PHARMACEUTICAL SOCIETY OF KENYA

CODE OF ETHICS FOR PHARMACISTS

1st Edition, January 2019

This Code of Practice enumerates the objectives and standards that the members of PSK, have committed to follow in order to raise and uphold the bar of ethical standards in their practices.

Contents

Note from the President

Enforcement has really been the Achilles heel of any regulatory board and the Pharmacy and Poisons Board is no exception. The sheer amount of finances and human capacity required to enforce policies and laws as well as time to probe all enquires causes paralysis and hence a chaotic and rogue pharmacy practice space to the detriment of public interest, safety and professionalism, as quackery and unethical practices become more and more rampant.

To curb this the Pharmaceutical Society of Kenya supports the government in its quest to have self-regulation as a way of minimize malpractice and protect the public.

With this document we have put in place structures and systems to ensure that we take full responsibility of upholding ethics and professionalism and enforcing the Good Pharmacy Practices in the country.

Our members will be bound by this code. They will be their brothers' keepers. As PSK we already have invested in and will avail tools to our members to facilitate compliance as follows: Scheduling of services and medicines available at the different levels of pharmacies; 100% presence of a Pharmacist in a Green Cross Pharmacy and 100% presence of a Pharmaceutical Technologist in the Blue Cross outlet; Compliance with the law on dispensing as per prescription from authorized persons; Record keeping.

We have empowered our Enforcement Committee to receive and evaluate public enquiries and complaints, with a goal to uphold public trust in the profession of pharmacy.

We shall use these systems like biometrics, competency framework, CPDs, doctors, patients and pharmacy apps to ensure collaboration, practice support and accreditation along best practice, accountability and public interest.

The next steps will be to entrench self-regulation in law. PSK remains fully committed to the health of the public through enforcing the highest attainable pharmaceutical practice standards.

Introduction

Established in 1964, the Pharmaceutical Society of Kenya (PSK) is the premier pharmaceutical professional body and the umbrella body of pharmacists in Kenya. PSK has its roots in the Pharmaceutical Society of East Africa that was registered in 1950.

All PSK members must abide to this Code of Ethics and any subsequent versions as ratified by the PSK. This code serves as a guide to maintain a high level of professionalism amongst pharmacists practising in Kenya. The code expresses that pharmacists are healthcare professionals who provide various scope of pharmacy services within the healthcare system which includes community pharmacies and hospitals; the pharmaceutical industry; regulation; academia; pharmaceutical supply chain; and research and development.

This code is intended to advocate the principles that form the fundamental roles and responsibilities of pharmacists, and sets the minimum standards of proper conduct and professionalism for guidance of pharmacists. The code thereby aims to foster an environment where the general public can be confident that choices regarding their treatment are being made in the best interest of their healthcare needs.

To avoid different interpretation and dispute to any statements contained herein or any contents that need further clarification, the following laws shall prevail and should be referred to:

- The Constitution of Kenya
- Pharmacy and Poisons Act, Cap 244

The following will be considered to add context and scope where applicable,

- Pharmacy and Poisons Board Rules & Guidelines
- International Federation of Pharmacists Global Competency Framework for Services provided by Pharmacy Workforce
- Scope of Contemporary Pharmacy Practice: Guide to Standards & Quality Assurance of Pharmacy Services under Green Cross
- Green Cross Accreditation Code
- Green Cross Hospital & Pharmacy Management Information System

Acknowledgements

In the development of this code, PSK has consulted widely and incorporated principles and advice from various codes around the world and from its own members. PSK acknowledges the following:

- Code of Ethics for Pharmacists and Pharmacy Technicians (Royal Pharmaceutical Society of Great Britain), 1 August 2007
- FIP Statement Of Professional Standards; Codes Of Ethics For Pharmacists (2014)
- Dr. Dorothy Aywak, MPSK and Secretary, Hospital Pharmacists Association of Kenya (HOPAK)
- Code Of Practice For The Kenya Pharmaceutical And Medical Devices Industry, by Kenya Association of Pharmaceutical Industry (KAPI)
- FIP Global Competency Framework For Services Provided by Pharmacy Workforce
- Professor Francis Ndemo, FPSK & Chair, PSK Policy and Practice Committee
- Dr. Sylvia Opanga, MPSK – contributor
- Dr. Joseph Kathare, MPSK - contributor
- Dr. Kwansah Ndemo – contributor
- Dr. Judith Getugi, MPSK – contributor
- Dr. Karigi Kibaara, MPSK - contributor

Objectives

The objectives of this Code of Ethics are to:

a) Provide guidance for pharmacists to maintain their competency and ethical behaviour in their professional conduct and practice;
b) Serve as a reference for disciplinary proceedings when the Pharmaceutical Society of Kenya considers cases of professional misconduct.
c) Provide guidance for staff working under a pharmacist including the roles of pharmacy technicians or pharmaceutical technologists.

Code of Ethics

A. THE PUBLIC

1. Make the care and safety of patients as the first priority.

a) Pharmacists have the obligations to act in the best interest of the individual patient.
b) Pharmacists have the responsibilities to provide professional care to patients in attaining optimal therapeutic/health outcomes.
c) Pharmacists shall promote the safe, quality and appropriate use of medicines and ensure timely access to medicines for the patients.
d) Pharmacists should always strive to provide information to patients regarding professional services truthfully, accurately, and clearly.
e) Pharmacists shall provide professional service to the best of their capabilities and to conduct themselves in such a manner as to hold their profession in high esteem and use professional judgement by following the laws and regulations pertaining to pharmacy.
f) Pharmacists shall bear the responsibility and accountability in the control and supply of medicines contributing to public health.
g) Pharmacists shall make use of professional knowledge in educating the public on medicine use, misuse, and abuse.
h) Pharmacists shall seek to maintain professional relationships with other pharmacists, colleagues, other members of the health care team and other stakeholders to achieve the highest standard of care for the best interest of the patient.

2. Respect and treat all patients equally, and protect their dignity and privacy.

a) Pharmacists shall treat patients without prejudice of race, age, gender, sexual orientation, nationality, religion, disability or socio-economic status; and not allow personal beliefs to influence the management of patients.

b) Pharmacists shall hold the details of patient information in confidence by taking all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information and should not disclose such information to anyone without proper patient authorization/consent except where the best interest of the patient requires or required by law.

B. THE PROFESSION

1. Comply with legal requirements and uphold professional standards and consistency in the promotion and provision of health services and products.

a) Pharmacists shall comply with the laws that govern practice in the course of their professional responsibilities.
b) Pharmacists shall ensure that the premise of practice must fulfil professional practice guidelines and standards so as to enable the provision of safe, high quality and cost effective health services and products.
c) Pharmacists shall take responsibility for all work done by them and ensure that those under their direct supervision are able to carry out their duties competently.
d) Pharmacists shall ensure appropriate standard operating procedures exist and are adhered to for the care and safety of the patient.
e) Pharmacists shall abide by governing laws, standards and guidelines pertaining to the research, manufacture, distribution, sale, promotion and advertising of all health services and products.
f) Pharmacists shall refrain from misleading the public by promoting or criticising any health product or services, through advertisements or other endorsements.
g) Pharmacists shall make sure that their professional judgement is not impaired by personal or commercial interests, incentives, targets or similar measures.

2. Behave in a way that justifies trust and maintains the reputation of profession.

a) Pharmacists shall act with honesty and integrity to uphold public trust and confidence in their profession.
b) Pharmacists shall maintain proper professional boundaries in the relationships they have with patients and other individuals that they come into contact with during the course of professional practice or with the public through any form of media including social media.
c) Pharmacists shall refuse to knowingly condone the dispensing, promoting, or distributing of drugs or medical devices that are not of good quality, that do not meet standards required by law, or that lack therapeutic value for the patient.
d) Pharmacists shall seek to avoid conflicts of interest and declare any personal or professional interests to those who may be affected.

e) Pharmacists shall comply with legal requirements, mandatory professional standards and accept best practice guidance, and adhere to acceptable standards of personal and professional conduct.
f) Pharmacists shall be receptive, respond promptly and politely to shortcomings, complaints and criticism pertaining to practices.
g) Pharmacists shall honour commitments, agreements and arrangements for the provision of professional services.
h) Pharmacists shall be liable to provide accurate information that do not mislead others or make claims that cannot be justified.
i) Pharmacists shall disclose to the relevant authorities including the Pharmaceutical Society of Kenya if they are self-aware of being a substance-abusing individual whose practice, judgment and skill could be impaired and may affect client care and safety.
j) Pharmacists shall be responsible, if they are of sound mind, to disclose to the relevant authorities including the Pharmaceutical Society of Kenya if they have been diagnosed with any medical condition that may render them unfit to continue to practice.

3. Always strive to develop and increase professional knowledge and competency.

a) Pharmacists shall keep abreast with the most current professional knowledge and skills up-to-date so as to maintain a high standard of competency in professional practice.
b) Pharmacists shall be prepared to learn and apply new knowledge and skills to expand their roles and responsibilities.
c) Pharmacists shall commit to continuous learning and professional development as a means of advancing their practice and professional role.

4. Inter-professional relationship.

a) Pharmacists shall maintain effective professional relationships with their colleagues and other healthcare professionals and offer assistance when called upon for advice and shall treat everyone equally.
b) Pharmacists shall refrain from publicly criticising their colleagues and other healthcare professionals.
c) Pharmacists shall demonstrate respect for the dignity, views, ability and rights of colleagues and other healthcare professionals in forming and maintaining professional relationship.

5. Impart knowledge, experience and skills to nurture future and new pharmacists.

a) Pharmacists shall promote the interest of individuals in entering the profession, assist and supervise them in professional responsibilities and accountable for them.
b) Pharmacists shall contribute to the development, education and training of colleagues and students, sharing relevant knowledge, skills and expertise to meet prescribed competency standards.

6. **Uphold professionalism.**

a) Pharmacists shall contribute the best of their abilities for the betterment of the profession of pharmacy and uphold their profession in a positive manner at all times.
b) Pharmacists shall don in proper and decent attire at all times. This shall include a means of identification as guided by the Society.

C. THE PRACTICE

1. Conduct or carry out responsibilities in a professional manner

a) Pharmacists shall use information obtained in the course of professional practice only for the purposes for which it was given or where otherwise lawful.
b) Pharmacists shall act in accordance to the policies and regulations of workplace regardless of the nature of work one is engaged in, be it research-related, academic-related, business-related, industry-related (including sales) or health institution-related. However this shall not be at the expense of best practice or the applicable laws and regulations governing pharmacy practice.
c) For community practice, subscribe to the "Scope of Contemporary Pharmacy Practice: Guide to Standards & Quality Assurance of Pharmacy Services under Green Cross"

D. MEMBERS PLEDGE

As a member of the Pharmaceutical Society of Kenya, I acknowledge my responsibility to adhere to the Code of Ethics & Pharmacy Practice in Kenya (The Code) in my commitment to uphold best practice, patient safety, public interest, integrity, and ethics.

I pledge to uphold the objectives of The Code to ensure that all my interactions with public and profession, other healthcare professionals, are at all times ethical, appropriate and professional.

As a member, I recognize my role in leading the promotion of The Code among my colleagues, the company I work for, and my company employees through information, education and thorough training.

