CONTENT

Bill for Introduction into the National Assembly —

The Pharmacy Practitioners Bill, 2014 .................................................. 3061
THE PHARMACY PRACTITIONERS BILL, 2014
ARRANGEMENT OF CLAUSES

Clause

PART I—PRELIMINARY
1—Short title and commencement.
2—Interpretation.

PART II—THE PHARMACY PRACTITIONERS BOARD
3—Establishment of the Board.
4—Functions of the Board.
5—Powers of the Board.
6—Composition of the Board.
7—Conduct of business and affairs of the Board.
8—Delegation by the Board.
9—Remuneration of Board members.
10—The Registrar.
11—Secretary to the Board.
12—Staff of the Board.
13—Protection from personal liability.

PART III—FINANCIAL PROVISIONS
14—Funds of the Board.
15—Financial year.
16—Annual estimates.
17—Accounts and audit.
18—Investment of funds.
19—Annual report.

PART IV—TRAINING, REGISTRATION AND ENROLMENT
20—Approved training institutions.
21—Supervisory role of the Board.
22—Application for registration.
23—Registration as a pharmacist.
24—Enrolment of pharmaceutical technologists.
25—Register of Pharmacists and Roll of Pharmaceutical Technologists.
26—Register or Roll as proof.
27—Removal of names from the Register or Roll.

PART V—LICENSING

28—Practising licence.
29—Application for practising licence.
30—Licensing of non citizens.
31—Licensing of premises.
32—Application for premise licence.
33—Types of licences.
34—Validity of licence.
35—Refusal to issue licence.
36—Renewal, cancellation and suspension of licence.

PART VI—ETHICS AND DISCIPLINARY COMMITTEE

37—Ethics and Disciplinary committee
38—Procedure of the committee.
39—Disciplinary measures.
40—Lifting of suspension.
41—Restoration of name in Register or Roll.

PART VII—ENFORCEMENT

42—Authorised officers.
43—Premises authorised officers may enter.
44—Powers of officers.
45—Use of records.
46—Entry of premise.
47—Inspection report.
48—Assistance of officers.
49—Obstruction.
50—Seizure.
51—Order for restoration.
52—Offences by partnership or bodies corporate.
53—Nature of evidence in proceedings.
54—Certificates.
55—Offences relating to registration or enrolment.
56—General penalty.

**PART VIII —PROVISIONS ON DELEGATED POWERS**

57—Rules.
58—Principles and standards of delegated power.

**PART IX —FINAL PROVISIONS**

59—Amendment of Cap. 244.
60—Transitional.

**FIRST SCHEDULE-** Provisions as to the Conduct of Business and Affairs of the Board

**SECOND SCHEDULE-** Types of Licences

**THIRD SCHEDULE-** Consequential amendments to the Pharmacy and Poisons Act
THE PHARMACY PRACTITIONERS BILL, 2014

A BILL for

AN ACT of Parliament to make provision for the training, registration and licensing of pharmacists and pharmaceutical technologists, to regulate their practice and professional conduct, to provide for the establishment, powers and functions of the Pharmacy Practitioners Board and for connected purposes

ENACTED by the Parliament of Kenya as follows-

PART I - PRELIMINARY

1. This Act may be cited as the Pharmacy Practitioners Act, 2014 and shall come into operation after the expiry of ninety days from its date of publication.

2. (1) In this Act, unless the context otherwise requires—

“approved institution” means a university and such other training institution as the Board may approve;

“Board” means the Pharmacy Practitioners Board established by section 3;

“Cabinet Secretary” means the Cabinet Secretary for the time being responsible for matters relating to health;

“community pharmacy” means the practice of pharmacy which involves patient care and dispensing of medicines to the end user;

“medicine” means any medicament or curative or preventive substance, whether proprietary or in the form of a preparation;

“pharmacy practitioner” means a person registered under this Act as a pharmacist or a pharmaceutical technologist;

“pharmacist” means a person registered as a pharmacist under section 23;

“pharmaceutical technologist” means a person enrolled as a pharmaceutical technologist under section 24;

“Register” means the Register of Pharmacists maintained under section 25;
“Roll” means the Roll of Pharmaceutical Technologists maintained under section 25; and

“Registrar” means the Registrar of Pharmacy Practitioners Board appointed under section 10.

“wholesale pharmacy” means the practice of pharmacy which involves breaking of bulk for medicines for the purpose selling or distribution to the community pharmacy outlets.

PART II—THE PHARMACY PRACTITIONERS BOARD

3. (1) There is established a Board to be known as the Pharmacy Practitioners Board.

(2) The Board shall be a body corporate with perpetual succession and a common seal, and shall, in its corporate name, be capable of—

(a) suing and being sued;

(b) taking, purchasing or otherwise acquiring, holding, charging or disposing of both movable and immovable property;

(c) borrowing money;

(d) entering into contracts;

(e) doing or performing all such other acts necessary for the proper performance of its functions under this Act, which may be lawfully done or performed by a body corporate.

4. (1) The object and purpose for which the Board is established is to exercise general supervision and control over the training and practice of pharmacists and pharmaceutical technologists in the national and county health facilities and to advise the Government in relation to all aspects thereof.

(2) Without prejudice to the generality of sub-section (1), the Board shall—

(a) promote the practice of pharmacy that complies with universally accepted norms and values;

(b) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be registered as pharmacists under this Act;
(c) prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be enrolled as pharmaceutical technologists under this Act;

(c) maintain a register of all persons registered or enrolled under this Act;

(d) prescribe and conduct examinations for purposes of registration or enrolment under this Act;

(e) approve institutions other than those established or accredited under the Universities Act, 2012 for the training of pharmacy practitioners;

(f) license the private practice of pharmacists and pharmaceutical technologists under this Act;

(g) approve and license the premises for the practice by pharmacists and pharmaceutical technologists under this Act;

(g) regulate the professional conduct of pharmacists and pharmaceutical technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards and ethics;

(h) establish, approve and accredit continuing professional educational programs for pharmacists and pharmaceutical technologists; and

(i) establish and maintain a professional code of conduct for pharmacists and pharmaceutical technologists.

5. (1) The Board shall have all powers necessary for the proper performance of its functions under this Act.

(2) Without prejudice to the generality of sub-section (1), the Board shall have power to—

(a) control, supervise and administer its assets in such manner and for such purpose as best promotes the purpose for which it is established;

(b) determine the provisions to be made for its capital and recurrent expenditure and for its reserves;

(c) receive any grants, gifts, donations or endowments and make legitimate disbursements therefrom;
(d) levy such fees as it may determine for its services rendered;

(e) enter into association with other bodies or organizations within or outside Kenya as may be desirable or appropriate in furtherance of the purpose for which it is established;

(f) open a banking account or banking accounts for its funds;

(g) invest any of its funds not immediately required for its purposes in the manner provided in section 18; and

(h) undertake any other activity that may be necessary for the fulfilment of any of its functions under this Act.

6. (1) The Board shall consist of—

(a) a Chairperson appointed by the Cabinet Secretary from amongst the persons nominated under paragraph (c);

(b) the Director of Pharmaceutical Services;

(c) five registered pharmacists appointed in accordance with sub-section (3) of whom one shall be from each of the following sectors -
   (i) public sector;
   (ii) community pharmacy;
   (iii) hospital pharmacy;
   (iv) pharmaceutical industry; and
   (v) pharmacist training institutions;

(d) four enrolled pharmaceutical technologists appointed in accordance with sub-section (4) of whom one shall be from each of the following sectors -
   (i) public sector;
   (ii) community pharmacy;
   (iii) hospital pharmacy;
   (iv) pharmaceutical technologists training institutions;
(e) the following ex-officio members with no right to vote-

(i) the Attorney-General or a designated representative of senior level; and

(ii) the Registrar.

