (b) provide a biosafety cabinet which is designed in accordance with the specifications of at least class 2B2 and fitted with ventilation mechanism that directly faces the exterior of the building and is at least two metres above the tallest building within the premises or/and surrounding building;

- (c) ensure that chemotherapy medication are prepared by a clinical pharmacist, an oncology pharmacist or an oncology pharmaceutical technologist who has valid certification on chemosafe or biosafety training;
- (d) provide personal protective equipment to the members of the health care team who prepare, mix, administer and transport hazardous chemotherapy medication;
- (e) monitor exposure to hazardous chemotherapy medication for all health workers working within the chemotherapy unit;
- (f) ensure that no pregnant and/or lactating health workers are assigned to an area where chemotherapy medication are handled;
- (g) train healthcare workers on chemosafe prior to assigning them their duties at the chemotherapy unit;
- (h) establish a mechanism that monitors the dosage and administration of cytotoxic medication to patients;
- (i) administer chemotherapy through infusion pumps for accuracy and safety;
- (j) provide for the management of extravasations and spills;
- (k) document the handling of hazardous waste;
- (l) store chemotherapy medicines separately from other medicines;
- (m) transport chemotherapy medicines in such a manner that maintains the integrity of the medicine;

- (n) ensure adequate labelling of all chemotherapeutic agents and wastes;
- (o) develop facility standard operating procedures for the designation, receipt, storage, compounding, dispensing, transportation, administration, monitoring adverse events, monitoring the environmental effects, and disposal of hazardous medicine;
- (p) develop standard operating procedures for the use and maintenance of proper engineering controls;
- (q) develop standard operating procedures for hand hygiene and the use of personal protective equipment;
- (r) develop standard operating procedures for the deactivation, decontamination, cleaning and disinfection; and
- (s) develop standard operating procedures for spill control and medical surveillance.

Palliative care
and
survivorship.

18. Every cancer centre shall, where applicable—

- (a) provide palliative care from the point of cancer diagnosis and at all times throughout the course of illness;
- (b) integrate palliative care with other health services;
- (c) provide effective relief of pain and other distressing symptoms;
- (d) provide timely rehabilitative and supportive services;
- (e) facilitate formation of patient support groups;

- (f) establish survivorship programs;
- (g) adhere to the National Palliative Care Policy and the National Palliative Care Guidelines; and
- (h) inform patients and relatives on therapeutic goals during treatment and the provision of care and comfort at the end of life.

Referrals.

19. Every cancer centre shall, where applicable—

- (a) develop standard operating procedures for patient referral which conform to the Kenya Health Sector Referral Implementation guidelines;
- (b) maintain records on referrals to and away from the facility;
- (c) promote upward, downward and horizontal referral where appropriate;
- (d) assess patients' fitness to travel and provide necessary supportive measures before referral; and
- (e) refer a patient to the specialist who offers treatment or care that is not within the scope of oncology services required.

Quality assurance.

20. Every cancer centre shall, where applicable—

- (a) ensure that all procedures are appropriately defined, documented, understood, implemented and regularly reviewed;
- (b) appoint a duly qualified quality assurance officer with formal training in quality assurance;
- (c) submit quarterly quality improvement reports to

the Institute;

- (d) appoint a qualified physicist who shall be responsible for regularly calibrating radiation emitted or detected in accordance with the International Atomic Energy Agency regulation for optimization of physical aspects of diagnostic and therapeutic procedures;
- (e) maintain accurate quality assurance documents including annual onsite calibration and dosimetry review reports;
- (f) establish risk assessment measures for systematic monitoring and evaluation which are capable of identifying problems and system failures and recommending the necessary action;
- (g) conduct monthly morbidity and mortality meetings to identify specific clinical performance indicators;
- (h) appoint a multidisciplinary quality assurance committee responsible for reviewing, documenting, implementing, monitoring and reporting cancer improvements
- (i) constitute safety needs for adverse events;
- (j) install adequate accessible eye washing facilities in chemotherapy reconstitution, chemotherapy administration and cancer laboratory units; and
- (k) meet international standards of care through accreditation by relevant bodies.