By signing this document or subscribing to the Pharmaceutical Society of Kenya I am bound by the code.

Pharmacist's Name: _____

Pharmacist's Registration Number: _____

Pharmacist's Signature: _____

Date: _____

PHARMACEUTICAL SOCIETY OF KENYA

Pharmacist's Oath

Being a duly qualified Pharmacist and a member of the Pharmaceutical Society of Kenya; promising to devote myself to a lifetime of service to others through the profession of pharmacy.

I _____ Registration No. _____

Do swear:

- That I will practice my profession of pharmacy with conscience to uphold its dignity and honor; holding myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.
- That I will actively search for and disseminate new skills and knowledge of the profession and related disciplines; accepting the lifelong obligation to improve my professional knowledge and competence.
- That I will use my knowledge, experience and skills to the best of my ability to ensure optimal outcomes for the patients and to relieve human suffering in sickness and illness while maintaining the welfare of Humanity.
- That I will consult, co-operate with, and seek counsel from fellow Pharmacists and other health Professionals.
- That I will practice the profession without prejudice while embracing and advocating changes that improve patient care.
- That I will not distribute or promote the use of substances in a manner that is harmful to humanity.
- That I will abide by the rules and regulations governing the practice of pharmacy including the objectives of the Code of Ethics & Pharmacy Practice in Kenya (The Code) and pledge to assist in their enforcement and promotion.
- That I will respect and protect all personal and health information, keeping all secrets that I learn and as entrusted to me in the course of my professional duties.
- That I make these solemn promises freely and upon my honour with the full realization of the responsibility with which I am entrusted by the public and society.

So help me God.

Sworn on this _____day of _____ in the year of our Lord _____

_____ Pharmacist Signature

_____ Dr. Louis S. Machogu
President, PSK

E. ENFORCEMENT OF THE CODE

i) Introduction

This is a self-regulatory Code. Members of PSK, are signatories to the Code.

Where a member of the public or a member of the society is concerned that the activities of any signatory to the Code may be in breach, a complaint may be submitted to PSK for consideration. Complaints may be submitted to PSK through email (compliance@psk.or.ke). A hardcopy may be requested in due course.

PSK's Enforcement Committee shall oversee the self-regulatory process and administration of this code. Complaints will be heard in the first instance by the Enforcement Committee. The committee will receive any alleged breaches of this code and arbitrate any disputes brought forward.

ii) The Enforcement Committee & Appeals Board

Composition

The Ethic Committee shall comprise of members made up of 6 PSK members that are appointed by the National Governing Council (NGC) of PSK who shall be:

i. Four pharmacists nominated by the NGC of PSK.
ii. One pharmacist, a nominee by the Pharmacy and Poisons Board
iii. One pharmacist, a nominee of the Committee of Honourable Fellows of the Pharmaceutical of Kenya.

The nomination of the above shall be coordinated by the National Executive Committee (NEC) of PSK. The constituted committee will be at liberty to request for external expertise from consultants when required.

In case of an appeal, the appeals board of at least five members shall be constituted by the PSK NGC. If any members are drawn from the Enforcement Committee to the appeals board, these shall be members who did not participate in the resolution of the particular dispute in the first instance.

A number of three members shall be considered minimum quorum to transact business for the Enforcement Committee. Similarly, three members shall be sufficient quorum to transact business for the Appeals Board.

Appointment

Nomination papers are sent by the PSK NEC to all members when a position(s) on the Enforcement Committee becomes available. The nominations are considered by the NGC, which selects the appropriate person(s) to serve on the Committee. If insufficient nominations are received, the NGC may fill any remaining vacancies as it deems appropriate.

A mix of skills and expertise across the Enforcement Committee is desirable and will be taken into account by the NGC in the selection process.

Term of Office

Appointment to the Enforcement Committee will be for a two year term. All members are eligible for re-selection for another term provided they do not serve for more than two consecutive terms.

Chairpersons

Both the Enforcement Committees and the Appeals Board shall nominate their respective chairs. This is to ensure that the work of the committee and the Board remains independent. Appointments of chairs shall be reviewed every two years unless there is a compelling reason to review this before completion of the two year term.

Consultation

The Enforcement Committee Chair and the Appeals Board Chair shall have the right to consult external experts.

Conflict of Interest

If an Enforcement Committee or Appeals Board member is employed by a company directly involved in a complaint, referral or appeal, either as Complainant or Respondent, such member cannot participate in the Enforcement Committee or Appeals Board to consider that complaint, referral or appeal.

It is recognized that, on occasion, members of the Enforcement Committee or Appeals Board while not employed directly by a company involved in a complaint, referral or appeal, may have some degree of conflict of interest. However, it may not be feasible or practicable to require such a member to stand down for consideration of a given complaint, referral or appeal. A member of the Enforcement Committee or Appeals Board should declare his or her interest to enable the relevant Chairperson to make an appropriate decision.

In cases where a significant number of the Enforcement Committee or Appeals Board membership declares conflict of interest, to a level that compromises quorum, the NGC shall reserve the right to co-opt other members.

Confidentiality must be maintained in this regard.

Substitution

No substitution or replacement is allowed on the Enforcement Committee or Appeals Board during the hearing of a particular complaint, referral or appeal.

Autonomy

Enforcement Committee and Appeals Board members must have autonomy vis-à-vis their company/employer in the context of their participation in the Enforcement Committee and Appeals Board.

Confidentiality

Absolute confidentiality must be maintained by Enforcement Committee and Appeals Board members. As a rule, parties to proceedings before the Enforcement Committee and Appeals Board shall maintain confidentiality concerning any matters before the committee or Board, until a final decision is reached.

In exceptional circumstances, parties involved in a matter may discuss issues before Enforcement Committee or Appeals Board with a third party with express permission of the Enforcement Committee and Appeals Board. The party must prove that it is necessary to do this due to the involvement of the third party in the matter. Such discussion must be factual, fair and balanced.

Accountability

The Enforcement Committee and Appeals Board are accountable to the Executive Committee for their satisfactory performance. The Enforcement Committee and the Appeals Board are responsible for their own conclusions and deliberations.

Code Complaints Procedure

i. Who can make a complaint?

Complaints may be made by a member, healthcare professional, patient, patient organization or any other aggrieved body or individual.

ii. Submission of Complaints

The following requirements must be satisfied when the Enforcement Committee processes a complaint:

a. The identity of the complainant including contact details (email, telephone etc.) for correspondence, must be noted. Anonymous complaints will not be considered by the Enforcement Committee.
b. The initial complaint must be in sent by email; hard copies will be requested at the appropriate juncture.
c. Specific complaints from members must be fully referenced indicating sections of the code that are alleged to have been breached.
d. The dates of the alleged breach must be provided.
e. All complaints must be accompanied with evidence.

Complaints handling and Timelines

Complaints will be judged on the materials provided by the parties and it is for the complainant to show there has been a breach on the balance of probabilities.

The Enforcement Committee will endeavour to consider and deal with complaints in accordance with the following procedure and timelines:

a) The "clock" starts when a complaint is received by the Enforcement Committee Chairperson.
b) The Enforcement Committee shall validate the complaint within 10 working days to ensure that:
    i. It appears to be genuine, submitted in good faith.
    ii. There is sufficient information to enable the complaint to be processed.
c) If the information provided is insufficient, the complainant must provide additional information within the 10 working days (above), allocated for validation. If the complaint cannot be validated, it shall not be processed and the complainant shall be notified accordingly.
d) Once validated, a copy of the complaint is sent to the company/member alleged to have breached the Code (i.e. the Respondent) within 5 working days. The respondent is requested to:
e) Provide a written response within 10 working days (No extensions of time shall be granted);

f) Provide an unqualified undertaking that the company/member will comply with every reasonable request of the Enforcement Committee or Appeals Board, if relevant;
g) Confirm that the company/member will accept the final decision of the Enforcement Committee, or Appeals Board, if relevant (although it may reserve the right to have recourse to law should it consider that route necessary).
h) Failure by the Respondent to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Enforcement Committee or Appeals Board, if relevant, will result in the matter being referred to the PSK NGC.
i) Following receipt of the document(s) and prior to the first meeting of the Enforcement Committee, the Enforcement Committee Chair, after consultation with the Enforcement Committee members, shall have the discretion to ask either party to supply any additional information considered necessary to establish the full facts of the alleged breach so as to enable the Enforcement Committee to reach a decision on the matters complained of;
j) Prior to the meeting of the Enforcement Committee, the PSK NEC will issue a copy of the complaint (and the response, if received) to each member of the Enforcement Committee
k) A meeting of the Enforcement Committee will be arranged within 30 working days of the date of receipt of the complaint (i.e. whether or not the Respondent has replied). If the Respondent has provided a Response but not the required written undertaking of compliance and confirmation of acceptance of the Decision of the Enforcement Committee or Appeals Board, if relevant, the clock will stop until the PSK NGC has considered the matter and advised how the complaint is to be dealt with;
l) It is desirable but not always possible to reach a decision at that meeting. From time to time, subsequent meetings may be required;

m) The Complainant and Respondent shall be kept informed of progress with the complaint. The names of the members of the Enforcement Committee hearing the complaint may only be made available to either party subsequent to the completion of a case and only then on request;
n) If necessary, the PSK NEC may convene a panel of experts to provide medical or technical advice and may therefore extend the timelines. However, for all cases, the Enforcement Committee must resolve the case and transmit its ruling to both the complainant and respondent within 60 working days from receipt of respondent's reply, or if respondent fails to submit a written response, from the lapse of the period for submitting such a response.
o) The Enforcement Committee will issue its final decision in writing to the complainant, together with any suggested sanctions.
p) The Respondent will have 10 working days from the date on which the decision is issued to either lodge an appeal or to confirm in writing its intention to comply with any recommendations/sanctions imposed. Failure by the company/member concerned to do so will result in the matter being referred to the PSK NGC;
q) The PSK NGC shall at this point reserve the right to inform the Pharmacy and Poisons Board and request for a response/intervention e.g. suspension, deregistration, citation etc.
r) The above time frame for the Enforcement Committee procedure can be shortened or lengthened at the discretion of the Enforcement Committee Chairperson, depending on the complexity of the issues presented and having regard to the availability of the Chairperson and members of the Enforcement Committee.
s) Any request for an extension of the 10-day timeline for submitting an appeal will be a matter for consideration by the Enforcement Committee Chairman.

Referral Matters (i.e. alleged breaches of Code where there is no formal written complaint)

Alleged breaches of the Code by a Code signatory which come to PSK's attention other than by way of a formal written complaint are defined as “referrals”. This could be for instance through a phone call or word of mouth from a non-PSK member who is not aware of the complaints process as explained in this code or a member company with no documented evidence accompanying the complaint. Members are however encouraged to follow the process as described in section 1.4.2 and 1.4.3.