(2) No person shall be appointed as Chairperson of the Board unless such person-

(a) is a registered pharmacist of not less than ten years standing;

(b) is a holder of at least a master’s degree in a pharmacy related discipline; and

(c) satisfies the requirements of Article 10 and chapters six and thirteen of the Constitution.

(3) The members representing the sectors referred to in paragraph (c) of sub-section (1) shall be appointed by the Cabinet Secretary having regard to gender and ethnic balance from a list of two names of either gender for each sector submitted by the Pharmaceutical Society of Kenya after a competitive and transparent nomination process conducted by the Society.

(4) The members representing the sectors referred to in paragraph (d) of sub-section (1) shall be appointed by the Cabinet Secretary having regard to gender and ethnic balance from a list of two names of either gender for each sector submitted by the Kenya Pharmaceutical Association after a competitive and transparent nomination process conducted by the Association.

(5) No person shall be appointed as a member of the Board under sub-section (1)(c) and (d) unless such person-

(a) is a registered pharmacist or enrolled pharmaceutical technologist as the case may be and holds a valid practising licence;

(b) is in good standing with the nominating professional body; and

(c) satisfies the requirements of Article 10, 232 and chapters six of the Constitution.

7. (1) The conduct and regulation of the business and affairs of the Board shall be as provided in the First Schedule.
(2) Except as provided in the First Schedule, the Board may regulate its own procedure.

8. The Board may, by resolution generally or in any particular case, delegate to any committee of the Board the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act.

9. The Board shall pay its members such remuneration, fees or allowances as may be determined by the Cabinet Secretary upon the advice of the Salaries and Remuneration Commission.

10. (1) There shall be a Registrar of Pharmacy Practitioners who shall be competitively recruited and appointed by the Board and whose terms and conditions of service shall be determined by the Board upon the advice of the Salaries and Remuneration Commission.

(2) No person shall be appointed under this section unless such person-

(a) is a registered pharmacist with a valid practising licence;

(b) has at least ten years’ post qualification working experience five of which should be in senior management; and

(c) satisfies the requirements of Article 10,232 and chapters six of the Constitution.

(3) The Registrar shall-

(a) be the chief executive officer of the Board;

(b) implement the decisions of the Board under this Act;

(c) subject to the directions of the Board, be responsible for the day to day management of the affairs and staff of the Board; and

(d) perform such other functions as may be provided for in this Act or as the Board may from time to time determine.

(4) The Registrar shall serve for a term of four years and shall be eligible for re-appointment for one further term.
11. (1) There shall be a Secretary to the Board who shall be competitively appointed by the Board from amongst persons who meet the requirements of articles 10, 232 and chapter six of the Constitution and are certified public secretaries under the Certified Public Secretaries Act of Kenya, 1988.

(2) The Secretary shall be responsible for arranging the business of the Board's meetings, keeping records of the proceedings of the Board, and shall perform such other duties as the Board may direct.

(3) In the performance of his or her duties under this Act, the Secretary shall be responsible to the Registrar.

(4) The Board may in the absence of the Secretary appoint any person to temporarily perform the functions of the Secretary under sub-section (2).

(5) Any functions delegated under sub-section (2) may be so delegated subject to such conditions or restrictions as the Board may either generally or specifically determine.

12. The Board may appoint such officers and other staff or hire such experts as may be necessary for the proper discharge of its functions under this Act and upon such terms and conditions of service as the Board may determine upon the advice of the Salaries and Remuneration Commission.

13. (1) No matter or thing done by a member of the Board or agent of the Board shall, if the matter or thing is done bona fide while executing the functions, powers and duties of the Board under this Act, render the member or agent or any person acting on their directions personally liable to any action, claim or demand whatsoever.

(2) The provisions of sub-section (1) shall not relieve the Board of the liability to pay compensation or damages to any person for any injury done to him, his property or any of his interests caused by the exercise of any power conferred by this Act, or by the failure, whether wholly or partially, of any works.

PART III—FINANCIAL PROVISIONS

14. (1) The funds of the Board shall comprise of –

(a) such membership, practising or other fees, monies or assets as may accrue to or vest in the Board in the
course of the exercise of its powers or the performance of its functions under this Act or under any written law;
(b) grants, gifts or donations that the Board may receive as a result of public and private appeal from local and international donors or agencies for the purposes of carrying out its functions; and
(c) all monies from any other lawful source provided for or donated or lent to the Board.
(2) The Board shall open a bank account for its funds.

15. The financial year of the Board shall be the period of twelve months ending on the thirtieth of June in each year.

16. (1) At least three months before the commencement of each financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Board for that year.

(2) The annual estimates shall make provision for all estimated expenditure of the Board for the financial year and in particular, the estimates shall provide for –
(a) the payment of the allowances and other charges in respect of members of the Board;
(b) the payment of salaries, allowances, pensions, gratuities and other charges in respect of the staff of the Board;
(c) the proper maintenance of the buildings and grounds of the Board;
(d) the maintenance, repair and replacement of the equipment and other property of the Board; and
(e) the creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance or replacement of buildings, equipment and other property of the Board, or in respect of such other matter as the Board may deem appropriate;
(f) the establishment and accreditation of continuous educational programmes for pharmacists and pharmaceutical technologists.
(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate and shall then be submitted to the Cabinet Secretary for approval and after the Cabinet Secretary’s approval, the Board shall not increase the annual estimates without the consent of the Cabinet Secretary.

17. (1) The Board shall cause to be kept all proper books and records of accounts of the income, expenditure and assets of the Board.

(2) Within a period of four months from the end of each financial year, the Board shall submit to the Auditor-General or to an auditor appointed under this section, the accounts of the Board together with-

(a) a statement of the income and expenditure of the Board during that year; and

(b) a balance sheet of the Board on the last day of that financial year.

(3) The accounts of the Board shall be audited and reported upon in accordance with the Public Audit Act, 2003.

18. The Board may invest any of its funds in securities, in which for the time being trustees may by law invest trust funds, or in any other securities or banks which the Treasury may, from time to time, approve for that purpose.

19. (1) The Board shall, within three months after the end of each financial year, prepare and submit to the Cabinet Secretary a report of the operations of the Board for the immediate proceeding year.

(2) The Cabinet Secretary shall lay the annual report before the National Assembly within three months of the day the National Assembly next sits after receipt of the report.

PART IV—TRAINING, REGISTRATION AND ENROLMENT

20. (1) No person being in charge of a training institution in Kenya shall—

(a) admit persons for training with a view to qualifying for registration under this Act;
(b) conduct a course of training or administer the examination prescribed for the purposes of registration under this Act; or

(c) issue any document or statement implying that the holder thereof has undergone a course of training or passed the examinations prescribed by the Board for purposes of registration;

unless such institution is established or accredited under the Universities Act 2012, or is approved and accredited by the Board for that purpose in accordance with this Act.

(2) A person who contravenes any of the provisions of sub-section (1) commits an offence and shall, on conviction, be liable to a fine not more than five million shillings, or to imprisonment for a term not less than two years, or to both.

(3) The Board shall prescribe the procedure for approving training institutions other than those established or accredited under the Universities Act, 2012 for the purposes of this section.

(4) The Board shall publish in the Gazette a list of the training institutions approved under this Act.

21. (1) The Board shall satisfy itself that the courses of study leading to the award of a qualification in pharmacy practice, including the standard of proficiency required for admission and the standards of examinations leading to the award of the qualification, are sufficient to guarantee that the holder of the qualification has acquired the knowledge and skill necessary for registration under this Act.

(2) For the purposes of this section, the Board may—

(a) appoint persons to visit any university or other institution in Kenya offering a course in pharmacy practice and to report to it on the course of study, staffing and facilities available for training in pharmacy practice and other arrangements available for such training;

(b) appoint persons to attend examinations in any aspect of pharmacy practice at any university or institution and to report to it on the sufficiency of the examinations and on such matters relating thereto as the Board may require; or
(c) require the dean or head of the pharmacy practice department at any university or institution to provide written information to it concerning any of the matters referred to in paragraphs (a) or (b).

