MODULE 10 | MEDICINES, PHARMACY, CONTROLLED DRUGS AND BLOOD SERVICES

Controlled Drugs Lawful Access, Safe Custody and Complete Records

Practical hospital governance in Punjab, Pakistan

44

LECTURE

Maintain access for legitimate treatment.
Account for every receipt, use, return and disposal.

AUTHOR

Dr Qurban Hussain Khan

Edition 1.0 | 5 October 2026

SELF-STUDY PDF

Control access without obstructing lawful care

For the Medical Superintendent (MS): controlled-drug governance combines lawful access, secure custody, patient-linked records and prompt action on discrepancies.

- Check the authority for each medicine and activity.
- Follow receipts, transfers, use and remaining stock.
- Keep valid orders, registers and correction records.
- Respond correctly to loss and suspected diversion.

OFFICIAL SOURCE

A principle tied to a named law, standard or official guidance.

WORKING METHOD

A practical control or teaching format to adapt to the authorised system.

TEACHING CASE

An invented hospital example, used to practise applying the correct process.

Study output

A controlled-drug authority file and a checked custody-and-records review.

Module 10 | Presentation 3 of 4. Allow 45-60 minutes with exercises. All explanations are on the pages; check the cited sources before live use.

Four forms of control

The same medicine may be subject to several requirements.

Control	Main question	Common mistake
Drug regulation	Is this product and supply channel lawful?	Assuming any licensed seller can supply every product.
Controlled-substance law	Who may possess, supply, prescribe or administer it?	Treating a hospital designation as complete authority.
Clinical safety	Is its use safe for this patient?	Treating secure storage as proof of safe treatment.
Financial control	Who may buy, pay, return or write off stock?	Treating clinical need as financial sanction.

Clinical high-risk medicines and legal controlled-drug schedules are different categories; check both.

WORKING METHOD | Illustrative material is identified in the text.

Federal and Punjab legal sources

Read the applicable instruments together and retain current authorisations on the hospital file.

Federal framework

- The Control of Narcotic Substances Act, 1997 and the 2001 regulatory rules address controlled activities and professional supply.
- This lecture cites the specific 2001 rules used for prescriptions, registers, custody and loss reporting.

Punjab framework

- Punjab also has the Control of Narcotic Substances Act 2025, with a 2026 amendment.
- Check current provincial requirements and notified authorities with the competent regulator and legal office. Do not assume one framework displaces the other.

A clinical need does not settle regulatory jurisdiction. Record the applicable route before procurement and routine supply.

Sources: **C1**: Act and regulatory rules | **C2**: Act 2025 and amendment

Build an authority file for the service

Suggested evidence checklist for the chief pharmacist and MS.

01 Medicine

Name, form, strength and applicable legal schedule.

02 Activity

Purchase, possession, storage, supply or administration.

03 Authority

Valid licences, permissions and institutional orders.

04 People

Authorised prescribers, suppliers and custodians.

05 Conditions

Quantity, location, period and reporting conditions.

06 Contacts

Competent Authority, Inspector and escalation route.

Recheck the file when the medicine, premises, personnel, scope or authorisation changes.

WORKING METHOD | Illustrative material is identified in the text.

Do not copy an ICT quota procedure into Punjab

ICT means Islamabad Capital Territory. A procedure's stated scope matters.

What the published DRAP SOP says

- The hospital-allocation document is expressly directed to tertiary care hospitals located in ICT.
- It does not establish that every Punjab hospital follows the same allocation application.

What a Punjab hospital should establish

- Obtain the applicable written supply and approval route for its setting and the product concerned.
- Distinguish hospital procurement permissions from a manufacturer's allocation, import or production authority.

Keep the regulator's written clarification where the route is uncertain. A neighbouring hospital's practice is not an authorisation.

Sources: **C3**: title, scope and hospital checklist

Professional roles and orders

The 2001 rules distinguish professional supply, prescriptions and institutional requisitions.

Rule	Subject	Administrative meaning
23	Professional supply	Check the category of authorised supplier and applicable professional conditions.
24	Prescription	An authorised practitioner gives a patient-specific treatment order.
25	Institutional requisition	An eligible person requests stock for treatment within the institution.
38	Register	The medicine movement must remain traceable at the relevant location.

A ward stock requisition does not replace the patient's prescription or administration record.

Sources: **C1**: rules 23-25 and 38

Plan legitimate requirements

Suggested forecast and service-readiness review.

01 Services

Identify emergency, anaesthesia, pain and other approved services.

02 Use

Review patient-linked consumption and unexplained variation.

03 Gaps

Account for stock-outs and unmet clinical need.

04 Lead time

Allow for the actual approval and delivery process.

05 Limits

Check quantity and storage conditions in authorisations.

