Pharmaceutical Services Qualification Standards

(19 standards, 78 sub-standards)

(Applies only to retail pharmacies serving health insurance beneficiaries)

Chapter I

Governance and Leadership (GL) (13 standards, 55 sub-standards)

This chapter focuses on the structure, roles and responsibilities of the organization's governance and senior leaders.

- Governance structure and functions
- Leadership structure and functions.
- Lead pharmacist credentials and role.
- Organization's mission, vision and strategy.
- Safety of stored medications.
- Manpower development.
- Quality management program
- Chronic disease management.
- Digitalization program and compliance with CCHI.

GL.1. The retail pharmacy's Governance is presented in a document.

GL.1.1. The document highlights the governance (ownership) structure.

GL.1.2. The document describes the governance rules and responsibilities.

GL.1.3. The document states any conflict of interest from governance members.

GL.1.4. Meetings of the governing body are documented reflecting compliance with regulators and evidence of improvement projects.

Intent:

The governing body (owner(s), board of directors) should highlight its structure, roles, and responsibilities in a written document. Roles and responsibilities include the development of the mission and vision, approval of strategic and operational plans and budget, scope of services, the risk management program, and the operational policies and procedures. Roles and

responsibilities also include appointing the pharmacy director and defining any leadership delegation authority in the absence of the center's director.

Evidence of compliance:

1) Governance structure and function document.
2) Terms of reference of board meetings.
3) Recent minutes of meeting.
4) Signed conflict of interest document.

GL.2. Leaders are identified in an updated organizational chart.

GL.2.1. The leaders are identified by name and designation in an organizational chart.

GL.2.2. The organization shares the credentials and contacts of its leaders with CCHI.

Intent:

The organizational chapter reflects the organizational behavior and provides an image of its functionality. Not infrequently, CCH classification and qualification staff contact providers for regulatory issues, hence the need to have the names, credentials, and contact information of the following:

- CEO
- Senior pharmacist.
- Compliance officer.

Evidence of compliance:

1) Copy of organizational chart.
2) Contacts and credentials of leaders.

GL.3. The retail pharmacy shares its updated strategy with CCHI.

GL.3.1. The retail pharmacy shares its mission, vision and values.

GL.3.2. The retail pharmacy shares its 3 – 5 years' strategic plan with performance indicators.

GL.3.3. The retail pharmacy shares its marketing strategy with CCHI.

Intent:

The organizational strategy sets the direction for the organization and establishes priorities for its business and improvement initiatives. It highlights the organization's goals and objectives that drives the integration and cooperation of the departments. The overall strategy is further projected in the departmental goals and objectives. The marketing strategy should be designed to reflect initiatives to improve the health and quality of life for the beneficiaries.

Evidence of compliance:

1) Mission, vision and value document.
2) Organizational strategy (3 – 5 years) with performance indicators document.
3) Marketing strategy document.

GL.4. A licensed pharmacist directs the pharmaceutical services.

GL.4.1. The director is a bachelor graduate with a minimum of 3 years' experience post-graduation, registered with SCFHS and licensed by MOH.

GL.4.2. The director ensures the availability of an updated insurance drug formulary covering the demands of its population.

GL.4.3. The director ensures the availability of drug information resources for the pharmacy staff.

GL.4.4. The director designs a pharmaceutical purchasing plan.

Intent:

To ensure the safe storage and dispensing of medications, pharmaceutical services must be directed by a licensed and qualified pharmacist. The director should ensure the availability of all the generic medications required by its population. This requires having an updated drug formulary and a purchasing plan that avoids any medication shortage. Pharmacists and assistants should have a backup pharmaceutical information resource, either as an online service or through known centers such as the Saudi poison control center.

Evidence of compliance:

1) Pharmacy director's MOH licensure and SCFHS registration.
2) Updated insurance drug formulary.
3) Evidence of formulary drugs availability list for the preceding year.
4) Evidence of pharmaceutical resources support for the pharmacy staff.

GL.5. The retail pharmacy implements policies and procedures to ensure the quality and safety of the stored pharmaceutical products.

GL.5.1. Medications are stored within the temperature range recommended by the manufacturer.

GL.5.2. Medications are secured in clean storage areas.

GL.5.3. High alert, look alike, and sound alike medications are secured and stored separate from other medications.

GL.5.4. Expired and recalled medications are not stored in the pharmacy.