Such matters shall be dealt with in accordance with the following procedure:

i. Establishment that the referral is appropriate and has substance.
ii. Use of the referral mechanism by a code signatory
iii. In order to expedite matters and while maintaining good will, the Enforcement Committee Chairperson shall write to the member that is alleged to have breached the Code before the first meeting of the Enforcement Committee seeking preliminary information for the Enforcement Committee to consider at its first meeting;
iv. In any case, the member will be required to provide the standard undertakings that apply to complaints, i.e. an unqualified undertaking that he / she shall comply with

every reasonable request of the Enforcement Committee and confirmation that he / she shall accept the final decision of the Enforcement Committee (or Appeals Board if relevant)

v. After its first meeting, the Enforcement Committee will issue a letter to the member setting out the alleged breaches of the Code and he / she will be required to submit a written response. The Enforcement Committee has the authority to seek any further additional information considered necessary from the member who is alleged to have breached the Code;

vi. All information requested by the Enforcement Committee Chairperson and Enforcement Committee must be provided within 10 working days, with extensions only possible at the discretion of the Enforcement Committee Chairperson;

vii. The member shall have a right of appeal to the Appeals Board in relation to the decision of the Enforcement Committee, including any sanctions applied. The procedures outlined in the appeals process of this Code shall apply to such appeals

viii. "Self-referrals" from Code signatories will not be accepted in any circumstances, i.e. it shall not be open to Code signatories to seek the views of the Enforcement Committee on any of their own activities.

The Appeals Process

Valid Appeal

The following requirements must be satisfied for an Appeal to be considered valid:

a. The Appeal must be in writing;
b. It must specify which aspects of the Enforcement Committee's Decision are being appealed and also the grounds for the Appeal which must be one or more of the following:
    I. the finding(s) is (are) wrong
    II. The sanction(s) is(are) excessive
    III. Presence of a procedural flaw or irregularities in the adjudication process.
c. It may refer to documentation already submitted to the Enforcement Committee and include any further material, including new evidence;

Who can lodge an Appeal?

Only the Respondent to a Complaint may lodge an Appeal to the Appeals Board in respect of the Decision of the Enforcement Committee on the Complaint.

Establishment of Appeals Board

On receipt of a written Appeal from the Respondent in respect of a Decision of the Enforcement Committee, the PSK NGC will establish an Appeals Board having due regard to conflicts of interest and other relevant matters. Depending on the specific matter, the Executive Committee shall from time to time be at liberty to pull into the membership of the Appeals Board, non-PSK members.

Committee members who have considered a Complaint at Enforcement Committee level are not eligible to consider the same Complaint at Appeals Board level.

A quorum of three is required to hear an Appeal and arrive at a final Decision.

Appeals Board Procedures & Timelines

The Appeals Board will endeavour to consider and deal with Complaints in accordance with the following procedure and timelines:

a. The “clock” starts when a valid Appeal is received at the PSK NEC;
b. A copy of the Appeal is sent to the other party involved in the Complaint, who is requested to provide a written Response, within 10 working days.
c. Upon receipt of the Response to the Appeal, NEC issues the documentation to each member of the Appeals Board, i.e. Appeal, Response to Appeal, Enforcement Committee Decision, as well as the original Complaint and Response to the Complaint, both of which will be included in the Appeals document provided by both parties;
d. A meeting of the Appeals Board is arranged within 30 working days of the date of receipt of the Appeal (i.e. whether or not the other party has replied);
e. It is desirable but not always possible to reach a Decision at the first meeting of the Appeals Board. From time to time, additional meetings may be required;
f. The two parties involved in the Appeal shall be kept informed of progress with the Complaint;

g. The Appeals Board may limit its deliberations to selected relevant additional evidence, at its discretion;
h. The names of the members of the Appeals Board hearing the Appeal may only be made available to either party subsequent to the completion of a case and only then on request;
   i. The Appeals Board issues a final Decision within 10 working days of its last meeting. The Appellant is also provided with a copy of the Response and gets a chance to have the last word on the result of the appeal e.g. if in agreement or if they would like the matter escalated to the PSK NGC
j. Where a breach of the Code is confirmed by the Appeals Board, the company/member concerned has 10 working days to confirm in writing its intention to comply with the recommendations/sanctions imposed and to provide details of any actions taken in that regard. Failure by the company/member concerned to do so will result in the matter being referred to the PSK NGC;
k. The above time frame can be shortened or lengthened at the discretion of the Appeals Board Chairperson in conjunction with the Appeals Board members depending on the complexity of the issues presented and having regard to the availability of the Chairperson and members of the Appeals Board.

Decision of the Appeals Board

The Decision of the Appeals Board is final and binding.

Personal Representation during Appeals

Each party involved in an Appeal has the right to make an oral presentation to the Appeals Board. The following conditions will apply to all such personal representations:

a. The PSK NGC must be notified in writing if the relevant party intends to exercise this right at least five working days before the date of the first meeting of the Appeals Board;
b. Details of the company/member representatives who will be in attendance must also be provided in writing. External advisors (including barristers or representatives from firms of solicitors) are not permitted to attend on behalf of either party. Additionally, the Appeals Board Chairperson has the right to limit the number of representatives;
c. A summary of each party's representations to the Appeals Board shall be submitted as soon as possible after the request for such representations and in any event, no later than five working days before the Appeals hearing. Each party to the Appeal will receive the summary of the other's representations in advance of the hearing;
d. Each party's presentation shall be limited in duration (generally to a maximum of 20 minutes followed by 10 minutes for questions from the Appeals Board);
e. No new material or data may be introduced during the oral presentation that was not previously included in the written documentation provided to the Appeals Board.

Withdrawal of Appeals

The Appellant may withdraw the Appeal at any time up until the Response has been received by PSK. If an Appeal is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the Appeal.

Requirement for Complaints to Have Substance

All complaints submitted for consideration must have substance. In the event of doubt about whether a complaint has substance, the PSK President will be asked to adjudicate.

Inter-member complaints should not be used as a competitive tool or abused by members or their companies for any hidden motives. The spirit of this self-regulatory code and the protection of the reputation of pharmacists, as well as public interest and safety as a whole should remain paramount at all times.

Sanctions

Where the Enforcement Committee, having considered a complaint or referral, has found that the Code has been breached it shall, without prejudice to the right of any affected party to have the matter resolved through the judicial process, have the authority to:

a. Require the member concerned to cease the practice found to be breach of the Code and take all necessary steps to avoid a similar breach in the future;
b. Reprimand the member for the breach of the Code;
c. Order the correction of mistake by way of a corrective notice to parties involved or public as may apply in terms approved by the Enforcement Committee/Appeals Board;
d. Order the immediate publication of the decision in whole or in part and specify how and to whom the decision is to be sent.
e. In the case of difficult and/or persistent breaches of the Code, refer the matter to the Member's employer, The Minister for Health and the Pharmacy and Poisons Board;
g. Recommend to the PSK NGC, the suspension or expulsion from PSK of the offending party.
h. Impose financial penalties as per the penalty scheme:

This list is not exhaustive and other sanctions may be applied by the Enforcement Committee/Appeals Board as appropriate.

In the event that the decision of the Enforcement Committee is appealed, the Appeals Board shall assume responsibility for the application of any or all of the above sanctions. In addition, the Appeals Board may uphold the decision of the Enforcement Committee but vary the sanctions applied.

As soon as a decision of the Enforcement Committee becomes the subject of an appeal, the decision and any sanctions imposed by the Enforcement Committee is deemed to be suspended.

Penalty Scheme

Financial penalties shall be imposed as follows:

a. First time offender shall be fined KSh. 50,000/-
b. A second similar offences shall be fined KSh. 100,000/=
c. Consequent similar offences will attract a fine not less than 5 times the already imposed fine.
d. Member companies will be required to pay the penalty within the year of membership to PSK.

If the member refuses to pay the penalty, the matter will be referred to the PSK NGC. The PSK NGC will deliberate on actions to take.

iii) Abuse of Code

Abuse of the Code procedure shall in itself be a breach of the Code.

iv) Recourse to Legal System

A member's right to have recourse to the legal system is not affected by participation in, and compliance with, the Code of Practice and the Enforcement Committee and the Appeals Board's decisions. However, it is envisaged that the transparency of procedures in this Code will ensure that the necessity for such action will not arise.

A Complainant/Respondent must advise the Enforcement Committee and the Appeals Board in the unlikely event of recourse to the legal system before or during a complaint. The Enforcement Committee or the Appeals Board, as appropriate, will have the right to take whatever action it sees fit under the circumstances.

F. HOUSE KEEPING

Review schedule

This code shall be reviewed annually and update deposited with the Pharmacy and Poisons Board.

Transition Period

The legal and ethics committee of the pharmaceutical Society of Kenya shall be the caretaker committee of enforcement of this code until the National Governing Council constitutes the Enforcement Committee

APPENDICES

1. Competency framework for community pharmacists - Scope of Contemporary Pharmacy Practice: Guide to Standards & Quality Assurance of Pharmacy Services under Green Cross
2. Competency framework for all pharmacists
3. Competency framework for pharmacy technicians

APPENDIX 1: Competency framework for community pharmacists - Scope of Contemporary Pharmacy Practice: Guide to Standards & Quality Assurance of Pharmacy Services under Green Cross

Scope of Contemporary Pharmacy Practice: Guide to Standards & Quality Assurance of Pharmacy Services under Green Cross

Pharmaceutical Society of Kenya

Table of Contents

Contents

I. Foreword from the President of the Pharmaceutical Society of Kenya (PSK)

The government of Kenya through the Pharmacy & Poisons Board has the legitimate need, mandate and responsibility to ensure all involved in delivery of pharmaceutical care, products and technologies adhere to the provisions of the Pharmacy & Poisons Act, Cap 244 & its policy documents & instruments.

We as the Pharmaceutical Society of Kenya subscribe to the same position and further appreciate the patient's needs and rights to pharmaceutical care, products, information & technologies with demonstrable quality, affordability & accessibility. These are well outlined in the Kenyan Constitution Articles 31 (1) (d) 43(1) (a) & 46; The Health Act 2017 as well as in the Universal Healthcare Coverage (UHC) declarations.

To implement this, we call on our members to further take on & uphold, principles of Global Best Practices on Patient Safety, Public Interest & Professionalism in the discharge of their duties. Through our affiliation to the International Pharmaceutical Federation (FiP), we use the various sector groups & associations under our umbrella to ensure that all patients under out care receive world class services whilst also ensuring that our members are up to date in their knowledge and aligned to the evolving health system demands.

Therefore to feed into the governments legitimate need for UHC & orderliness in the pharmaceutical sector.

II. Preface

The issue of medication-related morbidity and mortality has been with us as long as drug therapy has been in use; however, the problem has grown to such a magnitude that something now must be done to address it. Medical errors where medication-related ones lead the pack are considered the third leading cause of death after cancer and cardiovascular causes. It is estimated that in USA alone 200 billion dollars are spent on adverse drug events of which 50% are preventable!

In Kenya the situation could be worse as the quality of the products and health care service are brought into question. The western world has responded to this public health problem by adopting a new philosophy of practice, the Pharmaceutical Care and the services offered as Medication Therapy Management. The emphasis of the philosophy is the patient-centered nature in which the pharmaceutical care practitioner (pharmacist) takes responsibility in meeting the patient's drug-related needs and is held accountable for that commitment. The pharmacist in this case has the social contract to ensure that every patient receives drug therapy that is safe, effective and economical. Numerous studies have demonstrated the positive impact of pharmaceutical care practice on the clinical, economic and humanistic outcomes of drug therapy.