(3) The Board shall forward a copy of any report made under sub-section (2) to the university or institution concerned and may, if it is satisfied that the standard of any course, examination or facilities is insufficient, and after it has given the university or institution an opportunity to make observations on the report, in writing, require the university or institution to take such measures as the Board may specify to improve the standard of the course, examination or facilities.

(4) If the Board is satisfied that the university or institution referred to in sub-section (3) has failed to take measures which are in the opinion of the Board necessary to improve the standard of any course, examination or facilities, the Board may cancel or suspend any recognition of the qualification awarded by that university or institution.

(5) A qualification awarded prior to a cancellation or suspension under sub-section (4) shall be subject to directions by the Board.

(6) This section shall not apply to universities established or accredited under the Universities Act, 2012.

22. (1) A person wishing to be registered as a pharmacist or enrolled as a pharmaceutical technologist under this Act shall apply for registration to the Board.

(2) The application under sub-section (1) shall be in the prescribed manner and shall be accompanied by the prescribed fee.

23. (1) Subject to the provisions of this section, a person shall be eligible for registration under this Act as a pharmacist if the person-

(a) is a citizen of Kenya;

(b) is the holder of a bachelor of pharmacy degree or its equivalent as recognized by the Board;

(c) after obtaining the qualification under paragraph (a), has engaged in internship under the supervision of a registered pharmacist of not less
than five years standing for such period and in such manner as the Board may prescribe;

(d) satisfies the Board that, while engaged in internship as specified in paragraph (b), has acquired sufficient knowledge of, and experience in the practice of pharmacy; and

(e) is a member of a relevant professional body recognized by the Board.

(2) A person who is the holder of a degree qualification from an institution outside Kenya shall be eligible for registration under this Act as a pharmacist if the person—

(a) is the holder of a degree qualification obtained from an institution that is accredited and recognized by the regulating authority responsible for the registration of pharmacists in the country where the person studied;

(b) satisfies the Board that the qualifications obtained by the person meet such requirements for a course leading to a qualification in pharmacy practice as the Board shall from time to time prescribe pursuant to section 4(2)(a); and

(c) fulfills the requirements of sub-section (1) (b),(c) and (d).

(3) Where the Board is not satisfied that a person has fulfilled any of the requirements for registration specified under this section, the Board may require that person to—

(a) attend such interview as may be appropriate;

(b) undergo and pass such written or oral examination as it may specify; or

(c) undergo such further period of training or undertake such courses in such institutions as the Board may specify prior to registration.

(4) Despite sub-section (3), all qualifications issued by a university or institution accredited under the Universities Act, 2012 shall be recognized by the Board.

(5) The Board may, where it considers it expedient, delegate the assessment of suitability for registration under
this section to a committee of the Board which shall, after making the assessment, make recommendations to the Board.

(6) The Board shall cause the Registrar to enter the prescribed particulars of every qualified pharmacist approved for registration under this section into the Register.

24. (1) Subject to the provisions of this section, a person shall be eligible for enrolment under this Act as a pharmaceutical technologist if the person-

   (a) is the holder of a diploma in a pharmacy course or its equivalent as recognized by the Board;

   (b) after obtaining the qualification under paragraph (a), has engaged in internship for such period and in such manner as the Board may prescribe;

   (c) satisfies the Board that, while engaged in internship as specified in paragraph (b), has acquired sufficient knowledge of, and experience in the practice of pharmacy; and

   (d) is a member of a relevant professional body recognized by the Board.

(2) The provisions of sub-sections (2), (3), (4) and (5) of section 23 shall apply with the necessary modifications to enrolment of pharmaceutical technologists.

(3) The Board shall cause the Registrar to enter the prescribed particulars of every qualified pharmaceutical technologist approved for enrolment under this section into the Roll.

25. (1) The Registrar shall maintain-

   (a) a register for persons registered as pharmacists under this Act to be known as the Register of Pharmacists; and

   (b) a roll of persons enrolled as pharmaceutical technologist under this Act to be known as the Roll of Pharmaceutical Technologists.

(2) The Register and Roll maintained under subsection (1) may be in such form as may be prescribed and different registers and rolls may be kept for different
categories of pharmacists or pharmaceutical technologists as the case may be.

(3) The Registrar shall—

(a) not later than the 31st of March in every year, publish in the Gazette, the names, addresses, qualifications and practising licence status of all registered pharmacists and enrolled pharmaceutical technologists; and

(b) subject to the directions of the Board, cause to be published any amendments or deletion from the Register or Roll as the case may be.

(4) Every pharmacist or pharmaceutical technologist shall notify the Registrar of any change in the registered address.

(5) Any person may inspect the Register or Roll and any documents relating to any entry therein, and may obtain from the Registrar, a copy of, or an extract from the registers on payment of the prescribed fee.

(6) If the Registrar is satisfied—

(a) on proof submitted by the registered or enrolled person concerned, that a registration or enrolment certificate has been destroyed; or

(b) by virtue of an affidavit submitted by the registered or enrolled person concerned, that a registration or enrolment certificate has been lost;

the Registrar may issue a duplicate registration or enrolment certificate to that person upon payment of the prescribed fee.

26. (1) A copy of the last published issue of a Register or Roll or any supplementary list purporting to be printed and published under the authority of the Board shall be prima facie proof, in all legal proceedings, of the facts therein recorded, and the absence of the name of any person from such copy shall be proof, until the contrary is proved, that such person is not registered or enrolled according to the provisions of this Act.

(2) Where a person’s name—

(a) does not appear in the copy under sub-section (1) or the name has been added to the Register or Roll
after the date of the last published issue, a certified copy under the hand of the Registrar of the entry of the name of such person in the Register or Roll, shall be proof that such person is registered or enrolled under the provisions of this Act;

(b) has been removed from the Register or Roll since the date of the last published issue and has not been restored, a certificate under the hand of the Registrar that the name of such person has been removed from the Register or Roll shall be proof that such person is not registered or enrolled according to the provisions of this Act.

27. (1) The Registrar shall remove from the Register or Roll-

(a) the names of all deceased persons;

(b) the names of all persons removed from the Register or Roll under this Act; and

(c) any entries fraudulently or erroneously made.

(2) The Registrar shall, as soon as reasonably practicable, cause the name and address of every person whose name is removed from the Register or Roll under this section, to be published in the Gazette.

PART V—LICENSING

28. (1) Subject to this Act or any other written law, no person shall engage in practice as a pharmacist or pharmaceutical technologist unless that person holds a valid practising licence issued under this Act.

(2) For the purposes of this Act, a person shall be deemed to engage in practice if the person —

(a) engages in, conducts or carries on the dispensing, compounding, or community pharmacying of any prescription medicines within Kenya either-

(i) on the persons own account and is entitled to receive the entire amount of all fees and charges earned for the persons own financial benefit; or

(ii) in partnership with others where the person is entitled to receive a share of the profits earned...
by such partnership and is liable to bear a share of any losses incurred by such partnership; or

(b) advertises or represents himself or herself by a title, sign, display, declaration, or other item to be a pharmacist or pharmaceutical technologist.

(3) A person shall not be deemed to engage in private practice under this section where the person is—

(a) employed by the Government or any other public body as the Board may prescribe; or

(b) employed by any person or partnership in the profession where all fees and charges earned are to the benefit of that employer, notwithstanding that the person is engaged in professional capacity as a pharmacist or pharmaceutical technologist.

(4) An employer referred to in subsection (3) shall, in compensation to registered or enrolled persons not engaging in private practice, undertake payment of non-practicing allowance to persons employed under that subsection.

(5) A person who contravenes the provisions of this section commits an offence and shall, on conviction, be liable to a fine not more than one million shillings, or to imprisonment for a term not less than one year, or to both.