06 Continuity

Define the lawful backup route and escalation point.

Low recorded use during a stock-out does not show low patient need.

WORKING METHOD | Illustrative material is identified in the text.

Receive and record controlled stock

Suggested receipt workflow; use the approved statutory forms and local procedure.

1	**Verify**	Check the supplier, product, order and any required permission.
2	**Inspect**	Check quantity, form, strength, batch, expiry, seals and transport condition.
3	**Record**	Enter receipt in the required register and link it to the invoice and receipt record.
4	**Secure**	Place accepted stock in its authorised secure location; isolate any discrepancy.

Do not sign for an unchecked quantity. A receipt entry must match the physical stock and supporting documents.

Sources: **C1**: rules 26, 38 and 42

Secure custody and access

Rule 42 requires secure storage and control over access.

Legal baseline

- Keep relevant drugs or chemicals in a vault, safe or other prescribed secure storage while in custody or control.
- Follow written directions of the Competent Authority concerning keys, combinations and unauthorised access.

Suggested hospital controls

- Name custodians for each location and shift; keep a clear key or access handover.
- Limit spare-key access, investigate compromised access and maintain approved emergency access arrangements.

Security must continue in wards, theatres and emergency areas as well as the central pharmacy.

Sources: **C1**: rule 42

WORKING METHOD

A safe shift handover

Suggested local control. The count frequency and participants should be defined in the approved procedure.

Count	Check physical stock by medicine, strength and formulation against the recorded balance.
Review	Account for receipts, issues, administration, returns, breakage and waste since the last check.
Sign	Record time, findings and the people making the handover; do not certify an unperformed check.
Escalate	Record and report an unresolved discrepancy. Preserve records and safe patient access.

Shift counts support control; they are not presented here as a universal statutory count interval.

WORKING METHOD | Illustrative material is identified in the text.

Prescription checks under rule 24

Use the prescribed format and all applicable fields; this is a practical summary, not a substitute for the rule.

Check	What to verify
Prescriber	Authority, identity, qualifications, registration details, signature and date.
Patient	The correct named patient and required identifying details.
Medicine	Name, quantity, form and strength, with clear treatment directions.
Validity	Issue date, permitted filling period and any authorised refill conditions.

Clarify unclear or unusual instructions with the prescriber. Never infer missing authority.

Sources: **C1**: rule 24(1)-(3)

Institutional requisitions under rule 25

A requisition is a request for the ward or dispensary; retain the link to its supply.

Requirement	Plain-language check
Eligible requester	Institution pharmacist, practising practitioner or person in charge of the ward.
Clear request	Requester and capacity; medicine name, quantity, form, strength and location.
Authentication	Requester signs and dates it.
Countersignature	The supplying pharmacist or a medical practitioner countersigns it.

Receipt at a ward and administration to a patient are separate movements and need their own evidence.

Sources: **C1**: rule 25(1)-(3)

Urgent oral orders

The 2001 rules permit defined urgent oral prescriptions and requisitions, with written confirmation within 24 hours.

What the rules establish

- Rule 24(4) addresses an urgent oral prescription.
- Rule 25(4) addresses an urgent oral institutional requisition. Both require written confirmation within twenty-four hours.

Suggested safeguards

- Confirm the identity and authority of the person giving the order; read back the details and record the time.
- Flag outstanding written confirmation and escalate promptly. Use the hospital's approved clinical and documentation procedure.

Urgency does not remove the need for patient identification, safe administration and accurate records.

Sources: **C1**: rules 24(4) and 25(4) | **C4**: indicator 55

Link stock use to the patient

Suggested traceable administration process.

1	**Order**	Confirm a valid current patient order and the necessary clinical checks.
2	**Prepare**	Select the correct product and quantity using the approved preparation procedure.
3	**Administer**	Record the actual patient, dose, time, route and administering staff member.
4	**Account**	Record the stock reduction, unused portion, return or waste so the quantities reconcile.

The stock register and patient record should agree. Neither document proves the other is complete.

Sources: **C1**: rule 38 | **C4**: indicators 62-69

Register entries and correction rules

These are specific requirements in the 2001 regulatory rules.

Rule	Requirement
38(2)-(3)	Enter the specified transactions within 24 hours; sign and date the entry.
38(4)	Correct a mistake by a signed, dated notation in a witness's presence; the witness countersigns.
38(5)	A person delivering to a ward, or witnessing administration in the stated settings, countersigns the relevant entry.
40	Do not make false or materially misleading entries or erase an entry to hide a change.

A local policy may require entries sooner. Keep the original entry readable when correcting a mistake.

Sources: **C1**: rules 38 and 40

What the record needs to connect

Suggested review of the required register against the supporting records.