However, for the pharmacist to succeed in this professional mission he/she must be in control of the total drug use process. This should be the prime responsibility because of the extensive training of the pharmacist in pharmaceutical and biomedical sciences. Additionally, the newer pharmacy curricula prepares the pharmacy graduates for clinical practice through advanced pharmacy practice degrees such as doctor of pharmacy (PharmD), master's degree in clinical pharmacy (MPharm) or doctor of philosophy in clinical pharmacy (PhD).

This best practice guide, therefore, is a milestone for Pharmacy Practice in Kenya which is still at its infancy. It will be an instrument that should be used by institutions that employ pharmacists and pharmaceutical technologists. Clearly, if the profession must meet its mandate of ensuring that all the patient drug-related needs are met, standards of practice must be defined.

Pharmaceutical Society of Kenya, as the legal professional body representing pharmacists must strive to define these practice standards and ensure that the members are using the best practices in the industry to deliver Pharmaceutical Care to the Kenyan people. Remember most of the drug-related problems are preventable making the expanded role of the pharmacist justifiable.

Prof. Francis Ndemo, BPharm (UK), PharmD (USA), MRPharmS (UK),FPSK
Associate Professor of Pharmacy Practice, University of Nairobi
Fellow of Pharmaceutical Society of Kenya
Chair, Practice Committee, Pharmaceutical Society of Kenya.

III. Acknowledgement

The preparation of this guide will have not been complete without the substantial input from the following professionals. Dr. Sylvia Opanga, PhD, for the invaluable input on the functions and job descriptions for the various pharmacy cadres as well as the professional fee guidelines. Her selfless work in compiling and editing this guideline is commendable. Dr. Kwansah Ndemo, PharmD, input in this respect is also highly appreciated. Dr. Judith Getugi Kerini contribution to data research and editing for this document is commended.

IV. List of Abbreviations

MTM	Medication Therapy Management
OTC	Over-The-Counter
PSURs	Review Periodic Safety Update Reports
BPMH	Best-Possible Medication History
DTP	Drug therapy problem

V. Definition of Terms

Medication Therapy Management Services
They are professional pharmaceutical activities needed to meet the standard of care that ensure each patient's medications(whether they are prescription, non-prescription, alternative, traditional, vitamins, or nutritional supplements are individually assessed to determine that each medication is appropriate for the medical condition being treated, that the medication is being effective and achieving the goals established, that the medication is safe for the patient in the presence of the comorbidities and other medications the patient may be taking , and the patient is able and willing to take the medications as intended. This assessment is completed in a systematic and comprehensive manner
(Pharmaceutical Care Practice,3rd Edition Cipolle, Strand and Morley)

Drug Therapy Problem
Any undesirable event experienced by a patient that involves, or is suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy and requires clinical judgement to resolve or prevent
(Pharmaceutical Care Practice,3rd Edition Cipolle, Strand and Morley)

Drug-Related Need
The health care needs of a patient related to drug therapy for which the pharmacist can offer professional assistance. This includes using the most appropriate medication for each medical condition, the most effective, the safest drug regimen possible and the willingness and ability of the patient to comply with the instructions for taking a medication
(Pharmaceutical Care Practice,3rd Edition Cipolle, Strand and Morley)

Pharmaceutical Care
A patient-centered practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment.
(Pharmaceutical Care Practice,3rd Edition Cipolle, Strand and Morley)

Practice Philosophy
A set of values that guides behaviors associated with a professional practice.
The philosophy of practice for pharmaceutical care includes meeting the social obligation to minimize drug-related morbidity and mortality, accepting direct responsibility to identify, resolve, and prevent drug therapy problems, and applying the caring paradigm in a patient-centered manner.
(Pharmaceutical Care Practice,3rd Edition Cipolle, Strand and Morley)

A. MANDATE OF PHARMACEUTICAL SOCIETY OF KENYA

Established in 1964, the Pharmaceutical Society of Kenya (PSK) is the premier pharmaceutical professional body and the umbrella body of pharmacists in Kenya. PSK has its roots in the Pharmaceutical Society of East Africa that was registered in 1950.

The role of PSK is three fold - Promote the welfare of pharmacists; Promote highest standards through self regulation; Advocate for better regulations, laws and policies in the pharmaceutical sector.

B. PHILOSOPHY OF PHARMACY PRACTICE

Pharmacy, in its most traditional sense, has been concerned with the development, manufacture (compounding) and distribution (dispensing) of drug products intended for patient use. Modern pharmacy on the other hand includes the development, distribution of knowledge and information about drugs intended to improve medication use. To this end there is overwhelming evidence that inappropriate use of medications, the most widely used intervention in healthcare, has led to significant drug-related morbidity and mortality.
In response to this public health problem the profession of pharmacy has expanded its social responsibility to include ensuring the safe, effective and economical use of medication therapies. This major paradigm shift in the philosophy of practice is enshrined in pharmaceutical care. *Pharmaceutical care practice is defined as a patient-centered practice in which the practitioner takes responsibility in meeting all the patient's drug-related needs and is held accountable for that commitment*. *It is a responsible provision of drug therapy to achieve definite outcomes that improve the patients' quality of life*. This means the practitioner ensures that each drug product is the most appropriate, the most effective, the safest possible and that the patient is able and willing to follow instructions for optimal drug therapy outcomes.

This requires the pharmacists to take responsibility for the outcomes of drug therapy, and to monitor the therapy during while the patient is taking medications. To achieve this, pharmacists provide medication therapy management services which require a step by step evaluation of patients to determine their drug related needs, identify and resolve them in collaboration with other relevant members of the multidisciplinary team involved in the patient's direct care. This involves but not limited to identifying the need for a drug, selecting the appropriate drug and regimen, provision of the drug, monitoring its effect as well as counseling and educating patients on the use of the medicines provided. In essence the pharmacist establishes a *"Pharmaceutical diagnosis"* of the drug-related needs are not met by identifying drug therapy problems and their respective causes and then designs a therapeutic plan to resolve them, mitigate further risks and optimize the outcomes (both patient-centred and disease-centred) in the most cost-effective and cost-efficient manner. Needless to say, a drug therapy problem is an undesirable/ unintended drug-related event that prevents the patient from achieving desirable drug therapy outcomes.

C. DRUG USE PROCESS

The healthcare system in modern society is a highly complex organization of health professionals, supportive personnel, facilities, equipment, and funding mechanisms. The objective of this array of resources are the diagnosis and treatment of disease and the caring for ill patients. The most common therapy for managing the diseases is drug therapy, a domain area of pharmacy. Pharmacy, therefore, is a vital health care service which has its own knowledge system.

In order to appreciate the intimate role played by the pharmacist within the health care system it is important to elucidate the components of the drug use process. Ten steps or events can be identified in this process:

Events in the Drug Use Process

1. Identifying patient's pharmaceutical problem (diagnosis)
2. Comprehensive medication history
3. Prescribing
4. Selection of the drug product
5. Drug Dispensing
6. Education and counseling of patient
7. Drug administration
8. Drug Therapy Monitoring
9. Drug Use Review
10. Pharmacologic education of health professionals (medicines information service)

The pharmacist is involved at any and all points in the drug use process. It is noteworthy that prescribing and dispensing are just two steps out of the ten steps required for rational drug therapy management. In order to take responsibility of ensuring effectiveness and safety of drug therapy the pharmacist must appear to and should be in control of the entire drug use process. A desirable outcome is only assured if the structure (skills and knowledge) and the process (competencies) used are optimal and evidence-based. The clinically trained pharmacist has the knowledge, skills and the competencies to deliver direct drug-related care to the patients.

The standards of practice that will follow reflects the various functions of the pharmacists that address the ten events or steps.

D. FUNCTIONS AND STANDARDS OF PHARMACEUTICAL SERVICES

SECTION ONE: DIRECT PATIENT CARE

1. REGISTERED PHARMACIST (GENERALIST)

(*Required Credentials: BPharm*)

i) Obtaining basic history of the patients with a focus on medication history and compliance to therapy
ii) Advices patients on selection of OTC products
iii) Describing the prescribed or dispensed drug, giving its name and indication
iv) Explaining the dose, dosage form, route of administration, and duration of drug therapy
v) Describing the intended use of the drug and expected action
vi) Giving special instructions required during preparation, administration and use
vii) Describing the use of medication use devices such as graduated cups, inhalers, insulin injections etc
viii) Providing information on common adverse effects, drug interactions or therapeutic contraindications
ix) Providing information on the techniques of self- monitoring
x) Providing instructions on storage of medication
xi) Supervising of dispensing of prescriptions by dispensing assistants
xii) Referral of patients with multiple drug regimens to pharmacists with MTM certification.

2. PRIMARY CARE PHARMACIST (COMMUNITY PHARMACY PRACTICE)

(*Required Credentials: BPharm with MTM Certification*)

RESPONSIBILITY FOR DRUG-RELATED ACTIVITIES

i) Supervises all drug distribution activities for drug use control and patient safety
ii) Selects for patients therapeutically effective prescription drug products at reasonable cost
iii) Records patients' medication history of drugs taken and any adverse reactions there from
iv) Monitors patients' response to drugs utilizing patient medication profile and other resources
v) Detects and diagnoses adverse drug reactions and drug interactions
vi) Counsels patients on the use of drugs to assure compliance
vii) Advise patients on selection of OTC drugs
viii) Helps establish dosage regimens for patients
ix) Promotes rational drug therapy by physicians
x) Integrates the psycho-socio-economic aspects of health care
xi) Prescribes for mild self-limiting diseases
xii) Supervises management of patients with acute and chronic diseases
xiii) Detects and overcomes incompatibilities in drug mixtures
xiv) Compounds drug preparations to meet specific patient requirements
xv) Supervises the dispensing of prescriptions by dispensing assistants
xvi) Has ability to evaluate the drug literature

xvii) Performs drug utilization review
xviii) Provides health care education to the public
xix) Conducts point-of-care tests for disease screening and monitoring
xx) Provides immunization services

3. CLINICAL PHARMACIST SPECIALIST (INPATIENT CLINICAL PRACTICE)
(*Required Credentials: MPharm /PharmD/PhD with MTM Certification/ MSc. CPIPP*)

As ambulatory but with additional responsibilities in acute care.

