THE SOUTH AFRICAN PHARMACY COUNCIL

Requirements and conditions for the evaluation of alternative models for delivery of chronic medication to patients

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Person responsible for implementing the Criteria (Designation)	Senior Manager Professional Affairs
This framework applies to:	Applicants who wish to apply for approval of alternative models for delivery of chronic medication to patients

DOCUMENT CONTROL

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REVISION RECORD

Date	Version	Revision description

Key Concept	Principle	Relevant Acts and Regulations	Relevant Rules
Access to medicine - a pharmacist or registered person must ensure that no unauthorised persons have access to medicines or scheduled substances	Healthcare providers by virtue of their registration with the various statutory health councils and their regulated scopes of practice have ACCESS to medicine in terms of having medicine under their control. Other than the various legislative scopes of practice of medical practitioners and nurses etc., the Medicines Act provides for the general principles of access to control medicines	Section 22 A of the Medicines Act - Medical Practitioners, Nurses, Pharmacists, Pharmacist Interns and Pharmacist's Assistants. In terms of the *Regulations relating to practice of pharmacy* see Regulations 4 -13 as these provide the scope of practice of persons registered with the South African Pharmacy Council	Good Pharmacy Practice
Accountability - a pharmacist/a person licenced to dispense registered person has a duty to accept responsibility or to account for his /her actions	Due to the fact that in alternative modes of delivery there is the issue of multiple pharmacies, and medicines moving away from the immediate pharmacy premises, the issue of accountability needs to be determined. The pharmacist/PSP performing each phase of dispensing process will be accountable for the medicine dispensed to the patient.	Section 22(5) of the Pharmacy Act states that the Responsible Pharmacist is accountable to SAPC, "unless he/she satisfies the Council that the responsibility for such act, rests upon another pharmacist employed by the owner of the pharmacy Regulations 20-22 of the *Regulations relating to practice of pharmacy* provide the conditions under which a pharmacy shall be conducted. This needs to be interpreted to include when pharmaceutical services are provided from a pharmacy to another point of collection/delivery	Good Pharmacy Practice

Key Concept	Principle	Relevant Acts and Regulations	Relevant Rules
Confidentiality – a pharmacist or registered person has a duty to keep a patient's personal health information private unless consent to release the information is provided by the patient.	A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to a patient and may not disclose such information except under certain prescribed circumstances. Confidentiality is the protection of personal health information and not telling others including co-workers, friends, family, etc.	Patients' Right Charter Right to confidentiality and privacy "Information concerning one's health, including information concerning treatment may only be disclosed with informed consent, except when required in terms of any law or an order of the court."	Ethical Rule 9 Code of Conduct Rule 1.3
Counselling – a pharmacist or registered person has a duty to furnish information and counsel the patient or caregiver on the safe and effective use of medicine supplied by him/her.	A pharmacist or registered person has a duty to provide medication information orally or in writing to the patients or their representatives on directions of use, advice on side effects, precautions, storage, diet and life style modifications When medicines are provided by any other means (for example, by post, courier, to caregiver or to a patient's agent) ensure that you provide the same standard of information, advice and services that would have been received by a patient present in a pharmacy and in direct face to face consultation with a pharmacist. A pharmacist or registered person must ensure that, where available a patient information leaflet is provided.		Ethical Rule 1 Good Pharmacy Practice

Key Concept	Principle	Relevant Acts and Regulations	Relevant Rules
Control of medicines - a pharmacist or registered person must at all-time exercise proper and/or reasonable care in respect of and control over medicines.	A pharmacist or registered person has a duty to supervise the safety, security, purchasing, storage and dispensing medicine	Regulation 36 of the General Regulations under Medicines Act – Responsible Pharmacist shall supervise the safety, security, purchasing, storage and dispensing medicine in a hospital See scope of practice of a Pharmacist in the *Regulations relating to the practice of pharmacy*	Ethical Rule 4 Code of Conduct Rule 1.9 Good Pharmacy Practice
Distribution of medicines – pharmacist or registered person has a duty to maintain quality, safety and efficacy of medicines. Medicine may only be stored at sites that comply with applicable storage conditions	A pharmacist or registered person must ensure that medicines are packaged in such a manner that it will guarantee the safety, quality and efficacy of medicines in accordance with the registration requirements for such medicine in terms of the Medicines Act, throughout the delivery process; A pharmacist or registered person must ensure that a report back system is introduced to ensure that problems with medicine distribution and delivery are detected timeously; A pharmacist or registered person must ensure that a control system is implemented that will enable the pharmacist to detect and correct a delay in the delivery process. A pharmacist or registered person must ensure that medicines which are prescribed for acute ailments or conditions (i.e. immediate need, not repeatable and non-chronic conditions) shall not be delivered to patients by mail/courier A pharmacist or registered person must ensure that medicines that are registered to be stored	See scope of practice of a Pharmacist in the *Regulations relating to the practice of pharmacy*	Code of Conduct Good Pharmacy Practice