01 Product

Name, strength, dosage form and quantity.

02 Movement

Receipt, issue, administration, return or disposal.

03 People

Supplier, recipient, prescriber and administering staff as relevant.

04 Place

The pharmacy, ward or other authorised location.

05 Evidence

Prescription, requisition, invoice and patient record references.

06 Balance

The quantity remaining and any discrepancy.

Use the form determined by the Competent Authority; a teaching worksheet is not a replacement.

Sources: **C1**: rule 38(1)-(2)

TEACHING CASE

Reconcile a stock balance

Invented example: all figures are counts of identical, unopened ampoules of one product and strength.

Opening and receipt	Opening stock 100; received 40. Total available = 140 ampoules.
Recorded movement	Issued to wards 55; returned to supplier 5; authorised disposal 2.
Expected closing	140 - 55 - 5 - 2 = 78 ampoules.
Physical count	The count is 76. There is a shortage of 2 against the records, requiring action.

Do not add a false issue to force the balance to match. A ward issue must also be accounted for at the ward.

TEACHING CASE | Illustrative material is identified in the text.

TEACHING CASE

Account for a partly used ampoule

Invented accounting example only. The quantities are not a dose recommendation or a product specification.

Quantity opened	One hypothetical ampoule contains 10 mg in total.
Patient record	A valid clinical order results in 6 mg being administered.
Remaining amount	10 - 6 = 4 mg must be accounted for under the approved waste procedure.
Record link	Record the ampoule opened, amount administered, remainder, disposal and required witness evidence.

Do not record the full ampoule as administered to conceal waste. Do not retain a remainder contrary to product or aseptic-use requirements.

TEACHING CASE | Illustrative material is identified in the text.

Returns, breakage and disposal

A stock adjustment, physical disposal and financial write-off are different actions.

Account for the medicine

- Identify the product, quantity, reason and responsible people. Secure returned or damaged stock pending a decision.
- Rule 38(2)(h) requires the disposal method and the responsible person's and at least one witness's details and signatures.

Use the lawful route

- Confirm the approvals, authorised method, environmental requirements and any regulator instructions before disposal.
- Retain the disposal evidence and reconcile the register and financial record separately.

A witness signature does not by itself authorise destruction. An internal write-off does not erase a loss-reporting duty.

Sources: **C1**: rule 38(2)(g)-(h)

Retention and electronic systems

Record retention must follow the relevant rule and any longer applicable hold.

Rule 38(6)

- Subject to written direction of the Competent Authority, retain the register and related prescriptions, requisitions and commercial documents for three years after the last register entry.
- Check other applicable retention requirements and any investigation or court hold before destruction.

Suggested electronic controls

- Confirm that the authorised format permits the electronic arrangement. Use individual access, traceable changes and recoverable backups.
- Keep a downtime process and reconcile entries after recovery without hiding the original timing.

Do not assume a spreadsheet alone satisfies a prescribed register or signature requirement.

Sources: **C1**: rule 38(6)

Know the external reporting duties

The 2001 rules distinguish problems in records from loss or theft of the drug.

Situation	Rule	Required action
Register lost or destroyed; discrepancy other than a mistaken entry	41	Record/report as applicable and notify the Competent Authority in writing forthwith.
Reasonable grounds to believe drug theft occurred	43(i)	Immediately inform an Inspector and authorised officer orally; report in writing within 24 hours.
Drug loss	43(ii)-(iii)	Immediately give the Inspector a written report of the circumstances and record relevant particulars.

Internal investigation does not suspend these duties. Use the currently designated authorities and preserve submission evidence.

Sources: **C1**: rules 41 and 43

Immediate action on a mismatch

Suggested response running alongside any mandatory external notification.

1	**Protect**	Secure stock and access while maintaining a lawful route for urgent patient care.
2	**Verify**	Recount and compare records, timings and transfers without altering the evidence.
3	**Report**	Notify the responsible pharmacist and management; meet the applicable external reporting duty.
4	**Preserve**	Keep records, access logs and relevant evidence; establish an authorised investigation and action plan.

A missing quantity is a finding. Theft and individual responsibility require evidence and the proper process.

Sources: **C1**: rules 41-43

Fair investigation and patient protection

Suggested management approach when diversion or unsafe practice is suspected.

Establish the facts

- Use an authorised, impartial inquiry with a clear scope. Preserve originals and document access to evidence.
- Compare stock movements with patient records, staffing, authorised access and genuine correction records.

Manage immediate risk

- Use lawful interim arrangements where needed and maintain clinical cover.
- Handle a staff health concern confidentially through appropriate clinical and employment procedures. Do not diagnose or accuse from a stock discrepancy alone.

Clinical care, employment procedure and criminal investigation can require separate decisions and authorities.