4. CLINICAL PHARMACIST SPECIALIST (AMBULATORY CLINICAL PRACTICE)
(*Required Credentials: MPharm /PharmD/PhD with MTM Certification/ MSc. CPIPP*)

i) Conduct a patient interview and interpret the result of the interview
ii) List and explain the monitoring parameters and therapeutic end points for the safe and efficacious use of each drug used in a patient.
iii) Prospectively monitor drug therapy for potential drug-drug, drug-laboratory test, drug-diet, drug-disease, and drug-condition interactions and recommend modifications in drug therapy, when appropriate to minimize such interactions.
iv) Use interviews, physical assessment skills, and interpretation of laboratory test results to monitor therapy for adverse and therapeutic effects.
v) Take a comprehensive medication history (ask about prescription, non-prescription, OTC, traditional meds, home remedies, supplements, family planning, anything else done to relieve the symptomisation of the patient complaints), assess the patient's attitude toward compliance and evaluate the influence of these factors on therapeutic response; initiate strategies to correct noncompliant behavior.
vi) Effectively counsel patients on drug use.
vii) Serve on health care team providing primary or consultative care.
viii) Prospectively formulate individualized drug regiments based on the purpose of the medication(s), concurrent disease (s) and drug therapies, pharmacokinetic parameters of the drug (s) and the patient's clinical condition.
ix) Competently devise individualized drug regimens and recommend adjustments based on therapeutic response.
x) Describe the clinical manifestations of potential toxicities associated with a patient's medication, assess the significance of the toxicity and recommend an appropriate course of action.
xi) Develop and conduct or assist in a collaborative clinical research project.
xii) Evaluate drug studies in the literature in terms of research design, validity of results, and clinical applicability.
xiii) Communicate effectively with patients, physicians (medical practitioners to include all specialties), nurses, other health professionals and peers.
xiv) Manage a patient's drug therapy by
    a. Designing a drug therapy treatment plan and advising prescribers on implementation.
    b. Using established therapeutic protocols
    c. Independently prescribing or adjusting drug therapy in instances where supportive legislation exists (examples?).
xv) Develop criteria for safe and effective drug use and coordinate drug use review and patient care audits.

xvi) Identify factors and key performance indicators to measure the quality of care provided by the pharmacy service which could be used in the development of a departmental quality assurance program, performance management protocol and assist in the advancement of pharmacy practice.

xvii) Explain the organization and operation of the outpatient pharmacy department; this could include physical accommodations, reference sources, computer applications, professional and supportive personnel, budgeting, relationships with other health care departments, assumed or designated responsibilities, and documentation of services.

xviii) (Automation?) Use personal computers to assist in the conduct of professional activities; these uses may include word processing, data base management, statistical analysis, graphics, and communication software.

5. BOARD CERTIFIED PHARMACOTHERAPY SPECIALIST (INPATIENT & AMBULATORY)
(*Required Credentials: MPharm /PharmD/PhD with MTM Certification, Board Certification*)

i) Can perform all roles cited for Clinical Pharmacy Specialist (are the 2 roles interchangeable?)
ii) Given a patient's diagnosis, can design a therapeutic regimen based on patient-specific parameters
iii) Establishes therapeutic goals
iv) Designs therapeutic alternatives
v) Applies in depth pharmacokinetic knowledge to design dosage regimens
vi) Critically evaluates therapeutic drug literature in particular the ones pertaining to the area of speciality such as pediatric pharmacotherapy, oncology pharmacotherapy e.t.c
vii) Acts as a pharmacotherapy consultant to the other clinicians including pharmacists
viii) Actively involved in clinical research in the area of speciality
ix) Function as therapeutic partners of the general internist physicians

6. COMPLIMENTARY AND ALTERNATIVE MEDICINE PHARMACIST SPECIALIST (ALL AREAS)
(*Required Credentials: MSc(Pharmacognosy)/MPharm /PharmD/PhD with MTM Certification*)

i) Identifying patients who require alternative/complementary medicine
ii) preparation and administration of the appropriate alternative medicines
iii) Counselling and educating patients on the use of alternative medicine
iv) Identifying drug interactions between conventional and alternative medicines and resolving them

SECTION TWO: NON-DIRECT PATIENT PHARMACY CARE SERVICES

1. PHARMACOEPIDEMIOLOGY AND PHARMACOVIGILENCE PHARMACIST SPECIALIST

(*Required Credentials: MSc (Pharmacoepi/Pharmacovig), MPH/PhD*)

i) Review Periodic Safety Update Reports (PSURs) to assess the risk-benefit balance of a marketed medicinal product.
ii) Identify and report suspected adverse drug events and poor-quality medicinal products to the regulatory authority in the prescribed fashion and provided feedback to the users of the products as well as any follow up information to the regulatory authority.
iii) Develop and implement programs that evaluate causality of adverse drug events.
iv) Review individual case reports of suspected Adverse Event/Adverse Drug Reaction.
v) Data mining on suspected adverse drug benefits and adverse events.
vi) Develop and implement risk management plans.
vii) Promote suspected adverse drug events and drug quality concerns reporting.
viii) Maintain a database on suspected adverse drug events.
ix) Implement post-marketing surveillance for public health programs
x) Drug utilization evaluation
    - Drug use evaluation and reviews.
    - Assessment of the outcomes of drug use both beneficial (intended and unintended) and undesired.
    - Assessment of the Clinical and Economic consequences of new policies.
    - Development and implementation and risk management plans
xi) Establishment of Medicine and Poison information centers.
xii) Establishment of databases on drug safety.
xiii) Development of drug use registries

SECTION THREE: PHARMACIST IN COLLABORATIVE PRACTICE MODELS OF CARE

Collaborative drug therapy management (CDTM) authorizes pharmacists to enter into agreements with physicians (consider referring to them as medical practitioners to cover the whole range of specialties) to jointly manage a patient's medication therapy, particularly in chronic disease management. Inasmuch as there may be a variation in the partnership agreements the following are the common activities that pharmacists carry out.

Collaborative Drug Therapy Management Activities.

1. Selecting, initiating, modifying, continuing, and discontinuing a patient's drug therapy
2. Ordering, performing, and interpreting medications-related laboratory tests as appropriate to monitor patient's response to medications
3. Providing assessment of the patient's response to therapy
4. Participating in disease state management for patients with chronic conditions that includes the coordination of care activities across the healthcare continuum
5. Educating and counseling the patient and/or caregiver on medication use
6. Administering medications and vaccines

Elements of a Collaborative Practice Agreement/Collaborative Drug Therapy Monitoring Agreement

1. Identification of the practitioner(s) and Pharmacist(s) who are parties to the Agreement.
2. Types and scope of decisions the Pharmacist is allowed to make
3. A method for the Practitioners to monitor compliance with the Agreement and clinical outcomes and to intercede/ intervene when necessary.
4. A description of the Continuous Quality Improvement Program used to evaluate the effectiveness of patient outcomes.
5. A provision that allows the Practitioner to override a collaborative Practice decision made by the pharmacist whenever he or she deems it necessary or appropriate and vice versa.
6. A provision that allows either party to cancel the Agreement by written notification.
7. An effective date
8. Signatures of all collaborating Pharmacist and Practitioners who are party to the agreement, as well as dates of signing.

Common conditions identified for clinical pharmacy specialist disease state management

1. Attention Deficit Hyperactivity Disorder (ADHD)
2. Anticoagulation therapy including the pharmacist-run VT Program
3. Asthma/COPD
4. Cardiovascular (CHF, HTN, lipids, MI, CAD)
5. Diabetes
6. Emergency contraception
7. Hepatitis
8. Home antibiotic care
9. Highly active antiretroviral therapy (HAART) for HIV infection
10. Iron supplementation for children
11. Medication assessment and adherence
12. Over-the-counter (OTC)triage protocols
13. Pain management (acute post-op pain and chronic nonmalignant pain)
14. Pharmacokinetic consultation
15. Smoking cessation
16. Travel medicine

17. Medically assisted therapy for people who are recovering from heroin addiction (using methadone, buprinorphine)

D. MEDICATION THERAPY MANAGEMENT

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. These services are independent of, but can occur in conjunction with the provision of a medication product. Medication Therapy Management include but are not limited to the following, according the needs of the patient:

1. Performing or obtaining necessary assessments of the patient's health status.
2. Formulating a medication treatment plan;
3. Selecting, initiating, modifying, or administering medication therapy
4. Monitoring and evaluating the patient's response to therapy, including safety, efficiency and effectiveness
5. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
6. Documenting the care delivered and communicating essential information to the patient's other primary care and healthcare providers
7. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications.
8. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens
9. Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

JOB DESCRIPTIONS OF PHARMACIST CADRES

A. PHARMACIST WITH B.PHARM (GENERALIST)

i) Pharmacy operational? management and supply chain management in the pharmacy at inpatient, outpatient and community pharmacy levels

ii) Supervision of pharmacy technicians, pharmacist and pharmaceutical technology interns and students

iii) Stock control and management (Commodity and Inventory management)

iv) Patient consultation aimed at improving compliance and optimizing the patients' therapeutic outcomes. In this consultation, the pharmacist shall exercise professional judgement to address the patient related and medicine-related needs. This consultation shall be chargeable and shall comprise of the following elements: ?

   1. Obtaining basic history of the patients with a focus on medication history and compliance to therapy
   2. Describing the prescribed or dispensed drug, giving its name and indication
   3. Explaining the dose, dosage form, route of administration, and duration of drug therapy
   4. Describing the intended use of the drug and expected action
   5. Giving special instructions required during preparation, administration and use
   6. Describing the use of medication use devices such as graduated cups, inhalers, insulin injections etc

7. Providing information on common adverse effects, drug interactions or therapeutic contraindications
8. Providing information on the techniques of self- monitoring
9. Providing instructions on storage of medication
10. Referral of patients with multiple drug regimens to pharmacists with MTM certification

v) Compound and dispense medications as prescribed by doctors and dentists (consider using the terms medical and dental practitioners because we are all doctors), by calculating, weighing, measuring, and mixing ingredients
   a. Review prescriptions from doctors to ensure accuracy, to ascertain the needed ingredients, and to evaluate their suitability for the patient
vi) Provide information and advice about drugs (Choose the term to use uniformly throughout the document: either drug or medicine), their side effects, correct dosage, and proper storage
vii) Keep records such as pharmacy files, patient profiles, charge system files, inventories, registries of poisons, narcotics or controlled drugs in accordance to the Laws of Kenya
viii) Plan, implement, or maintain procedures for mixing, packaging, or labeling pharmaceuticals, according to policy and legal requirements, to ensure quality, security and proper disposal
ix) Assess the identity, strength, or purity of medications
x) Work with other health care professionals to plan, monitor, review, or evaluate the quality or effectiveness of drugs and report any discrepancies in the prescribed fashion to the regulatory authority
xi) Order and purchase pharmaceutical supplies, medical supplies, or drugs, maintaining stock and storing and handling it properly
xii) Analyze prescribing trends to monitor patient compliance and to prevent excessive usage or harmful interactions
xiii) Advise customers on the selection of medication brands, medical equipment, or healthcare supplies
xiv) All other duties that may arise, be assigned or assumed based on professional competencies as appropriate

B. REGULATORY AFFAIRS PHARMACIST

i) Does registration and practice licensing of pharmacists and pharmaceutical technologists fall under their jurisdiction?
ii) Receipt, review and approval of registration applications of all medicines in applicable countries.
iii) Maintenance/ update of registrations in accordance with the relevant legislation, regulations and guidelines
iv) Compilation of registration dossiers for submissions to?
v) Regulatory Coordinator Function, Ensure that the local Regulatory Affairs unit applies the latest Procedures and Guidelines as published, Ensure that the applicable country specific Fees are paid on time (applicable if supervising more than one locale?)
vi) Perform QA on all artwork and approve all printed packaging material
vii) Ensure compliance with quality requirements on release of medicine for sale in line with GMP and company policies and procedures.
viii) Establish and maintain effective relationships with all stakeholders that may affect the practice of pharmacy in the area of jurisdiction and even internationally

Key Performance Indicators

i. Organizational, Departmental and Team Objectives and Goals
ii. All RA activities, including labelling reviews are performed according to the due dates set by company as well as regulatory bodies
iii. Promotional material reviewed within 3 days

Traits:

i. Sound project management capabilities
ii. Experience in Quality Control and/or Quality Assurance.
iii. Good analytical, organizing and communication skills.
iv. Self-starter, able to work independently
v. Able to handle multiple projects simultaneously.