GL.5.5. Sold medications are not allowed to be returned to the pharmacy under any circumstances.

Intent:

The retail pharmacy should have policies and procedures in place to manage the safe storage of pharmaceuticals and recalled or expired ones. Medications can lose its potency if not stored in the appropriate environment as recommended by the manufacturer. Loss of potency during storage may influence pharmaceutical efficacy and safety. Proper environmental control (i.e., proper temperature, light, and humidity; sanitation, ventilation, and segregation conditions) must be maintained wherever pharmaceuticals are stored. Vaccines are more susceptible to temperature fluctuations, therefore it is best to be stored separately from other refrigerated medications that are in a more demand for opening and closing the refrigerator. All medication refrigerators must be connected to an electrical outlet that has an alternate power supply that starts immediately if there is an interruption to the main power supply. The policies include a process for dealing with medications that were affected by out of range temperature fluctuations. To avoid risk from improper dispensing, special precautions should be taken to avoid storing

medications that look alike and sound alike in the same place. To avoid risk from confusing high alert medications with others, high alert medications should be stored well identified and separate from other medications in a locked store. Recalled and expired medications are not stored inside the pharmacy to avoid its inadvertent dispensing.

Evidence of compliance:

1) Policy and procedure on medication storage.
2) Policy and procedure on expired medications.
3) Policy and procedure on medication recall.
4) Pharmacy inspection (can be done virtually).

GL.6. Controlled and psychotropic medications' storage, dispensing and accountability are guided by a policy and procedure conforming with local laws and regulations.

GL.6.1. Controlled and psychotropic medications are stored behind locked steel doors or inside steel cabinets with double locks and/or double doors.

GL.6.2. Controlled and psychotropic medications are dispensed and re-dispensed against the MOH approved prescription form that is signed by an authorized physician.

GL.6.3. The policy clearly describes the required auditing process to ensure how controlled and psychotropic medications are accounted for as per directives from SFDA and MOH.

GL.6.4. The retail pharmacy appoints a Saudi pharmacist or assistant pharmacist to manage controlled and psychotropic medications.

Intent:

Controlled and psychotropic medications are those agents, either naturally or compounded, that are included in schedule #1 and schedule #2 in the SFDA regulations manual. The pharmacy must implement the related rules and regulations of the SFDA and MOH as stated. Medications are stored and secured behind locked steel doors or inside steel cabinets with double locks and/or double doors all over the center. The documentation process should be maintained for all related steps, such as requisition, procurement, ordering, dispensing, distribution, endorsement, registration, and discarding of the unused portion and empty containers. All medication

processes related to psychotropic and controlled medications must be performed by a registered Saudi pharmacist or assistant pharmacist.

Evidence of compliance:

1) Policy and procedure on managing controlled and psychotropic medications.
2) Credentials of controlled and psychotropic medications pharmacist / assistant.
3) Virtual inspection of controlled and psychotropic medications' storage.

GL.7. Medication dispensing follows a policy and procedure, complying with local laws and regulations.

GL.7.1. The dispensing pharmacists ensures the beneficiary's eligibility before dispensing.

GL.7.2. Medications are dispensed against a complete prescription including beneficiary's name, age, allergies, weight, clinical diagnosis, dispensing duration and prescriber's signature.

GL.7.3. Medications are dispensed according to approved generic nomenclature.

GL.7.4. Chronic medications are re-dispensed only with an approved prescription from payer or provider.

GL.7.5. Appropriateness review is done by the pharmacist before dispensing.

GL.7.6. The pharmacist / assistant has access to prescribers to clarify orders, when needed.

Intent:

To avoid fraud, the pharmacist must ensure the beneficiaries' identity and eligibility before dispensing medications. Dispensing should be against a complete and valid prescription written by an authorized physician. The prescription should include the elements of the sub-standard GL.6.2. To avoid medication duplication, re-dispensing of chronic medications is done only against a valid prescription from payers or providers. Medications are dispensed generically against the medication list approved by the payers. To eliminate beneficiary's harm from inappropriate medications, a licensed pharmacist must evaluate the appropriateness of prescriptions before dispensing. This includes ensuring the completeness of the prescription, verifying with the prescribers any unclear orders, orders for unapproved indications, dosage

concerns, duplications, or possible interactions. Therefore, the retail pharmacy must keep contact information for prescribers, to be contacted when needed.