29. (1) An application for a practising licence shall be made to the Board in such manner and form as may be prescribed.

(2) Every application under this section shall be accompanied by the prescribed fee.

(3) The Board shall, within sixty days of receipt by the Board of the application, issue to the applicant a practising licence in the prescribed form upon being satisfied that the applicant—

(a) is duly registered or enrolled under this Act as the case may be;

(b) is not for the time being suspended from practice; and

(c) has complied with such other conditions as the
Board may prescribe including fulfillment of the prescribed requirements for continuous professional education for that year.

30. A non-citizen pharmacist or pharmaceutical technologist who wishes to obtain a practising licence in Kenya shall-

(a) submit a written application in the form prescribed by the Board;

(b) possess at the time of initial licensing as a pharmacist in a foreign country all qualifications necessary to have been eligible for licensing at that time in Kenya;

(c) present to the Board proof of initial licensing in a foreign country and evidence that such practising licence is in good standing in that country in that it has not been suspended, revoked, or otherwise restricted for any reason except non-renewal or for the failure to obtain the required continuing education credits in that country;

(d) present proof of membership of the foreign country’s respective professional association;

(e) pay the fees prescribed by the Board; and

(f) fulfil such other conditions as may be prescribed by the Board.

31. (1) No person shall operate a premise for the manufacture, production, sale, distribution, possession, or dispensing of medicines requiring a prescription unless such premise is licensed by the Board.

(2) The following conditions shall apply to a premise licence issued under this Act-

(a) where operations are conducted at more than one location, each location must be licensed by the Board;

(b) each pharmacy shall have a pharmacist or pharmaceutical technologist-in-charge as appropriate;

(c) the licence must be displayed in a conspicuous place in the premise for which it was issued in such a manner that will enable a customer to see
its contents with clarity;
(d) the licence shall be issued subject to a satisfactory inspection of the premise by the Board;
(e) a community pharmacy licence shall only be issued in the name of a pharmacist or pharmaceutical technologist;
(f) no person shall be licensed for more than one category of premise licence;
(g) no premise shall be licenced for more than one category of premise licence; and
(h) a medical facility may be controlled by a pharmacist or pharmaceutical technologist except for medical facilities with inpatient services of which the pharmacy must be under the control of a pharmacist or a pharmaceutical technologist of such experience as may be prescribed.

32. (1) An application for a premise licence shall be made to the Board in such manner and form as may be prescribed.

(2) Every application under this section shall-
(a) be accompanied by the prescribed fee;
(b) be submitted at least thirty days before the proposed date of opening of the premises;
(c) be accompanied by an inspection report of the premise conducted by the Board; and
(d) contain such other matters as required by this Act as may be prescribed by the Board.

(2) The Board shall, within sixty days of receipt by the Board of the application, issue to the applicant a premise licence in the prescribed form upon being satisfied that the applicant has fulfilled the requirements of this Act.

(3) Nothing in this Act shall be construed as excluding public health facilities from the requirements of this Act that require-
(a) distributing or dispensing prescription medicines to be licensed by the Board; and
(b) each pharmacy to have a pharmacist or
pharmaceutical technologist-in-charge.

33. (1) The Board may issue to a pharmacist or pharmaceutical technologist as may be appropriate-
   (a) any of the practising licences of the type specified in the Part A of the Second Schedule; and
   (b) any of the premise licences of the type specified in Part B of the Second Schedule.

(2) The Board may, with the approval of the Cabinet Secretary, amend the Second Schedule.

34. (1) Every licence shall bear the date on which it is issued and shall have effect from that day.

(2) A licence issued under this Act shall-
   (a) not be transferable and any change of ownership in the case of a sole proprietorship or a gain or loss of a partner in the case of a partnership or a change of name or location invalidates the licence;
   (b) be valid for the year from the date it is issued; and
   (c) expire on the 31st of December of the year it is issued.

(3) A holder of a licence that expires on the 31st of December of the year it is issued shall not be held to be in breach of this section for continuing to practice without a renewed license for no later than the last day of February of the succeeding year.

(4) The Registrar shall enter in the Register or Roll the date of issue of every licence issued under this Act.

(5) Where the name of the pharmacist or pharmaceutical technologist is removed or struck off the Register or Roll, any licence issued shall expire forthwith.

(6) A person whose name is removed from the Register or Roll or in the case of a deceased person, his legal representative shall, within thirty days of the publication of such removal, surrender the certificate of registration or enrolment of that person to the Board.

35. (1) The Board may deny or refuse to issue or renew a licence under this Act if it determines after due process that-
   (a) the applicant has failed to comply with the
requirements of this Act or its rules; or

(b) the granting or renewing of such licence would not be in the public interest.

(2) The Board shall, where it declines an application under sub-section (1), notify the applicant in writing of its decision and the reasons for its decision.

(3) An applicant who is aggrieved by the decision of the Board under this section shall have the right of appeal to the Cabinet Secretary in such manner as may be prescribed within thirty days of being notified of the decision under this section.

(4) An applicant who is aggrieved by the decision of the Cabinet Secretary under sub-section (3) may appeal to the High Court of Kenya within sixty days of being notified of that decision.

36. (1) A pharmacist or pharmaceutical technologist issued with a licence under this Act may apply for renewal of the licence in the prescribed form at least thirty days before the date of expiry thereof.

(2) A pharmacist or pharmaceutical technologist who fails to renew a licence within the prescribed period shall, when applying for a renewal, be required to pay such late application fee, as shall be prescribed.

(3) The Board shall have the power to renew any practising certificate and may, refuse to renew, cancel, withdraw or suspend a licence for a period not exceeding twelve months, if satisfied that the pharmacist or pharmaceutical technologist has committed a professional misconduct or is in breach of any provisions of this Act or its rules.

PART VI—ETHICS AND DISCIPLINARY COMMITTEE

37. (1) There Board shall establish An Ethics and Disciplinary Committee which shall inquire into any matter referred to it by the Board under sub-section (2) and make its recommendations thereon to the Board.

(2) The Board may refer a matter to the Ethics and Disciplinary Committee if it has reason to believe that a person registered or enrolled under this Act has been,
The Pharmacy Practitioners Bill, 2014

either before or after registration or enrolment—

(a) convicted of an offence punishable by imprisonment for more than six months, the commission of which in the opinion of the Board, has dishonored him in the public estimation; or

(b) commits an act of negligence, impropriety or professional misconduct in respect of the profession.

38. (1) Upon an inquiry under section 37, the pharmacist or pharmaceutical technologist subject to the inquiry shall be afforded an opportunity to be heard either in person or through an advocate.

(2) For the purpose of proceedings at any inquiry by the Committee, the Committee may administer oaths or affirmations and may, subject to any rules made under this Act, enforce the attendance of persons as witnesses and the production of any books or other documents relevant to the inquiry.

(3) The Committee shall, subject to any rules made under this Act, have power to regulate its own procedure in any disciplinary proceedings.

39. (1) Where on the recommendations of the Committee the Board is satisfied that a pharmacist or pharmaceutical technologist is in breach of any of the terms or conditions of practice prescribed by the Board, the Board may—

(a) issue the pharmacist or pharmaceutical technologist with a letter of admonishment;

(b) impose a fine which the Board deems appropriate in the circumstances;

(c) suspend the registration or enrolment of the pharmacist or pharmaceutical technologist for a specified period not exceeding five years; or

(d) remove the name of the pharmacist or pharmaceutical technologist from the Register or Roll as may be appropriate.

(2) The Board may order a pharmacist or pharmaceutical technologist to reimburse costs and expenses incurred in connection with a disciplinary hearing and such costs shall be a civil debt recoverable summarily
by the Board.