C. HOSPITAL PHARMACIST (GENERALIST)

i) Prepares medications by reviewing and interpreting physician orders (prescriptions and treatment sheets?); detecting therapeutic incompatibilities.
ii) Dispenses medications by compounding, packaging, and labeling pharmaceuticals
iii) Controls medications by monitoring drug therapies; advising on appropriate interventions.
iv) Completes pharmacy operational requirements by organizing and directing technicians' work flow; verifying their preparation and labeling of pharmaceuticals; verifying order entries, charges, and inspections.
v) Medicines information service: Provides pharmacological information by answering questions and requests of health care professionals;
vi) Medication use counseling patients on drug therapies to optimize both patient-related and disease-related outcomes
vii) CMEs/ CPDs: Develops hospital staff's pharmacological knowledge by participating in clinical education programs; training pharmacy staff, students, interns, externs, residents, and other health care professionals.
viii) Complies with state and federal (in Kenya?) drug laws as regulated by the state board of pharmacy, the drug enforcement administration, and the food and drug administration by monitoring nursing unit inspections; maintaining records for controlled substances; r
ix) Commodity and inventory management: removing outdated and damaged drugs from the pharmacy inventory; supervising the work results of support personnel;
x) Compliance with legal requirements of pharmacy practice: maintaining current registration; studying existing and new legislation; anticipating legislation; advising management on needed actions.
xi) Infection control and waste management: Protects patients and staff by adhering to infection-control protocols.
xii) Maintains safe and clean working environment by complying with procedures, rules, and regulations.
xiii) Maintains pharmacological knowledge by attending educational workshops; reviewing professional publications; establishing personal networks; participating in professional societies especially the Pharmaceutical Society of Kenya (PSK).
xiv) Contributes to team effort by accomplishing related results as needed

D. PHARMACISTS WITH B. PHARM AND MTM CERTIFICATION

These pharmacists shall provide patient-centered care, and the consultation shall be chargeable. They shall refer patients with complex drug regimens to Specialist Pharmacists. Their services will be provided at inpatient, outpatient and community pharmacy levels. The activities they shall carry out will comprise of (but not limited to):

i) Establishing the need for drug therapy by taking a detailed history of the patient (bio-data, past medical and medication history, family and social history)
ii) Selection of the appropriate medicines after identifying and ruling out drug interactions, calculation of appropriate doses
iii) Provision of the medication with appropriate administration devices where required
iv) Monitoring the drug therapy for effectiveness or adverse effects and correcting them
v) Patient advice and education on each drug
vi) Evaluating effectiveness and reviewing therapy

E. PRIMARY CARE PHARMACIST (COMMUNITY PHARMACY PRACTICE)

1. Dispense prescription medicines to the public
2. Ensure that different treatments are compatible (Evaluate prescriptions for compatibility and advice both the patient/ patient carer and the prescriber as appropriate)
3. Check dosage and ensure that medicines are correctly and safely supplied and labeled (pharmacists are legally responsible for any dispensing errors)
4. Supervise the preparation of any medicines (not all are supplied ready made-up by the manufacturer)
5. Keep a register of controlled drugs (Schedule 2 and antibiotics) for legal and stock control purposes
6. Liaise with doctors (Prescribers?) about prescriptions
7. Sell over-the-counter medicines exercising professionalism
8. Advise the public on the treatment of minor ailments (Examples?)
9. Advise patients of any adverse side-effects of medicines or potential interactions with other medicines, treatments, food and drinks
10. Perform point-of-care tests (Examples?)
11. Manage, supervise and train pharmacy support staff
12. Manage finance and budgets
13. Keep up to date with current pharmacy practice, new drugs and their uses through continuous medical education and professional development.

F. CLINICAL PHARMACIST SPECIALIST

Specialist pharmacists provide their services within inpatient and outpatient settings and handle patients with complex drug therapy in their areas of specialization. The areas of specialization include (and are not limited to): Paediatrics, Infectious diseases,, Chronic medical conditions and lifestyle diseases (including cardiology, renal and hepatic), Oncology, Surgery, psychiatry and mental health, emergency and critical care, geriatrics, organ transplant , reproductive health, amongst other upcoming areas of practice. The services provided vary with the group of patients and the complexity of the therapy, but in general, they will perform the following duties, which will be chargeable:

i) Obtaining detailed medication and clinical history from patient, patient carers and other members of the multidisciplinary team as appropriate, review of systems and conducting physical examination that is relevant to drug therapy

ii) Monitoring and adjustment of drug therapy according to clinical, laboratory and other monitoring parameters
iii) Therapeutic drug monitoring
iv) Development of a detailed Pharmaceutical care plan
v) Identification and resolution of medication-related problems
vi) Medication use reconciliation, counselling and documentation
vii) Recommending appropriate choice of optimized therapy with special attention to cost factors
viii) Recommending appropriate routes, duration and frequency of drug therapy administration
ix) Provision of drug information to the patient and/or caregivers and other healthcare providers
x) Identifying and addressing potential medication safety issues including contraindications, drug interactions, inappropriate doses and routes of administration, duplicate therapy, monitoring for toxicity,etc.
xi) Preventing, identifying and reporting adverse drug reactions
xii) Patient education and counselling on medication therapy
xiii) Provision of vaccination and health promotion services
xiv) Collaboration with physicians (? Medical practitioners to cater for all specialties) and other health care workers, participating in clinical rounds and specialized outpatient clinics
xv) Provision of evidence-based medicines information to the healthcare team? Educating physicians (? Medical practitioners to cater for all specialties) and other health care workers on drug related issues
xvi) Training and mentoring non-specialist pharmacists (include specialist pharmacists, too, because we have many who are newly qualified and posted in various areas of practice. International guidelines require that newly qualified specialists work under the supervision of already recognized specialists for a period of time… mainly 2 years)
xvii) Identifying and reporting suspected adverse drug reactions and poor quality medicinal products to the regulatory body in the prescribed fashion
xviii) Continuous medical and professional education and development in order to stay updated and provide the best quality of pharmaceutical service possible

G. PHARMACOEPIDEMIOLOGY AND PHARMACOVIGILANCE SPECIALISTS

This cadre of pharmacists, with a Masters in Pharmacoepidemiology shall provide public health roles of pharmacists, with patient safety as a focus. Since their services are not direct patient services, they will be charged based on their duration and complexity.

i) Review Periodic Safety Update Reports (PSURs) to assess the risk-benefit balance of a marketed medicinal product.
ii) Identify and report adverse drug events and poor-quality products
iii) Develop and implement programs that evaluate causality of adverse drug events.
iv) Review individual case reports of Adverse Event/Adverse Drug Reaction.
v) Data mining on adverse drug benefits and adverse events.
vi) Develop and implement risk management plans.
vii) Promote adverse drug events and drug quality concerns reporting.
viii) Maintain a database on adverse drug events.

ix) Implement post-marketing surveillance for public health programs
x) Drug utilization evaluation
- Drug use evaluation and reviews.
- Assessment of the outcomes of drug use both beneficial and undesired.
- Assessment of the Clinical and Economic consequences of new policies.
- Development and implementation and risk management plans

xi) Establishment of Medicine and Poison information centers.
xii) Establishment of databases on drug safety.
xiii) Development of drug use registries

This has been captured in the previous section

H. PHARMACY SPECIALISTS IN COMPLEMENTARY AND ALTERNATIVE MEDICINE

These pharmacists, with a Masters degree in Pharmacognosy and complementary medicine, shall provide their services at inpatient, outpatient and community pharmacy settings, where applicable. The charges for clinical specialists shall apply.

1. Identifying patients who require alternative/complementary medicine
2. preparation and administration of the appropriate alternative medicines
3. Counselling and educating patients on the use of alternative medicine
4. Identifying drug interactions between conventional and alternative medicines and resolving them

This has been captured in the previous section

I. PHARMACY ASSISTANTS (PHARMACEUTICAL TECHNICIANS / TECHNOLOGISTS)

Key work output and Accountabilities

Dispensing of medication under the direct supervision of a pharmacist

- Assist Pharmacist in all aspects of dispensing
- Assist and advise on the usage, side effects, contra-indications and storage of medication to patients and other members of the healthcare team under direct supervision of pharmacist.
- Re-packing of medicine
- Capture all dispensed items to patients account.

Stock control

- Involved in all aspects of cyclical and full stock-take processes including procurement and ethical stock control.
- Processing of stock for internal departments and inter-clinic sales
- Assist in the management of stock in accordance to Stock Management policy with special emphasis on designated stock areas.

QUALITY ASSURANCE OF PHARMACISTS SERVICES

CLINICAL PHARMACY KEY PERFORMANCE INDICATORS FOR HOSPITAL PHARMACISTS (perhaps consider separation of KPIs for CPs and HPs due to the differences in scope of practice and hierarchy of qualification)

(*Please note that these KPI need to be contextualized to staffing norms, training, availability of resources and facilitative supportive supervision so that they don't form the basis against which pharmacists are victimized and professionally ostracized because this document outline practice as it is in the developed world.)*

1. Number (or proportion) of patients who receive a formal documented best-possible medication history (BPMH) by a pharmacist or pharmacy technician.
   (Thematic Critical Activity Area: BPMH)

2. Number (or proportion) of patients who receive formal documented admission medication reconciliation and the resolution of identified discrepancies by a pharmacist
   (Thematic Critical Activity Area: Admission medication reconciliation)

3. Number (or proportion) of pharmacists who actively participate in interprofessional patient care rounds to improve medication management
   (Thematic Critical Activity Area: Interprofessional patient care rounds)

4. Number (or proportion) of patients for whom clinical pharmacists have completed a pharmaceutical care plan.
   (Thematic Critical Activity Area: Pharmaceutical care)

5. Number of total drug therapy problems (DTPs) resolved by pharmacists.
   (Thematic Critical Activity Area: Pharmaceutical care)

6. Number of DTPs resolved for "high-alert" medications by pharmacists.
   (Thematic Critical Activity Area: Pharmaceutical care)

7. Number (or proportion) of patients with health record documentation by a pharmacist.
   (Thematic Critical Activity Area: Pharmaceutical care)

8. Number (or proportion) of patients who have received in-person education from a pharmacist about their disease(s) and medication(s) during their hospital stay.
   (Thematic Critical Activity Area: Patient education/Discharge counseling)

9. Number (or proportion) of hospital patients who receive medication counseling by a pharmacist at discharge.
   (Thematic Critical Activity Area: Patient education/Discharge counseling)

10. Number (or proportion) of hospital patients who receive formal documented seamless care activities by a pharmacist.
    (Thematic Critical Activity Area: Patient education/Discharge counseling)

11. Proportion of patients who receive formal documented discharge medication reconciliation and resolution of identified discrepancies by a pharmacist.
    (Thematic Critical Activity Area: Discharge medication reconciliation)

12. Number (or proportion) of patients discharged with complex and high-risk medication regimens for whom pharmacists have documented assessments of the patients' response to treatment plans by following up between 3- and 7-days post discharge.
    (Thematic Critical Activity Area: Post discharge follow-up)

13. Number (or proportion) of heart failure patients with an ACE inhibitor or ARB initiated or titrated to target doses prior to discharge.
    (Thematic Critical Activity Area: Disease- or drug-specific quality indicators)

14. Number (or proportion) of ischemic heart disease patients who receive ASA prior to Discharge.
    (Thematic Critical Activity Area: Disease- or drug-specific quality indicators)

15. Number (or proportion) of ischemic heart disease patients who receive a statin prior to discharge.
    (Thematic Critical Activity Area: Disease- or drug-specific quality indicators)

PROFESSIONAL FEE GUIDE FOR PHARMACISTS FEES

Medication therapy management is a complex process that ensures that the best outcome from medicines is achieved while minimizing adverse effects and medication-related problems. It is also time consuming and requires high intellectual output. Just like any consultation, the patients shall be billed according to the established market rates as detailed in Table 1.
All activities are under the umbrella of Medication Therapy Management Services (MTMS).
These are specific activities the pharmacist performs during their course of work.