Evidence of compliance:

1) Policy and procedure on dispensing.
2) Contact list of prescribers.

GL.8. The Pharmacy director ensures the continuous medical education of its staff.

GL.8.1. The director performs an educational assessment needs for the staff yearly.

GL.8.2. The director develops and ensures the execution of an educational calendar, fulfilling the staff needs.

GL.8.3. Employee records show documented evidence of education and training.

Intent:

Staff professional development is a strong driver for improving the services rendered by the pharmacy and reduces medication errors. The director should assess the staff educational needs assessment before formulating an educational calendar. The topics in the calendar must be delivered by subject matter experts. Evidence of education should be available in staff files.

Evidence of compliance:

1) Educational needs assessment document.
2) Yearly educational calendar.
3) Policy on staff files.
4) Sample of attendance certificate.

GL.9. The retail pharmacy director develops and monitors the implementation of a quality and patient safety program.

GL.9.1. The program is based on the pharmaceutical activities' performance indicators and input from beneficiaries and staff.

GL.9.2. The program utilizes a performance improvement tool.

GL.9.3. The retail pharmacy conducts at least 2 performance improvement programs yearly.

GL.9.4. Program outcomes are discussed with the staff monthly.

GL.9.5. Quarterly reports on the pharmacy performance are submitted to governance including indicators' findings and actions for improvements.

Intent:

Pharmacies must maintain its medication integrity to ensure patient safety. A quality and patient safety program should be developed by the pharmacy director and implemented by its staff. The program relies on the reporting and collection of the relevant medication errors and safety data and the targeted improvement programs. A performance improvement tool must be uniformly utilized in the pharmacy such as "PDCA". Staff are educated on the tool and at least 2 performance improvement projects are completed every year. Staff should be informed of the program's findings in formal meetings at least monthly. The pharmacy owner(s) or board of directors (governance) are responsible for the quality of medications and patient safety, therefore, they must receive regular reports on the program at least quarterly. Improvement actions are supported by the governance as evidenced by their approval and resource allocation.

Evidence of compliance:

1) Quality and patient safety program.
2) Monthly staff meeting agenda.
3) Sample, quarterly submission report to governance.

GL.10. The retail pharmacy director measures its performance.

GL.10.1. The pharmacy has a policy on reporting prescribing medication errors to prescribers.

GL.10.2. The pharmacy implements a policy on collecting medication errors related to procurement, storage and dispensing.

GL.10.3. The pharmacy collects information on beneficiaries' experience.

GL.10.4. The pharmacy collects information on its staff satisfaction.

GL.10.5. The director compiles a yearly report on the pharmacy's performance highlighting areas for improvement.

Intent:

In order to efficiently and effectively manage the pharmacy services, the director must measure its performance utilizing the suitable tools. The director should develop a policy and procedure on the reporting and collection of medication errors whether arising from outside prescriptions or from procurement, storage and dispensing internal activities. The director regularly collects information on beneficiaries' experience and staff satisfaction. The director must comply a yearly report on the pharmacy's performance with emphasis on how to improve its services to beneficiaries, avoid medication errors and enhance staff satisfaction in the following year.

Evidence of compliance:

1) Policy on medication errors reporting.
2) Monthly medication errors' reports to prescribers and staff.
3) Beneficiaries' experience reports.
4) Staff satisfaction reports.
5) Yearly pharmacy performance report.

GL.11. A policy and procedure guide the execution of chronic disease management program for beneficiaries.

GL.11.1. The service is provided in an isolated space inside the pharmacy to maintain beneficiary's privacy and confidentiality.

GL.11.2. A qualified Clinical pharmacist provides the service.

GL.11.3. The program implements disease specific clinical practice guidelines.

GL.11.4. Medication dosage or frequency of administration are not changed without permission from the treating physician.

GL.11.5. The pharmacy keeps a register of beneficiaries' demographics, clinical information and treating physicians.

GL.11.6. The program is monitored by disease specific performance indicators.

Intent:

Providing chronic disease management to beneficiaries is an optional service that requires a dedicated knowledgeable team and an implemented policy and procedure that is compliant with the sub-standards GL.00.1. through GL.00.6.

Evidence of compliance:

1) Policy and procedure on chronic disease management by the pharmacist.
2) Pharmacy design plan or actual photo of chronic disease management area.
3) Credentials of pharmacists executing the program.
4) Disease specific indictors' outcomes.