(3) Where, after the hearing in disciplinary proceedings under this Act the Committee recommends to the Board that a pharmacist or pharmaceutical technologist is unfit to practise as a result of ill-health, the Board may, if satisfied with the Committee’s recommendations, withdraw the certificate of registration or practising certificate of the pharmacist or pharmaceutical technologist until such time as the Board is satisfied that the pharmacist or pharmaceutical technologist is fully recovered to resume his duties.

(4) A pharmacist or pharmaceutical technologist who is aggrieved by the decision of the Board in the exercise of its powers under this section may, within sixty days from the date of the decision of the Board, appeal to the High Court.

40. (1) A pharmacist or pharmaceutical technologist who has been suspended from practising may appeal to the Board for the lifting of the suspension at any time before the expiry thereof.

(2) Where the Board is satisfied that the suspension of a pharmacist or pharmaceutical technologist should be lifted, the Board shall, upon the receipt of the prescribed fee, lift the suspension and restore to the pharmacist or pharmaceutical technologist the registration or enrolment and practising certificates and licences issued under the Act.

41. (1) A pharmacist or pharmaceutical technologist whose name has been removed from the Register or Roll may, after the expiry of such period as may be prescribed, appeal to the Board for restoration of his name in the Register or Roll.

(2) The Board may, after considering the appeal made under sub-section (1), cause the name of the applicant to be restored in the appropriate Register or Roll, upon payment of the prescribed fee.

PART VII- ENFORCEMENT

42. (1) The Board shall appoint any pharmacist or pharmaceutical technologist to be an authorised officer for
purposes of this Act.

(2) The Board shall issue a certificate of appointment to every person appointed under this section.

(3) Notwithstanding the provisions of this section, any other person upon whom any written law vests functions of the maintenance of law and order shall be deemed to be authorised officers for the purposes of this Act.

43. (1) For the purposes of ensuring compliance with this Act, an authorised officer may, at any reasonable time, enter any premise in which the officer believes on reasonable grounds that any person or persons is in any way contravening the provisions of this Act.

(2) An authorised officer entering any premises under this section shall, if so required, produce for inspection by the person who is or appears to be in charge of the premises the certificate issued to him under section 42(2) unless he falls under the officers described in section 42(3).

(3) The right to privacy enshrined in Article 31 of the Constitution and the right to property enshrined in Article 40 of the Constitution are limited as specified in this section for the purpose of ensuring the health and safety of the public.

44. In carrying out an inspection in any place pursuant to section 43, an authorised officer may—

(a) examine any medicine or any related thing;

(b) require any person in such place to produce for inspection, in the manner and form requested by the officer, the medicine or thing;

(c) open or require any person in the place to open any container or package found in the place that the officer believes on reasonable grounds contains the medicine or thing;

(d) conduct any test or analysis or take any measurements; or

(e) require any person found in the place to produce for inspection or copying, any written or electronic information that is relevant to the administration or enforcement of this Act.

45. In carrying out an inspection in a place,
authorised officer may-

(a) use or cause to be used any computer system in the place to examine data contained in or available to the computer system that is relevant to the administration or enforcement of this Act;

(b) reproduce the data in the form of a print-out or other intelligible output and take it for examination or copying;

(c) use or cause to be used any copying equipment in the place to make copies of any data, record or document;
or

(d) scrutinize any other record system in use in that place.

46. (1) An authorised officer may not enter a premise except with the consent of the occupant or under the authority of a warrant issued under sub-section (2).

(2) Upon an ex-parte application, a magistrate or judge of the High Court, may issue a warrant authorising the authorised officer named in the warrant to enter and inspect a premise, subject to any conditions specified in the warrant, if the magistrate or judge is satisfied by information on oath that –

(a) the premise is a place referred to in section 43;

(b) entry to the premise is necessary for the administration or enforcement of this Act; and

(c) the occupant does not consent to the entry, or that entry has been refused or there are reasonable grounds for believing that it will be refused.

(3) The time of such entry shall be between six o’clock in the forenoon and six o’clock in the afternoon of any day of the week.

(4) An authorised officer executing the warrant issued under this section shall not use force unless such officer is accompanied by a police officer and the use of force is specifically authorised in the warrant.

47. (1) An authorised officer who carried out an inspection under this Act shall-

(a) make a preliminary report immediately upon
completion of the inspection in a prescribed format, a copy of which shall be retained in the premises; and

(b) file a full written report with the Board within fourteen days of the last day of inspection.

(2) The report referred to in sub-section (1) shall consist of such matters and shall be dealt with by the Board in such manner as may be prescribed.

48. (1) The owner of a premise inspected by an authorised officer under this Act or the person in charge of the premise and every person found in the premise shall —

(a) provide all reasonable assistance to enable the authorised officer to carry out his duties under this Act; and

(b) furnish the authorised officer with such information as the officer reasonably requires for the purpose for which entry into the place has been made.

(2) The inspecting agent in sub-section (1) shall issue the respective inspection completion certificate once satisfied with the inspection.

49. (1) No person shall obstruct or hinder, or knowingly make a false or misleading statement to an authorised officer who is carrying out duties under this Act.

(2) A person who contravenes sub-section (1) commits an offence.

50. (1) During an inspection under this Act, an authorised officer may seize any medicine or related thing by means of which or in relation to which the officer believes, on reasonable grounds, that this Act has been contravened and a full inventory thereof shall be made at the time of such seizure by the officer.

(2) The authorised officer may direct that any medicine or thing seized be kept or stored in the premise where it was seized or that it be removed to another place.

(3) Unless authorised by an officer, no person shall remove, alter or interfere in any manner with any medicine or other thing seized.

(4) Any person from whom a medicine or thing was
seized may, within thirty days after the date of seizure, apply to court for an order of restoration, and shall send notice containing the prescribed information to the Board within the prescribed time and in the prescribed manner.

51. (1) The court may order that the medicine or thing be restored immediately to the applicant if, on hearing the application, the court is satisfied that-

(a) the applicant is entitled to possession of the medicine or thing seized; and

(b) the medicine, or thing seized is not and will not be required as evidence in any proceedings in respect of an offence under this Act.

(2) Where upon hearing an application made under sub-section (1) the court is satisfied that the applicant is entitled to possession of the medicine, or thing seized but is not satisfied with respect to the matters mentioned in paragraph (b) of sub-section (1), the court may order that the medicine, or thing seized be restored to the applicant on the expiration of thirty days from the date of seizure if no proceedings in respect of an offence under this Act have been commenced before that time.

52. (1) Any act or omission which is an offence under this Act or any rules made hereunder shall, if done by a body corporate, be deemed to be an offence committed by every director of the body corporate unless proved that the offence was committed without consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions and the circumstances of the case.

(2) If an offence under this Act or any rules made hereunder is committed by a partner in a firm, every person who, at the time of the commission of the offence, was a partner in that firm, or was purporting to act in that office shall be deemed to have committed the offence unless there is proof that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions and the circumstances of the case.

(3) In any prosecution for an offence under this Act,
it shall be sufficient proof of the offence to establish that the offence was committed by an employee or agent of the accused.

(4) Any act done or omitted to be done by an employee in contravention of any of the provisions of this Act shall be deemed also to be the act or omission of the employer, and any proceedings for an offence arising out of such act or omission may be taken against both the employer and the employee.

53. (1) In any prosecution for an offence under this Act, a copy of any written or electronic information obtained during an inspection under this Act and certified to be a true copy thereof shall be admissible in evidence and shall, in the absence of evidence to the contrary, be proof of its contents.

(2) Subject to this Part, a certificate or report purporting to be signed by an officer stating that the officer analyzed anything to which this Act applies and stating the results of the analysis, shall be admissible in evidence in any prosecution for an offence under this Act without proof of the signature or official character of the person appearing to have signed the certificate or report.

(3) The certificate or report may not be received in evidence unless the party intending to produce it has, before the trial, given the party against whom it is intended to be produced notice of not less than seven days of that intention together with a copy of the certificate or report.