Insurance Billing Codes	**A. GENERAL PHARMACISTS (B.Pharm with MTM certification)**	**Minimum (Ksh.)**	**Maximum (Ksh.)**
PHARM.MTM01	Personal Medication Review & Reconciliation	1,800.00	5,000.00
PHARM.MTM02	Personal Medication Action Plan	1,800.00	5,000.00
	Home/House visits (consultation only. Incidentals to be agreed upon by the parties)		
	Day Time	3,600.00	7,500.00
	Night Time	6,000.00	12,000.00
	Institutional Locum Fees per hour - Daytime	2,000.00	5,000.00
	Institutional Locum Fees per hour - Nighttime	3,000.00	6,000.00
PHARM.IMM01 (certified immunizer)	Immunizations	2,000.00	4,000.00
	Court Appearance	25,000.00	50,000.00

Insurance Billing Codes	**B. PHARMACOTHERAPY SPECIALISTS (M.Pharm & PharmD)**	**Minimum (Ksh.)**	**Maximum (Ksh.)**
PHARM.CDM100	Pharmacotherapy Workup & General Consultation	3,600.00	10,000.00
	Home/House visits (consultation only. Incidentals to be agreed upon by the parties)		
	Institutional Locum Fees per hour - Daytime	4,000.00	10,000.00
	Institutional Locum Fees per hour – Night time	6,000.00	12,000.00
PHARM.ONC01	Oncology Specialist Pharmacist	10,000.00	20,000.00
PHARM.ID01	Infectious disease Specialist Pharmacist	10,000.00	20,000.00
PHARM.PED01	Pediatric Specialist Pharmacist	10,000.00	20,000.00

PHARM.DERM01	Dermatology Specialist Pharmacist	10,000.00	20,000.00
PHARM.GER01	Geriatrics Specialist Pharmacist	10,000.00	20,000.00
PHARM.SURG01	Surgical Specialist Pharmacist	10,000.00	20,000.00
PHARM.REPR01	Reproductive Health Specialist Pharmacist	10,000.00	20,000.00
PHARM.PULM01	Pulmonary Specialist Pharmacist	10,000.00	20,000.00
PHARM.GASTRO01	Gastroenterology and Hepatology Specialist Pharmacist	10,000.00	20,000.00
PHARM.CDM200	Chronic Disease Specialist Pharmacist in Chronic Disease Management Programs for complex patients with multiple conditions on multiple drug therapies eg nephrology, diabetes, cardiovascular disease, hypertension etc	20,000.00	40,000.00
PHARM.AMBC100	Ambulatory Care Specialist Pharmacist	20,000.00	40,000.00
PHARM.NEUROPSY100	Neurology & Psychiatric Specialist Pharmacist	20,000.00	40,000.00
PHARM.NAT01	Natural Medicine Specialist Pharmacist	2,000.00	5,000.00
PHARM.EMS01	Emergency and Critical Care Specialist Pharmacist	10,000.00	20,000.00
PHARM.IMM01 (certified immunizer)	Immunizations	2,000.00	4,000.00
	Court Appearance	50,000.00	100,000.00

Annex One:

Sample Quality Assurance guidelines

No.	Criteria	Standard	Exceptions	Audit procedure
1.	A pharmacist will review and verify from the physician's order, all drug orders prior to drug administration	100%	Drug used from floor stock or emergency cart will be reviewed retrospectively	Pharmacist's initial on order indicate order has been reviewed and verified; concurrent audit of 100 randomly selected physician's order
2.	All drug orders are reviewed to avoid drug application or additive effects	100%	None	Concurrent review of 100 randomly selected drug profiles for drug duplication or drugs of similar effects
3.	All drug orders are reviewed for appropriateness of drug dosage, route, schedule and dosage form	100%	None	Concurrent review of 100 randomly selected drug orders and corresponding patient medication profiles; pharmacist notation (with physician or clinical pharmacist on physician order indicates verification of unusual dosage regimen
4.	All drug orders are reviewed for significant drug interaction	100%	None	Concurrent review of 100 randomly selected patient medication profile for significant drug interactions.
5.	All drug orders checked against known drug allergies or sensitivities listed on the patient medication profile	100%	None	Concurrent review of 100 randomly selected patient medication profile
6	Drug information center provision of quality answers to drug information questions	95%	None	95% of return "User Evaluation Cards" must be positive toward the drug information service
7	Provide background materials for all drugs reviewed by the Pharmacy Therapeutics Committee	100%	New emergency drugs with unquestionable efficacy	Review pharmacy and therapeutics committee background materaisl and actions for 12 month interval
8.	Drug order reviewed and accurately entered on patient medication profile	100%	None	Concurrent review of 100 randomly selected patient medication profile

9.	Stat drug orders dispensed within 15 minutes of receipt	100%	None	Review time clock stamps on 100 randomly selected stat medication orders
10.	All medications are correctly dispensed	100%	None	Review 100randomly selected medications in unit-dose cart against patient medication profile
11.	No physically incompatible admixtures are dispensed	100%	None	Check 100 randomly selected admixtures for incompatibilities
12.	All admixture containers are correctly and completely labeled	100%	None	Check label on 100 randomly selected admixtures and compare with original orger
13.	Patient discharge drug counseling provided at discharge upon request	90%	None	Check discharge summary form in the medical record for pharmacist drug counseling notation concurrent review of 100 randomly selected requests for discharge counseling
14.	Within 24 hours of patient admission, obtain drug history from patient (or from patient's family) and record findings in chart	90%	None	Concurrent audit of 100 randomly selected patients on series which clinical pharmacist are assigned
15	Develop individualized digoxin, theophylline and aminoglycoside dosage regimens, based on available pharmacokinetic information and the patient data base and record recommendations in patient's chart (in progress notes)	90%	None	Concurrent audit of 100 randomly selected patients on series which clinical pharmacist are assigned

Annex Two:

Sample Prescription

[INSERT PRESCRIBERS OR HOSPITAL NAME & ADDRESS] *

Patient File Number: _____

Name: _____ **Date: __/__/____**

Age: _____ **Sex: _____** **Weight: _____Kgs**

Diagnosis: _____

RX

**

Refill: ☐ Times

Prescribed by: **Date Dispensed: __/__/____ Dispensed By:**

MPDB ☐ COC ☐ NC ☐ KVB ☐ No: _____ PPB Registration ☐ Enrolment ☐ No: _____

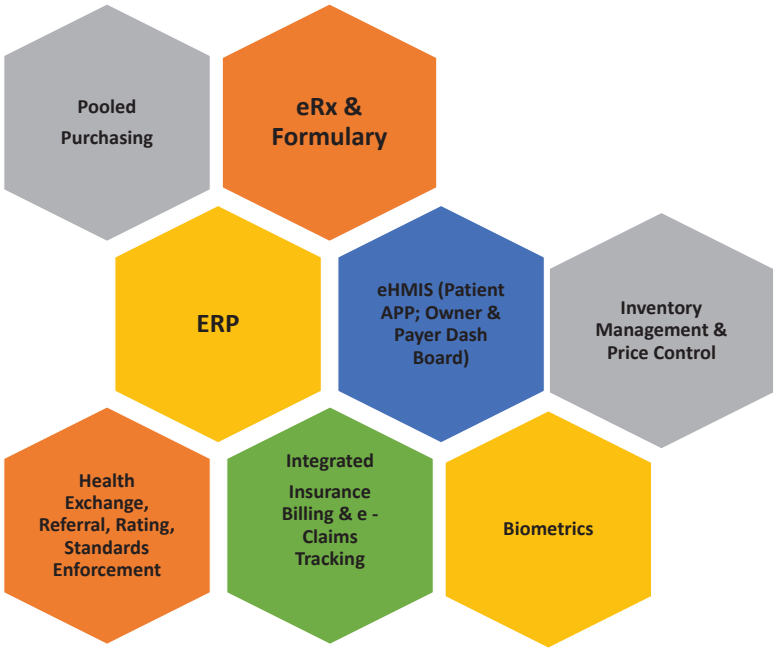
**A Rubber stamp with those details can suffice in absence of a letter headed prescription pad.*

***The medicine name, dose, frequency clearly written*

****If an electronic version, within a HMIS, it must capture all these details*

GREEN CROSS HMIS & DATA CAPRTURING STANDARD

GREEN CROSS Hospital Management Information System (HMIS)



All patient records must be kept in prescribed manner by PPB

All prescriptions dispended must at least record as per the current version of the Green Cross adopted ICD classifications list

Green Cross will need access to HR biometric data as well as scheduled dispensing lists to enforce standards and protocols as well as offer incentives and remedial actions to boost professionalism and public interest

BIBLIOGRAPHY

1. Pharmaceutical Care Practice, 3rd edition.Cipolle,Strand and Morley
2. The Practice of Pharmacy. Donald C.McLeod and William Miller
3. Best Practices for Health-System Pharmacy .American Society of Health System Pharmacist 2000-2001 edition
4. Handbook of Institutional Pharmacy Practice 4th edition. Thomas R.Brown, American Society of Health System Pharmacists
5. ACCP White Paper. Collaborative Drug Therapy Management and Comprehensive Medication Management. Pharmacotherapy 2015;35(4):e39-e50
6. Development of Clinical Pharmacy Key Performance Indicators for Hospital Pharmacists Using a Modified Delphi Approach Annals of Pharmacotherapy 2015, vol.49(6)656-669