GL.12. The retail pharmacy ensures compliance with CCHI's digitization requirements.

GL.12.1. The retail pharmacy is connected electronically with the payers.

GL.12.2. The retail pharmacy utilizes "CRM" application for reporting its activates with CCHI.

GL.12.3. The retail pharmacy approves its documents integrity through CCHI's minimum data set, MDS and data quality maturity index, DQMI portals.

GL.12.4. The retail pharmacy integrates (or ready to integrate) with NPHIES.

GL.12.5. The retail pharmacy ensures serving the beneficiaries in the event of interruption of its electronic system (business continuity plan).

Intent:

The retail pharmacy need to ensure its connectivity and full access to CCHI's CRM application. This is the main portal connecting providers with CCHI for information exchange including the classification process and receiving and replying to beneficiaries' complaints.

NPHIES is the state of the art information management platform intended to integrate the providers and payers with a 2-way communication and shall produce a wealth of information amenable to business and artificial intelligence. Confirming service eligibility, pre-authorization

and claim management shall all take place through this unified medical insurance platform. NPHIES shall provide the medical insurance market with medical records inter-operability. The connectivity and utilization of CCHI's applications is crucial for achieving CCHI's regulatory strategies. The retail pharmacy need to ensure the quality of its data and its compliance with the minimum data set requirements of CCHI "MDS" and "DQMI" portals. It is crucial to maintain the services to beneficiaries and avoid service interruptions. The retail pharmacy must have a business continuity plan. The plan includes a pro-active approach including cyber-security, regular data backup and a remote recovery IT system. The retail pharmacy must also have a manual dispensing plan in case all pro-active measures fail. Staff must be competent on using the manual back up plan.

Evidence of compliance:

1) Log reports with CRM.
2) Log reports from MDS and DQMI (phased out when fully integrated with NPHIES).
3) NPHIES integration reports.
4) Business continuity plan.
5) Staff competency on the manual backup plan.

GL.13. The retail pharmacy complies with CCHI rules for claims' submission to insurance companies and TPA's.

GL.13.1. Claims are organized following the CCHI Billing System and conforming with the minimum data set requirements.

GL.13.2. Claims are submitted within 45 calendar days from the end of the patient's episode.

GL.13.3. Re-submission of rejected claims should not exceed 30 calendar days from receiving the rejection notification from the insurance company or TPA.

Intent:

CCHI has unified the process of claims submissions to the insurance companies and TPA's, including contents and time frames. The Saudi billing system should be followed. The quality of submitted documents is also controlled by CCHI minimum data set. All claims are submitted within 45 calendar days from closing the patient's episode. Resubmission for rejected claims should be within 30 calendar days of receiving the notification from the insurance company or TPA.

Evidence of compliance:

1) Average Claims' submission and resubmission rates.
2) Claims format conforming to MDS and Saudi billing c

Chapter II

Beneficiary's Rights (BR) (3 standards, 14 sub-standards)

This chapter focuses on the pharmacy preparedness to exceed beneficiaries' expectations and enhance their medication knowledge and safety.

BR.1. The retail pharmacy ensures the customer experience focus of its staff.

BR.1.1. Staff receive "on boarding" customer focused education relevant to their job function.

Personal file review

BR.1.2. The retail pharmacy conducts a customer focus educational program for its staff at least yearly.

BR.1.3. Staff are tested competent on handling registration and approvals of beneficiaries.

BR.1.4. Customer centricity is included in the staff probationary and yearly evaluations.

Intent:

The retail pharmacy's business should be focused on the beneficiaries. The retail pharmacy should ensure the employees' understanding of beneficiaries' centricity. Therefore, the retail pharmacy should conduct a yearly customer focus program for all its employees. The retail pharmacy should educate the pharmacist / assistants on registration and approval requirements (eligibility queries, inclusion and exclusion criteria, deductibles, policy limits) and any additional operational mandates. Staff should be tested competent on this education, initially and yearly thereafter. Customer centricity is included in the employee's probationary and yearly evaluation.

Evidence of compliance:

1) Customer focus general educational program.

2) Competency assessment of pharmacist / assistants.

3) Evidence of customer centricity is included in employees' probationary and yearly evaluation.

BR.2. Beneficiaries receive education on dispensed medications.

BR.2.1. Dispensed medications are labelled with the beneficiary's name, medication dose, frequency, duration of use and any special remarks.