(4) The party against whom the certificate or report provided for under sub-section (3) is produced may, with leave of the court, require the attendance of the officer for purposes of cross examination.

(5) In a prosecution for a contravention of this Act-

(a) information on a package indicating that it contains a medicine is, in the absence of evidence to the contrary, proof that the package contains that medicine; and

(b) a name or address on a package purporting to be the name or address of the person by whom the medicine was manufactured is, in the absence of evidence to the contrary, proof that it was
manufactured by that person.

54. (1) A person who—

(a) destroys or defaces a certificate of registration or enrolment or any licence issued under this Act;

(b) without reasonable excuse, is in possession of a certificate of registration or enrolment or licence not issued to him or her; or

(c) fails to surrender a certificate of registration or enrolment or licence in accordance with section 34(5),

commits an offence and shall, on conviction, be liable to a fine not less than one hundred thousand shillings, or to imprisonment for a term not exceeding three months, or to both.

55. (1) No person while in charge of an institution or any other organization in Kenya, shall allow a person who is not registered or enrolled under this Act to practise as a pharmacist or pharmaceutical technologist in that institution.

(2) A person who contravenes the provisions of sub-section (1) commits an offence and shall, on conviction, be liable to a fine not more than five hundred thousand shillings, or to imprisonment for a term not less than twelve months, or to both.

(3) Any person who, in an application for registration, enrolment or licence, willfully makes a false or misleading statement or submits a false certificate, commits an offence and shall, on conviction, be liable to a fine not more than two hundred thousand shillings, or to imprisonment for a term not less than one year, or to both.

(4) The sub-section (1) shall not be construed as restricting or limiting the practice of any profession authorised by any written law.

56. Any person convicted of an offence under this Act for which no other penalty is provided shall be liable to a fine not exceeding five hundred thousand shillings, or to imprisonment for a term not exceeding three years, or to both.

PART VIII —PROVISIONS ON DELEGATED
57. (1) The Cabinet Secretary shall, on the recommendation of the Board, make rules generally for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of the foregoing, such rules may provide for—

(a) prescribing anything required to be prescribed under this Act;

(b) the form and method of keeping the registers and other records under this Act;

(c) the conditions under which training institutions other than those established or accredited under the Universities Act, 2012 may be approved;

(d) the course content, examination and internship for persons wishing to be registered or enrolled as pharmacist or pharmaceutical technologists under this Act;

(e) the code of conduct and conditions of professional practice of registered pharmacists and enrolled pharmaceutical technologists including the standard international best practices on-

(i) good manufacturing practice;

(ii) good distribution practice;

(iii) good laboratory practice;

(iv) good warehousing or storage practice; and

(v) good dispensing practice;

(f) the scale of fees to be levied by registered or enrolled persons under this Act;

(g) the forms and fees for the purposes of this Act;

(h) the form and method of conducting any disciplinary proceeding, inspection, assessment, evaluation, examination or regulation required under this Act;

(i) the minimum requirements for establishing a place to be licensed as a premise to carry out pharmacy services; and

(j) any other matter that may related to the practice of
pharmacy in Kenya.

58. The principles and standards applicable to the delegated power referred to under section 57 are those found in-

(a) the Statutory Instruments Act, 2013;
(b) the Interpretation and General Provisions Act,
(c) the general rules of international law as specified under Article 2(5) of the Constitution; and
(d) any treaty and convention ratified by Kenya under Article 2(6) of the Constitution.

PART IX — FINAL PROVISIONS

59. The provisions of the Pharmacy and Poisons Act specified in the first column of the Third Schedule are amended in the manner respectively set out in the second column of that Schedule.

60. (1) In this section—

“effective date” means the day upon which this Act comes into operation; and

“former Board” means the Pharmacy and Poisons Board established under the Pharmacy and Poisons Act.

(2) On the effective date, all the funds, assets and other property, both movable and immovable, which immediately before such date were vested in the former Board, shall by virtue of this sub-section, vest in the Board.

(3) On the effective date, all rights, powers and liabilities, whether arising under any written law or otherwise which immediately before such day were vested in, imposed on or enforceable against the former Board shall, by virtue of this sub-section, be deemed to be vested in, imposed on or enforceable against the Board.

(3) On the effective date, any person who, immediately before the commencement of this Act—

(a) was a member of the former Board shall be deemed to be a member of the Board for the unexpired term;

(b) was serving as the Registrar to the former Board shall be deemed to be the Registrar appointed
under this Act for the unexpired term unless the holder exercises his option to be redeployed in the service of the Government;

(c) was a member of staff of the former Board shall be deemed to be a member of staff of the Board for the unexpired period of his or her service;

(d) was registered as a pharmacist or enrolled as a pharmaceutical technologist by the former Board shall be deemed to be registered or enrolled by the Board under this Act; and

(e) was the holder of a licence issued by the former Board shall be deemed to be the holder of a corresponding licence issued by the Board under this Act for its unexpired term.

(5) Any reference in any written law or in any document or instrument to the former Board shall on and after the appointed day, be construed to be a reference to the Board.

(6) The annual estimates of the former Board for the financial year in which the appointed day occurs shall be deemed to be annual estimates of the Board for the remainder of that financial year but such estimates may be varied by the Board in such manner as the Cabinet Secretary may approve.

(7) The administrative directions made by the former Board or by the Cabinet Secretary which are in force immediately before the appointed day shall, on and after such day, have force as if they were directions made by the Board or the Cabinet Secretary under this Act.

FIRST SCHEDULE (s.7)

PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

1. The Chairperson or a member of the Board other than ex-officio members shall, subject to the provisions of this Schedule, hold office for a period of three years, on such terms and conditions as may be specified in the instrument of appointment, but shall be eligible for re-appointment for one further term.

2. (1) A member other than an ex-officio member
may-

(a) at any time resign from office by notice in writing to the Cabinet Secretary;

(b) be removed from office by the Cabinet Secretary on recommendation of the Board if the member –

(i) has been absent from three consecutive meetings of the Board without its permission;

(ii) is found to have contravened the provisions of chapter six or thirteen of the Constitution;

(iii) is convicted of a criminal offence that amounts to a felony in Kenya;

(iv) is incapacitated by prolonged physical or mental illness for a period exceeding six months; or

(v) is otherwise unable or unfit to discharge his functions.

3. (1) The Board shall meet not less than four times in every financial year and not more than four months shall elapse between the date of one meeting and the date of the next meeting.

(2) Notwithstanding sub-paragraph (1), the Chairperson may, and upon requisition in writing by at least five members shall, convene a special meeting of the Board at any time for the transaction of the business of the Board.

(3) Unless three quarters of the total members of the Board otherwise agree, at least fourteen days' written notice of every meeting of the Board shall be given to every member of the Board.

(4) The quorum for the conduct of the business of the Board shall be half of the total members (including the Chairperson or the person presiding) with at least two pharmacists and two pharmaceutical technologist's members present.

(5) The members of the Board shall, during their first meeting after appointment elect one of their number to be the Vice chairperson who shall preside whenever the Chairperson is absent, with all the powers of the Chairperson with respect to that meeting and the business
transacted thereat.

(6) Unless a unanimous decision is reached, a decision on any matter before the Board shall be by a majority of the votes of the members present and voting, and in case of an equality of votes, the Chairperson or the person presiding shall have a casting vote.

(7) Subject to sub-paragraph (6), no proceedings of the Board shall be invalid by reason only of a vacancy among the members thereof.

(8) Subject to the provisions of this Schedule, the Board may determine its own procedure and the procedure for any committee of the Board and for the attendance of other persons at its meetings and may make standing orders in respect thereof.

4. (1) The Board may establish such committees as it may deem appropriate to perform such functions and responsibilities as it may determine.

(2) The Board shall appoint the chairperson of a committee established under sub-paragraph (1) from amongst its members.

(3) The Board may where it deems appropriate, co-opt any person to attend the deliberations of any of its committees.