Infection
prevention
and control.

21. Every cancer centre shall where applicable—

- (a) establish an infection prevention and control

program in accordance with the National Infection Prevention and Control Guidelines for Health Care Services in Kenya and World Health Organization Practical Guidelines for Infection prevention and control;

- (b) install adequate hand-washing facilities and provide hand sanitizers at every work station;
- (c) designate isolation rooms and practice barrier nursing; and
- (d) ensure availability and use of personal protective equipment.

Occupational
health and
safety.

22. Every cancer centre shall where applicable—

- (a) train the members of staff on safety and health at least once every three years;
- (b) adhere to the requirements of the Occupational health and safety Act 2010;
- (c) label chemicals as per PPB regulations for identification and classification;
- (d) establish a system for identification and surveillance of exposure, an annual medical review form that is duly filled accompanied by biannual medical tests including—
 - (i) a full haemogram and urinalysis;
 - (ii) a record of the number of workers who come into contact with substances and are employed in occupations with increased carcinogenic risk;
 - (iii) reducing the number of workers exposed;

- (iv) the duration of exposure, and the degree of exposure;
- (e) ensure medical surveillance of all healthcare workers handling hazardous medicines and their clinical assessment and maintain records;
- (f) develop guidelines and recommendations for proper use and handling of carcinogenic chemicals;
- (g) monitor services at the workplace and assess occupational exposures through clinical audits;
- (h) inform the members of staff about their exposures and risks; and
- (i) monitor the performance, mental health, work-life balance and establish debriefing programs for the members of staff.

Waste
management.

23. Every cancer center shall—

- (a) dispose radioactive, cytotoxic and radiopharmaceutical waste produced in the process of the diagnosis and treatment of cancer in accordance with international and pharmacy and poisons guidelines on waste management;
- (b) segregate, package, label, collect, transport, store and conduct on site or off site treatment and disposal of hazardous waste within the centre;
- (c) provide waste disposal amenities and commodities;
- (d) conduct quarterly capacity building on waste disposal for all healthcare providers, support staff and waste handlers;
- (e) provide appropriate protective personal equipment for

handling hazardous waste;

- (f) incinerate hazardous waste using special incinerators and maintain documentation on the same;
- (g) minimize the risk of contaminating the local water supply and soil with hazardous drugs; and
- (h) provide disposal systems for radioactive effluents which effectively and carefully maintained to prevent contamination and exposure of personnel to the radioactive waste.

Emergency
medical care.

24. Every cancer centre shall, where applicable—

- (a) establish facilities that are capable of handling oncologic and palliative care emergencies; and
- (b) appoint members of staff who are capable of handling oncologic and palliative care emergencies.

Adverse
events.

25. Every cancer center shall maintain records of any adverse event that occurs as a result of cancer diagnosis or treatment and submit reports of the adverse event to the Pharmacy and Poisons Board, the Nuclear Regulatory Authority and the Institute.

Death of
cancer
patients.

26. Every cancer centre shall—

- (a) maintain records of all deaths occurring whilst cancer patients are undergoing diagnosis or treatment;
- (b) offer bereavement support including psychosocial support to cancer patients and members of their families;
- (c) hold quarterly mortality meetings where the deaths of cancer patients are tabled for discussion by the multidisciplinary team;

- (d) maintain records of all deaths occurring whilst cancer patients are undergoing diagnosis or treatment;
- (e) offer bereavement support including psychosocial support to cancer patients and members of their families; and
- (f) hold quarterly mortality meetings where the deaths of cancer patients are tabled for discussion by the multidisciplinary team.

Protection of
the general
public.

27. Every cancer center shall dispose cytotoxic waste in accordance with international and pharmacy and poisons guidelines on waste management.

Protection of
the health care
worker.

28. Every cancer centre shall—

- (a) provide the necessary protective gears;
- (b) ensure utilization of personal protective gears;
- (c) ensure employees adhere to the safety surveillance measures;
- (d) ensure measures to reduce exposure are in place; and
- (e) provide the necessary protective gears.

Made on the, 2023.

SUSAN NAKHUMICHA,
Cabinet Secretary for Health