	in conditions under 8°C shall not be delivered to patients by mail/courier unless cold chain management is ensured.		
Generic substitution - A pharmacist shall inform all members of the public who visit his/her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine	Dispense an interchangeable multi-source medicine instead of the medicine prescribed by an authorised prescriber, unless expressly forbidden by the patient or authorised prescriber. A pharmacist shall not sell an interchangeable multi-source medicine if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine	Medicines Act and Section 22F and Regulations relating to transparent of medicines (dispensing fee for pharmacists) (GNR. 553 of 30 April 2004). Pharmacy Act 42 Charges by pharmacists,43 Commission of Rx	Good Pharmacy Practice Code of Conduct
Patient safety or well-being of patient- A pharmacist's prime concern in the performance of his/her professional duties must be for the wellbeing of both the patient and other members of the public	The pharmacist's goal in the provision of medicine therapy should be to achieve appropriate therapeutic outcomes that contribute towards the patient's health and quality of life. The attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist should therefore be focused on primarily benefiting the patient and the public as a whole.	Patient's Rights Charter	CCPO 1.1 ; GPP 2.8
Record keeping/ Disposal - a pharmacist or registered person must ensure that there is a system is in place to guarantee the confidentiality of data relating to individual patients. A pharmacist must ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.	A pharmacist or registered person must take the necessary action to prevent the acquisition and misuse of personal information relating to patients. Disposal of any materials containing or including patient specific or confidential information must be conducted in such a manner as to preserve patient confidentiality.	In terms of the National Health Act 61 of 2003 all information concerning patients, including information relating to his/her health status, treatment or stay in a health establishment is confidential	GPP 2,92.91-2.92 ; 2.30 4.4 (1-17)
Privacy – a pharmacist has both ethical and legal obligations to respect the confidential nature of their patients'	Patient health information must be collected, recorded and used in a manner that protects confidentiality and privacy.		GPP; 2.14; 2.30; 2.8;1.2.13

personal health information and protect the privacy of the individual.	Patient medication records must respect the patient's privacy.		
Patient autonomy / right to choice –a pharmacist or registered person must recognize and support the rights of their patients to choose.	Respect the rights of individual patients to participate in decisions about their treatment and encourage them to do so. Patient must give consent to participate in the program regarding the indirect supply of medicine and may exit the program at any time	Patients' Rights Charter	GPP 1.6.1 ©© ; 2.8.1 2.7.3.8.11 2.8.1
Returned stock or uncollected medicines – a pharmacist or registered person must ensure that there is a system in place to manage the uncollected, spoilt, damaged, and incorrect medicine's	A pharmacist should not re-dispense a medicine, previously returned to the pharmacy by another patient, which had been in that patient's possession. A pharmacist or registered person must ensure that there is a control system in place to manage uncollected medicines and must ensure that the uncollected medicines are returned to a pharmacy		Good Pharmacy Practice
Professional independence – a pharmacist or registered person should refrain from entering into, or being part of any transaction or agreement, which may reflect negatively on his or her professional independence or the professionalism, or ethics of the profession as a whole**.**	A pharmacist is responsible and accountable for the work and all services provided under his/her direct supervision. This includes all dispensing activities undertaken or directly supervised by him/her regardless of the packaging, manufacturing or compounding process involved.		CCPO 6.
Storage of medicines - a pharmacist or registered person must at all times ensure that medicines are only stored at sites that comply with applicable storage conditions	Medicine may only be stored at sites that comply with applicable storage conditions		Good Pharmacy Practice

Abbreviations

1. GPP= Rules relating to Good Pharmacy Practise
2. COGC= Rules relating to the Code of Conduct
3. Ethical rules = Acts and omissions which may lead to disciplinary action
4. Medicines Act=Medicines and Related Substances Act 101 of 1965
5.Pharmacy Act= Pharmacy Act 53 of 1974
6. NHA=National Health Act, 61 of 2003
7. POPI = Protection of Personal Information Act, 4 of 2013

Note –

This framework identifies the key concepts, principles and the supporting regulatory provisions that govern the pharmaceutical profession and any model of delivery of medicine to patients. Council acknowledges that there are high level principles to support the use of alternative pick up points to realise the right of access to healthcare and hence to medicine. This framework serves as a guidance document of the regulatory provisions ALREADY in place to which any proposed alternative model of delivery of medicine to patients must comply.