(4) All decisions by the committees appointed under sub-paragraph (1) shall be ratified by the Board.

(5) Without prejudice to the generality of sub-paragraph (1), the Board shall ensure the establishment of separate committees responsible for-

(a) management issues;
(b) practice issues; and
(c) training and assessment issues.

5. (1) A member who has an interest in any contract, or other matter present at a meeting shall at the meeting and as soon as reasonably practicable after the commencement, disclose the fact thereof and shall not take part in the consideration or discussion of, or vote on, any questions with respect to the contract or other matter, or be counted in the quorum of the meeting during consideration of the

Disclosure of interest.
matters.

(2) A disclosure of interest made under sub-paragraph (1) shall be recorded in the minutes of the meeting at which it is made.

(3) A member of the Board who contravenes sub-paragraph (1) commits an offence and is liable to a fine not exceeding two hundred thousand shillings.

6. Any contract or instrument which, if entered into or executed by a person not being a body corporate would not require to be under seal, may be entered into or executed on behalf of the Board by any person generally or specially authorised by the Board for that purpose.

7. (1) The affixing of the common seal of the Board shall be authenticated by the signature of the Chairperson and the Registrar and any document not required by law to be made under seal and all decisions of the Board may be authenticated by the signatures of the Chairperson and the Registrar.

    (2) The Board shall, in the absence of either the Chairperson or the Registrar in any particular matter, nominate one member to authenticate the seal of the Board on behalf of either the Chairperson or the Registrar.

SECOND SCHEDULE (s.33)
TYPES OF LICENCES
PART A- PRACTISING LICENCES

1. Pharmacist Practising Licence
This licence shall authorise the scope of activities to be involved in by a registered pharmacist within the practice of pharmacy in a hospital or community setup to include, but are not limited to-

(a) the interpretation and evaluation of prescriptions;

(b) participation in medicine selection;

(c) provision of patient counselling;

(d) pharmacist initiated therapy;
(e) performing medicine management reviews;

(f) provision of pharmaceutical care;

(g) vaccination in the prescribed form;

(h) receiving telephone, e-mail or verbal prescriptions from licensed healthcare practitioners;

(i) supervision of the activities of a pharmacist intern or pharmaceutical technologist or pharmaceutical technologist intern to ensure all activities are performed completely, safely, and without risk of harm to patients; and

(j) such other activities as may be prescribed by the Board.

2. **Pharmaceutical Technologist Practising Licence**

This licence shall authorise the scope of activities to be involved in by an enrolled pharmaceutical technologist within the practice of pharmacy in a community or hospital setup to be limited to-

(a) the interpretation and evaluation of prescriptions;

(b) participation in medicine selection;

(c) provision of pharmaceutical care;

(d) special compounding of external preparations;

(e) pharmaceutical technologist initiated therapy;

(f) provision of patient counselling;

(g) receiving telephone, e-mail or verbal prescriptions from licensed practitioners; and

(h) supervision of the activities of a pharmaceutical technologist intern to ensure all activities are performed completely, safely, and without risk of harm to patients;
(i) such other activities as may be prescribed by the Board

3.  **Specialist Pharmacy Practising Licence.**

(a) The Board shall recognize the various levels of specialist pharmacy practice.
(b) Provision of veterinary services shall fall under this licence.

4.  **Professional Review Pharmacy Practising Licence**

The following services pertaining to the scope of practice of a pharmacist may be provided for by a Professional Review pharmacy—

(a) the initiation and conducting of pharmaceutical research and development;

(b) the application for the registration of a medicine;

(c) the supervision of a pharmacy;

(d) the promotion of public health and the advancement of pharmacy knowledge, skills and competencies in specific areas of practice; and

(e) any other health service as may be approved by the Board from time to time.

**PART B- PREMISE LICENCES**

5.  **Pharmaceutical Manufacturing Licence**

1.(1) Except as provided for in the Pharmacy and Poisons Act, only the following services pertaining to the scope of practice of pharmacy, may be provided in a manufacturing pharmacy—

(a) the manufacturing of active pharmaceutical ingredient, non active pharmaceutical ingredient, any medicine or scheduled substance;

(b) the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;

(c) importation and exportation of active and non-active pharmaceutical ingredients;
(d) the furnishing of information and advice to any person with regard to medicine manufactured by him, her or it;
(e) the application for the registration of a medicine.

(f) the formulation of medicine for the purposes of registration as a medicine;

(g) the distribution of medicine or scheduled substances;

(h) the repackaging of medicine;

(i) the initiation and conducting of pharmaceutical research and development and formulations;

(j) medical and pharmaceutical marketing, subject to regulations established by the Board; and

(k) any other health service as may be approved by the Board from time to time.

1.(2). A manufacturing pharmaceutical plant shall only sell medicines manufactured by it or on its behalf to a licensed distributor.

6. Distribution Practising Licence

2. (1) The following services pertaining to the scope of practice of pharmacy, may be provided in a distribution or import pharmacy practice—

(a) the distribution to a wholesale dealer of any medicine or authorised scheduled substance through the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;

(b) the furnishing of information and advice to any person with regard to medicine distributed by him, her or it;

(c) importation or exportation of the medicines or medicinal substances;

(d) importation or exportation of active pharmaceutical ingredients and non-active pharmaceutical ingredients from bona fide manufacturers and warehousing in accordance with good storage practices prescribed by the board;
(e) the application for the registration of a medicine as domicile agents of foreign manufacturers;

(f) medical and pharmaceutical marketing, subject to regulations established by the Board; and

(g) any other health service as may be approved by Board from time to time.

2. (2) This licence does not allow a distributor to sell directly to the community outlet or end-user.

7. Wholesale Pharmacy Practising Licence.

3.(1) The following services pertaining to the scope of practice of pharmacy, may be provided in a wholesale pharmacy—

(a) the wholesale distribution of any medicine or scheduled substance through the purchasing, acquiring, keeping, warehousing and storage, possessing, using, supplying or selling of any medicine or scheduled substance;

(b) the furnishing of information and advice to any person with regard to medicine distributed by him, her or it;

(c) breaking bulk to quantities of the community outlets but limited to the multiples of consumer packs as a minimum quantity; and

(d) any other health service as may be approved by Board from time to time;

3. (2) A licensed pharmaceutical technologist may engage in this practice for the scheduled medicines.

3.(3) This licence shall not prohibit the repackaging of medicine in wholesale pharmacies owned or controlled by an organ of the State.

3.(4) This licence shall not allow a wholesale pharmacy to sell directly to the end-user.

8. Community or Institutional Pharmacy Practising Licence.

4. (1) The following services pertaining to the scope of practice of pharmacy, may be provided in a community or institutional pharmacy—
(a) the provision of pharmaceutical care by taking responsibility for the patient’s medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions-

(i) evaluation of a patient’s medicine related needs by determining the indication, safety and effectiveness of the therapy;

(ii) dispensing of any medicine or scheduled substance on the prescription of an authorised prescriber;

(iii) furnishing of information and advice to any person with regard to medicine;

(iv) determining patient compliance with the therapy and follow up to ensure that the patient’s needs are being met;

(v) provision of pharmacist initiated therapy;

(vi) the compounding, manipulation or preparation of any medicine or scheduled substance;

(vii) the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance; and

(viii) the re-packaging of medicine;

(b) the promotion of public health in accordance with guidelines and standards as determined by a competent authority which includes but shall not be limited to-

(i) the provision of information and education regarding the promotion of human health;

(ii) the provision of immunisation, mother and childcare, blood pressure monitoring; health education; blood-glucose monitoring; and
(iii) screening tests for pregnancy; family planning; cholesterol screening tests; diagnostic screening tests; urine analysis; and visiometric and audiometric screening tests;

(c) the provision of human health care services which includes-

(i) the compounding and dispensing of prescriptions written by licensed medical practitioners;

(ii) the provision of information and education regarding the promotion of rational use of human medicines;

(d) the provision of primary care medicine therapy;

(e) the provision of animal health care services which includes-

(i) the compounding and dispensing of prescriptions written by licensed veterinary surgeons;

(ii) the provision of information and education regarding the promotion of animal health;

(f) the provision of primary animal care medicine therapy; and

(g) any other human or animal health service as may be approved by Board from time to time.