APPENDIX 2: Competency framework for all pharmacists

1. Pharmaceutical Public Health Competencies	
Competencies	Behaviours
1.1 Health promotion	1.1.1 Assess the primary healthcare needs (taking into account the cultural and social setting of the patient)
	1.1.2 Advise on health promotion, disease prevention and control, and healthy lifestyle
1.2 Medicines information and advice	1.2.1 Counsel population on the safe and rational use of medicines and devices (including the selection, use, contraindications, storage, and side effects of non-prescription and prescription medicines)
	1.2.2 Identify sources, retrieve, evaluate, organise, assess and disseminate relevant medicines information according to the needs of patients and clients and provide appropriate information
2. Pharmaceutical Care Competencies	
Competencies	Behaviours
2.1 Assessment of medicines	2.1.1 Appropriately select medicines (e.g. according to the patient, hospital, government policy, etc)
	2.1.2 Identify, prioritise and act upon medicine-medicine interactions; medicine-disease interactions; medicine-patient interactions; medicines-food interactions
2.2 Compounding medicines	2.2.1 Prepare pharmaceutical medicines (e.g. extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.)
	2.2.2 Compound under the good manufacturing practice for pharmaceutical (GMP) medicines
2.3 Dispensing	2.3.1 Accurately dispense medicines for prescribed and/or minor ailments and monitor the dispense (re-checking the medicines)
	2.3.2 Accurately report defective or substandard medicines to the appropriate authorities
	2.3.3 Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal
	2.3.4 Dispense devices (e.g. Inhaler or a blood glucose meter)
	2.3.5 Document and act upon dispensing errors
	2.3.6 Implement and maintain a dispensing error reporting system and a 'near misses' reporting system

	2.3.7 Label the medicines (with the required and appropriate information)
	2.3.8 Learn from and act upon previous 'near misses' and 'dispensing errors'
2.4 Medicines	2.4.1 Advise patients on proper storage conditions of the medicines and ensure that medicines are stored appropriately (e.g. humidity, temperature, expiry date, etc.)
	2.4.2 Appropriately select medicines formulation and concentration for minor ailments (e.g. diarrhoea, constipation, cough, hay fever, insect bites, etc.)
	2.4.3 Ensure appropriate medicines, route, time, dose, documentation, action, form and response for individual patients
	2.4.4 Package medicines to optimise safety (ensuring appropriate re-packaging and labelling of the medicines)
2.5 Monitor medicines therapy	2.5.1 Apply guidelines, medicines formulary system, protocols and treatment pathways
	2.5.2 Ensure therapeutic medicines monitoring, impact and outcomes (including objective and subjective measures)
	2.5.3 Identify, prioritise and resolve medicines management problems (including errors)
2.6 Patient consultation and diagnosis	2.6.1 Apply first aid and act upon arranging follow-up care
	2.6.2 Appropriately refer
	2.6.3 Assess and diagnose based on objective and subjective measures
	2.6.4 Discuss and agree with the patients the appropriate use of medicines, taking into account patients' preferences
	2.6.5 Document any intervention (e.g. document allergies, medicines and food, in patient medicines history)
	2.6.6 Obtain, reconcile, review, maintain and update relevant patient medication and diseases history

3. Organisation and Management Competencies

Competencies	Behaviours
3.1 Budget and reimbursement	3.1.1 Acknowledge the organisational structure
	3.1.2 Effectively set and apply budgets
	3.1.3 Ensure appropriate claim for the reimbursement
	3.1.4 Ensure financial transparency
	3.1.5 Ensure proper reference sources for service reimbursement

3.2 Human Resources management	3.2.1 Demonstrate organisational and management skills (e.g. know, understand and lead on medicines management; risk management; self management; time management; people management; project management; policy management.)
	3.2.2 Identity and manage human resources and staffing issues
	3.2.3 Participate, collaborate, advise in therapeutic decision-making and use appropriate referral in a multi-disciplinary team
	3.2.4 Recognise and manage the potential of each member of the staff and utilise systems for performance management (e.g. carry out staff appraisals)
	3.2.5 Recognise the value of the pharmacy team and of a multidisciplinary team
	3.2.6 Support and facilitate staff training and continuing professional development
3.3 Improvement of service	3.3.1 Identify and implement new services (according to local needs)
	3.3.2 Resolve, follow up and prevent medicines related problems
3.4 Procurement	3.4.1 Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality
	3.4.2 Develop and implement contingency plan for shortages
	3.4.3 Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms
	3.4.4 Ensure there is no conflict of interest
	3.4.5 Select reliable supplies of high-quality products (including appropriate selection process, cost effectiveness, timely delivery)
	3.4.6 Supervise procurement activities
	3.4.7 Understand the tendering methods and evaluation of tender bids
3.5 Supply chain and management	3.5.1 Demonstrate knowledge in store medicines to minimise errors and maximise accuracy
	3.5.2 Ensure accurate verification of rolling stocks
	3.5.3 Ensure effective stock management and running of service with the dispensary
	3.5.4 Ensure logistics of delivery and storage
	3.5.5 Implement a system for documentation and record keeping
	3.5.6 Take responsibility for quantification of forecasting
3.6 Work place management	3.6.1 Address and manage day to day management issues
	3.6.2 Demonstrate the ability to take accurate and timely decisions and make appropriate judgments

	3.6.3 Ensure the production schedules are appropriately planned and managed)
	3.6.4 Ensure the work time is appropriately planned and managed
	3.6.5 Improve and manage the provision of pharmaceutical services
	3.6.6 Recognise and manage pharmacy resources (e.g. financial, infrastructure)

4. Professional/Personal Competencies

Competencies	Behaviours
4.1 Communication skills	4.1.1 Communicate clearly, precisely and appropriately while being a mentor or tutor
	4.1.2 Communicate effectively with health and social care staff, support staff, patients, carer, family relatives and clients/customers, using lay terms and checking understanding
	4.1.3 Demonstrate cultural awareness and sensitivity
	4.1.4 Tailor communications to patient needs
	4.1.5 Use appropriate communication skills to build, report and engage with patients, health and social care staff and voluntary services (e.g. verbal and non-verbal)
4.2 Continuing Professional Development (CPD)	4.2.1 Document CPD activities
	4.2.2 Engage with students/interns/residents
	4.2.3 Evaluate currency of knowledge and skills
	4.2.4 Evaluate learning
	4.2.5 Identify if expertise needed outside the scope of knowledge
	4.2.6 Identify learning needs
	4.2.7 Recognise own limitations and act upon them
	4.2.8 Reflect on performance
4.3 Legal and regulatory practice	4.3.1 Apply and understand regulatory affairs and the key aspects of pharmaceutical registration and legislation
	4.3.2 Apply knowledge in relation to the principals of business economics and intellectual property rights including the basics of patent interpretation
	4.3.3 Be aware of and identify the new medicines coming to the market
	4.3.4 Comply with legislation for drugs with the potential for abuse
	4.3.5 Demonstrate knowledge in marketing and sales
	4.3.6 Engage with health and medicines policies

	4.3.7 Understand the steps needed to bring a medicinal product to the market including the safety, quality, efficacy and pharmacoeconomic assessments of the product
4.4 Professional and ethical practice	4.4.1 Demonstrate awareness of local/national codes of ethics
	4.4.2 Ensure confidentiality (with the patient and other healthcare professionals)
	4.4.3 Obtain patient consent (it can be implicit on occasion)
	4.4.4 Recognise own professional limitations
	4.4.5 Take responsibility for own action and for patient care
4.5 Quality Assurance and Research in the work place	4.5.1 Apply research findings and understand the benefit risk (e.g. pre-clinical, clinical trials, experimental clinical-pharmacological research and risk management)
	4.5.2 Audit quality of service (ensure that they meet local and national standards and specifications)
	4.5.3 Develop and implement Standing Operating Procedures (SOP's)
	4.5.4 Ensure appropriate quality control tests are performed and managed appropriately
	4.5.5 Ensures medicines are not counterfeit and quality standards
	4.5.6 Identify and evaluate evidence-base to improve the use of medicines and services
	4.5.7 Identify, investigate, conduct, supervise and support research at the workplace (enquiry-driven practice)
	4.5.8 Implement, conduct and maintain a reporting system of pharmacovigilance (e.g. report Adverse Drug Reactions)
	4.5.9 Initiate and implement audit and research activities
4.6 Self-management	4.6.1 Apply assertiveness skills (inspire confidence)
	4.6.2 Demonstrate leadership and practice management skills, initiative and efficiency
	4.6.3 Document risk management (e.g. critical incidents)
	4.6.4 Ensure punctuality
	4.6.5 Prioritise work and implement innovative ideas

APPENDIX 3: Competency framework for pharmaceutical technologists

Goal 1:	Assist the pharmacist in collecting, organizing, and evaluating information for direct patient care, medication	Goal 19:	Resolve conflicts through negotiation.
Goal 2:	Receive and screen prescription/medication orders for completeness and authenticity	Goal 20:	Understand the principles for managing change.
Goal 3:	Prepare medications for distribution.	Goal 21:	Appreciate the need to adapt direct patient care to meet the needs of diversity.
Goal 4:	Verify the measurements, preparation, and/or packaging of medications produced by other technicians	Goal 22:	Appreciate the benefits of active involvement in local, state, and national technician and other pharmacy organizations.
Goal 5:	Distribute medications.	Goal 23:	Appreciate the value of obtaining technician certification.
Goal 6:	Assist the pharmacist in the administration of immunizations.	Goal 24:	Understand the importance of and resources for staying current with changes in pharmacy practice.
Goal 7:	Assist the pharmacist in the identification of patients who desire/require counseling to optimize the use of medications, equipment, and devices.	Goal 25:	Communicate clearly when speaking or writing.
Goal 8:	Initiate, verify, assist in the adjudication of, and collect payment and/or initiate billing for pharmacy services and goods.	Goal 26:	Maximize work efficiency through the use of technology.
Goal 9:	Purchase pharmaceuticals, devices, and supplies according to an established purchasing program.	Goal 27:	Efficiently solve problems commonly encountered in one's own work.
Goal 10:	Control the inventory of medications, equipment, and devices according to an established plan.	Goal 28:	Display a caring attitude toward patients in all aspects of job responsibilities.
Goal 11:	Assist the pharmacist in monitoring the practice site and/or service area for compliance with federal, state, and local laws; regulations; and professional standards.	Goal 29:	Maintain confidentiality of patient and proprietary business information.
Goal 12:	Maintain pharmacy equipment and facilities.	Goal 30:	Understand direct patient care delivery systems in multiple practice settings.
Goal 13:	Assist the pharmacist in preparing, storing, and distributing investigational medication products.	Goal 31:	Efficiently manage one's work whether performed alone or as part of a team.
Goal 14:	Assist the pharmacist in the monitoring of medication therapy.	Goal 32:	Function effectively as a member of the health care team.
Goal 15:	Participate in the pharmacy department's process for preventing medication misadventures.	Goal 33:	Balance obligations to one's self, relationships, and work in a way that minimizes stress.
Goal 16:	Take personal responsibility for assisting the pharmacist in improving direct patient care.	Goal 34:	Understand the use and side effects of prescription and nonprescription medications used to treat common disease states.
Goal 17:	Demonstrate ethical conduct in all job-related activities.	Goal 35:	Assist the pharmacist in assuring the quality of all pharmaceutical services.
Goal 18:	Maintain an image appropriate for the profession of pharmacy.		

A Resource Paper of the Council on Credentialing in Pharmacy (©2009)

PHARMACEUTICAL SOCIETY OF KENYA

Email: info@psk.or.ke | Mobile: 0722 817 264
www.psk.or.ke