WORKING METHOD | Illustrative material is identified in the text.

Audit the system by following one movement

Suggested audit method: select a receipt and follow its destination.

01 Authority

Was the supplier, medicine and activity authorised?

02 Receipt

Does physical receipt match the invoice and register?

03 Transfer

Can the ward receipt be linked to the pharmacy issue?

04 Patient use

Can administration be linked to the order and patient?

05 Remainder

Are unused stock, returns and waste explained?

06 Closure

Were discrepancies reported and corrective actions checked?

Repeat across shifts and locations. A correct central-store balance can coexist with a ward-level failure.

WORKING METHOD | Illustrative material is identified in the text.

TEACHING CASE

A missing ampoule at handover

Invented scenario for applying the reporting and evidence rules.

Finding	The ward has one fewer ampoule than the recorded balance.
First response	Secure stock, repeat the count and check recent patient use and transfers.
Unresolved mismatch	Record the discrepancy and escalate. Follow the relevant external reporting requirements.
Later evidence	A delayed entry, breakage or suspected theft leads to different factual conclusions. Preserve the sequence and correction history.

Do not delay a required notification until an internal inquiry reaches its final conclusion.

TEACHING CASE | Illustrative material is identified in the text.

Apply the controlled-drug rules

Write your answer and the reason before turning to the next page.

1. Urgent request

An eligible ward requester makes an urgent oral requisition.

What follow-up does rule 25 require?

2. Balance shortage

Expected closing stock is 78; physical stock is 76.

What is the difference, and what must not be done?

3. Old register

A closed register has reached the rule 38 period but is relevant to a pending case.

Can it be destroyed automatically?

State the rule or working method you are using.

TEACHING CASE | Illustrative material is identified in the text.

Answers and reasons

Use the evidence, the calculation and the cited source.

1. Written confirmation within 24 hours

Rule 25(4) requires it. Also apply the approved urgent-order, identity and safe-supply process.

2. A shortage of two ampoules

Verify, preserve, record and report appropriately. Do not create a fictitious transaction or erase evidence to force agreement.

3. No automatic destruction

Check written directions, other applicable retention requirements and the legal hold. Preserve material required for the pending case.

The hospital process should make the lawful action easy to carry out.

Sources: **C1**: rules 25, 38, 40-43

Prepare a controlled-drug assurance file

Use a non-confidential real case or the invented examples in this lecture.

Authority map

Record the product, legal basis, supplier, permissions and responsible staff.

Traceability test

Follow one receipt through a ward transfer to use, remaining stock and waste.

Gap and action

Record the issue, reporting duty, interim protection, owner and completion evidence.

Review with the chief pharmacist and relevant clinical and legal leads. Use non-confidential material in teaching.

Keep the current legal text and institutional orders with the operational procedure.

WORKING METHOD | Illustrative material is identified in the text.

Sources and continued use | 1

Select a source title or its official-source link to open the document.

C1

Control of Narcotic Substances Act, 1997 and Rules, 2001

Official judicial-academy compilation. The 2001 Regulation of Drugs of Abuse rules: 23-25 professional supply and orders; 38-43 records, security and loss. Use the current law and applicable notifications.

Government of Pakistan | Sindh Judicial Academy copy | **Official source** | **ANF legal catalogue**

C2

Punjab Control of Narcotic Substances Act 2025

Act LXIV of 2025. Read with the 2026 amendment and later notifications. This lecture does not determine criminal jurisdiction or reproduce offence penalties.

Government of Punjab | Law and Parliamentary Affairs | **Official source** | **2026 amendment**

C3

DRAP SOP: allocation of controlled substances to hospitals

The published hospital-allocation SOP specifically identifies tertiary hospitals in Islamabad Capital Territory. It must not be treated as a universal Punjab hospital quota procedure.

Drug Regulatory Authority of Pakistan | **Official source**

Educational material by Dr Qurban Hussain Khan. Source editions are stated; verify later amendments and applicable institutional orders before live use.

Sources and continued use | 2

Select a source title or its official-source link to open the document.

C4

PHC hospital Minimum Service Delivery Standards

2024 manual; standards 8-10, indicators 51-71: authorised orders, high-risk checks, storage, dispensing and administration. These operate alongside controlled-drug requirements.

Punjab Healthcare Commission | **Official source**

C5

Minimum Standards for Establishment of Hospital Pharmacies

DRAP PHSR/GL/HP/012, edition 1, effective 25 May 2024. Organisation, medicine security, preparation, monitoring and records. Guidance does not replace a statutory authorisation.

Drug Regulatory Authority of Pakistan | **Official source**

Educational material by Dr Qurban Hussain Khan. Source editions are stated; verify later amendments and applicable institutional orders before live use.