BR.2.2. The beneficiary receives education on the medication use as prescribed, as well as any special remarks related to storage, timing with food and side effects.

BR.2.3. The beneficiary receives information on method of serious side effects reporting.

BR.2.4. The beneficiary receives information on how to safely store and dispose medication packages, especially needles.

BR.2.5. The beneficiary is given time to ask questions when needed.

BR.2.6. The retail pharmacy performs periodic beneficiaries' experience survey including education given on medications.

Intent:

A crucial safety step in medication management is educating the beneficiary on the medication dispensed. The pharmacist / assistant must ensure the beneficiary's full understanding on the use, interactions, storage and any anticipated side effects. The beneficiary must be given time to ask related questions as well. The pharmacy setup should provide the privacy and confidentiality required for this educational process. The pharmacy should also provide access to safe disposal of needles and lancets.

Evidence of compliance:

1) Photo of the dispensing area.
2) Beneficiaries experience survey highlighting education on medication.

BR.3. Beneficiaries acknowledge any additional financial requirements.

BR.3.1. Staff explain the deductible pay, and any additional payments to the beneficiaries, before receiving the service.

BR.3.2. Beneficiaries sign an agreement for paying additional services, outside the scope of their insurance policy, before receiving the service.

BR.3.3. Beneficiaries are provided with an itemized service bill for paid services, when requested.

BR.3.4. The process is evaluated as part of the beneficiaries' experience survey.

Intent:

It is not uncommon that beneficiaries ask for additional services such as requesting a specific medication brand or requesting injection services or chronic disease management. The staff should clearly explain the deductible payments. Beneficiaries have the right to ask for the

services' prices and an itemized bill for medications dispensed and any additional services provided.

Evidence of compliance:

1) Beneficiaries' experience survey reports.

Chapter III

Governmental Requirements (3 Standards, 9 sub-standards)

The standards in this chapter are the pre-requisites for the retail pharmacies' qualification and include mandatory governmental regulatory documents.

The standards in this chapter require 100% compliance from the retail pharmacy. Any requests for initial or renewal of classification shall be denied if the compliance is below 100%.

GR.1. The organization is licensed to operate in KSA by the Ministry of Health "MOH".

GR.1.1 The organization has a final MOH license to provide pharmaceutical services in KSA, including additional services such as provision of chronic disease management.

GR1.2. All pharmacists / assistants are classified by SCFHS and licensed by MOH.

Intent:

The organization is required to maintain its MOH license and similarly the licenses of all its healthcare providers.

Evidence of Compliance:

1) Valid MOH final license.
2) Valid pharmacists' / assistants' SCFHS classification and licensing by MOH.

GR.2. The organization submits a complete set of Governmental requirements.

GR.2.1. The organization submits a request for classification endorsed from the Chamber of Commerce.

GR.2.2. The organization submits a current and valid commercial register.

GR.2.3. The organization submits a current income and zakat certificate.

Intent:

Compliance with Governmental requirements is a must. The documents in the sub-standards GR.2.1. through 2.3. are crucial for the classification process.

Evidence of Compliance:

1) Request for endorsed accreditation / classification from the Chamber of Commerce.
2) Current and valid commercial register (CR).
3) Current income and zakat certificate.

GR.3. The organization complies with the CCHI's Bylaws.

GR.3.1. The organization signs a compliance statement for the CCHI's "Unified Contract".

GR.3.2. The organization signs a compliance statement for the CCHI's "Regulations of the Cooperative Health Insurance Law".

GR.3.3. The organization signs a compliance statement for the CCHI

قائمة المقابل المالي السنوي لاعتماد مقدمي خدمات الرعاية الصحية

GR.3.4. The organization signs a compliance statement for the CCHI's supportive statements for the above documents.

Intent:

The organization must comply with all regulatory documents from CCHI including the "Unified Contract" and rules and "Regulations of the Cooperative Health Insurance Law" and any supplemental directives related to both documents. The organization must endorse both documents, and any related supplements, by signing a compliance statement at registration.

Evidence of Compliance:

1) Signed compliance statement for the CCHI's "Unified Contract". العقد الموحد
2) Signed a compliance statement for the CCHI's "Regulations of the Cooperative Health Insurance Law".
3) Signed a compliance statement for the CCHI's:
قائمة المقابل المالي السنوي لاعتماد مقدمي خدمات الرعاية الصحية
4) Signed statements for individual regulation supplements.