4. (2) Pharmaceutical technologists are authorised to perform the functions under-

(a) sub-paragraph (a)(ii), (iii), (iv), (vi), (viii);

(b) sub-paragraph (b) (i);

(c) sub-paragraph (c); and

(d) such other subparagraphs as the Board may prescribe.
THIRD SCHEDULE (s.58)
CONSEQUENTIAL AMENDMENTS TO THE PHARMACY AND POISONS ACT (CAP.244)

Amendment

Delete the definitions of-

(a) “authorised officer”;
(b) “authorized seller of poisons”
(c) “Board”;
(d) “enrolled pharmaceutical technologist”;
(e) “register”;
(f) “registered pharmacist”;
(g) “registrar”; and
(h) “Roll”;

insert the following new definitions in their proper alphabetical sequence-

“authorized seller of poisons” means a person authorised as such under the Pharmacy Practitioners Act;

“Board” means the Pharmacy Practitioners Board established under the Pharmacy Practitioners Act;

“pharmacist” means a person registered as such under the Pharmacy Practitioners Act;

“pharmaceutical technologist” means a person enrolled as such under the Pharmacy Practitioners Act; and

“wholesale dealer” means a person licensed as such under the Pharmacy Practitioners Act.

Delete
Delete the words “licensed under section 27 of this Act”;
Delete the words “section 23 of this Act” and substitute therefor the words “the Pharmacy Practitioners Act”;

Section 26(1)(b)

Delete

Section 27

Delete the words “a person licensed under section 27 to deal as”

Section 29(1)

Delete the words “a person licensed under section 27 to deal as”.

Section 33(1)(a)

Delete the words “licensed under section 27”

Section 33(2)

Delete the words “the Pharmacy and Poisons Board” and substitute therefor the words “the Cabinet Secretary upon recommendation by the Pharmacy Practitioners Board through a competitive and transparent process conducted by the Board with due regard to gender and regional balance principles”.

Section 35F(1)

Delete the word “twenty” and substitute therefor the words “three hundred”.

Section 40(1)(a)

Delete the word “thirty” and substitute therefor the words “five hundred”.

Section 40(1)(b)
MEMORANDUM OF OBJECTS AND REASONS

Statement of Objects and Reasons

The principal object of this Bill is to provide for the training, registration and licensing of pharmacy practitioners, so as to regulate their practice.

Part I (Clauses 1-2) contains preliminary matters

This Part contains the title of the Bill and the interpretation of terms used in the proposed Act.

Part II (Clauses 3-13) provides for the establishment of the Pharmacy Practitioners Board

This Part provides for the establishment, composition, functions and powers of the pharmacy practitioners Board of Kenya. It is proposed that the Board shall be the regulatory body in respect of the training, licensing and control of the practice of pharmacy practice in Kenya. The Part also contains matters to do with the conduct of business and affairs of the Board. It further contains powers of delegation by the Board as well as remuneration of Board members. The Part also establishes the office of the Registrar and the Secretary to the Board. It finally provides for the hiring of staff of the Board as well as the protection from personal liability of the members and agents of the Board.

Part III (Clauses 14-19) contains the financial provisions of the proposed Act

This Part contains provisions relating the financial aspects of the Board including sources of funds for the Board, the financial year, annual estimates and accounting and auditing provisions. It also provides for guidelines on investment of funds as well as the preparation and submission of the Board’s annual report to the Cabinet Secretary.

Part IV (Clauses 20-27) provides for the training, registration and enrolment of pharmacy practitioners

This Part contains provisions relating to the training and registration of pharmacy practitioners under the proposed Act. This Part will affect mostly institutions and courses that are foreign based as well as exempt institutions and courses approved under the Universities Act from the requirements of this Part. The Part further provides for a Register or Roll to be maintained of Pharmacy Practitioners and cases that might lead to removal from that Register or Roll.

Part V (Clauses 28-37) contains matters to do with licensing

This Part contains provisions relating to private practice. It is proposed that pharmacy practitioners wishing to offer their services
directly to the public be issued with an annual practising certificate by the Board so as to safeguard the public from unfit persons purporting to offer these services. The Part also contains provisions on the validity of those licences and instances of refusal to issue the licence. It further provides guidelines on the renewal, cancellation and suspension of the licence.

**Part VI (Clauses 37-41)** provides for the establishment of the Ethics and Disciplinary Committee

This Part contains provisions relating to discipline of registered pharmacy practitioners. It is proposed to establish an Ethics and Disciplinary Committee that will undertake the task of ensuring that registered pharmacy practitioners undertake the practice of their profession within their professional norms and standards. The Part also contains the procedure to be followed by the Committee as well as the disciplinary measures it may choose to employ on the practitioner. It further provides for conditions of lifting of a suspension on a practitioner as well as his or her restoration of name in the Register or Roll.

**Part VII (Clauses 42-56)** contains enforcement provisions of the proposed Act

This Part provides for the appointment of authorised officers who have powers to enter premises in the enforcement of the Act and inspect their records to confirm compliance with the Act. It further mandates for assistance to be given to this officers and the offence of obstruction. The Part also provides for the powers of the High Court in restoring seized medicine, or related things as well as the nature of taking evidence during proceedings. It finally provides for offences concerning interference with certificates against the Act; offences relating to registration or enrolment; offences by partnerships or body corporates; as well as a general penalty for all offences under the Act.

**Part VIII (Clauses 57-58)** contains provisions on delegated powers

This Part contains the power of the Cabinet Secretary to make rules under the Act as well as the principles and standards applicable to the exercise of that delegated power.

**Part VIII (Clauses 59-60)** contains miscellaneous provisions

This Part contains the consequential amendments to the Pharmacy and Poisons Act as well as transitional provisions.

**The First Schedule** contains provisions relating to meetings of the Boards and their conduct.

**The Second Schedule** contains the types of licences to be issued under the proposed Act.
The Third Schedule contains the consequential amendments to the Pharmacy and Poisons Act.

Statement on the Delegation of Legislative Powers and Limitation of Fundamental Rights and Freedoms

This Bill delegates legislative powers in accordance with provisions of Article 94(6) of the Constitution as well as Standing Order 118 of the National Assembly Standing Orders.

The Bill proposes to limit fundamental rights and freedoms specifically the right to privacy and the right to property enshrined in Article 31 and 40 of the Constitution respectively. It is important to note however that Article 24 of the Constitution allows limitation of fundamental rights and freedoms if the limitation is reasonable and justifiable taking into account all relevant factors which interalia includes the importance of the purpose of the limitation and the nature and extent of the limitation.

In any case, Standing Order 158 of the National Assembly Standing Orders provides that no private Bill which directly affects the private right or property of any persons, shall originate in the House unless a notice has been published in not less than three separate issues of the Gazette, specifying the general nature and objects of the Bill; the last of such publications being not less than fourteen days before the presentation of the Petition referred in standing order 159 (Petition for Leave).

Statement on How the Bill Concerns County Governments

The Bill concerns county governments in terms of Article 110(1)(a) of the Constitution as it affects the functions and powers of county governments recognized in the Fourth Schedule to the Constitution. It specifically touches on premise licences to be issued to various pharmacies in terms of the services that could be offered under those licences which is within the purview of the functions of county governments under the Fourth Schedule to the Constitution.

Statement of the Financial Implication of the Bill

The enactment of this Bill shall occasion additional expenditure of public funds.

RACHAEL NYAMAI,
Chairperson,
National Assembly Committee on Health.