



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་ བླམ་ཕུ།
Royal Government of Bhutan
Ministry of Health
Department of Health Services
"A Nation with the Best Health"



MoH/DHS/HITAD(02)/2025-26/ 2233

February 16, 2025

OFFICE ORDER

Sub: Implementation of Healthcare Services Rules and Regulations 2025

In exercise of the powers conferred under the Healthcare Services Rules and Regulations (HSRR) 2025 and the Notification issued by the Ministry of Health (MoH) vide Letter No. *MoH/Executive Order-43/2024-25/2500* dated 12th March 2025, all healthcare centres (HHCs) operating in Bhutan shall comply with the following regulatory requirements with effect from 13th March 2026:

1. Legal applicability

1.1. The HSRR 2025 applies to:

- all categories of HCCs and services;
- any person or entity involved directly or indirectly in the provision of healthcare services; and
- all establishments that do not primarily provide clinical services but deliver services which, if not properly managed, pose risks related to hygiene, sanitation, and infection prevention.

2. Mandatory technical authorisation

- No HCC shall operate or provide healthcare services without technical authorisation (TA) issued by the MoH as required under Section 47 of the HSRR 2025.
- HCCs currently operating, both public and private, shall:
 - apply for TA in the prescribed format;
 - ensure TA certificates are kept valid, prominently displayed, and renewed prior to expiry; and
 - in the case of changes in services, ownership, or physical premises, submit proposals to and obtain prior approval from the MoH.
- Operating without authorisation or continuing operations after TA expiry is prohibited and constitutes regulatory non-compliance subject to enforcement actions, including suspension, cancellation, or prosecution.
- All HCCs must complete and submit their TA applications on or before **31st March 2026**.

3. Governance, management and accountability

- All HCCs shall maintain documented governance systems, clinical oversight mechanisms, and designated compliance focal points responsible for regulatory adherence.
- All written policies, SOPs, and operational directives shall be aligned with the requirements of the HSRR 2025 and related guidelines and documents.

4. Service standards and patient protection

- All HCCs shall ensure that:
 - services rendered are within the approved scope of services and in compliance with national clinical standards, protocols and guidelines; and
 - mechanisms are established for reporting adverse events, clinical incidents, abuse, neglect and complaints.
- HCCs shall uphold patient rights, including informed consent, confidentiality, respectful care and dignified treatment.

5. Transparent pricing and billing

- All fees, charges, prices and related information for healthcare services shall be transparent, disclosed upfront, and submitted to MoH for approval, where applicable.
- Patients shall be provided itemised statements for all services rendered.

6. Health infrastructure and standards

- HCCs shall meet relevant infrastructure, hygiene, safety, and accessibility standards relevant to their service category.



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་ ཐིམ་ཕུ།

Royal Government of Bhutan

Ministry of Health

Department of Health Services

"A Nation with the Best Health"



6.2. Documented systems for emergency preparedness, fire safety, utilities (water, sanitation, power backup) and disabled-friendly provisions shall be established and maintained.

7. Infection prevention and control

- 7.1. All HCCs shall implement and maintain effective infection prevention and control (IPC) systems and medical waste management mechanisms consistent with national guidelines and relevant legal requirements.
- 7.2. HCCs shall develop, document, and operationalise IPC programmes tailored to the level and complexity of services provided.

8. Human resources and workforce standards

- 8.1. All medical, health and support personnel must possess valid authorisation, credentials and qualifications appropriate to their roles.
- 8.2. HCCs shall maintain up-to-date credential records and support continuous professional development and role-aligned supervision.

9. Quality management system

- 9.1. All HCCs shall establish, implement and maintain a documented Quality Management System (QMS) that systematically measures, evaluates and improves patient care and service delivery, as mandated under Section 101 of HSRR 2025.
- 9.2. QMS records, improvement plans, audit reports, KPI dashboards and continuous quality improvement outputs shall be retained as part of HCC operational records.

10. Reporting and documentation

- 10.1. HCCs shall maintain accurate records of clinical services, patient care, adverse events, infection control efforts, quality improvement activities, and other regulatory reporting obligations.

11. Regulatory compliance, monitoring, and enforcement

- 11.1. The Department of Health Services (DHS) is hereby designated as the competent regulatory authority responsible for monitoring and compliance with the HSRR 2025.
- 11.2. DHS shall carry out both scheduled and unscheduled inspections, audits, and compliance assessments of all HCCs, regardless of ownership type.
- 11.3. Non-compliance with regulatory provisions may attract administrative sanctions, fines, suspension, or other enforcement actions as stipulated in Chapter XIV of the HSRR 2025.

A copy of Healthcare Services Rules and Regulations 2025 is available online at https://moh.gov.bt/wp-content/uploads/2025/03/HSRR_2025.pdf

This Office Order is issued for strict compliance.

(Pemba Wangchuk)
SECRETARY

Copy to:

1. The PS to Hon'ble Minister, Ministry of Health for kind appraisal;
2. The Dasho Dzongdag, Dzongkhag Administration, All Dzongkhags for necessary action;
3. The President, NMS and JDWRH for compliance;
4. The DHO(s), Dzongkhag Administration, All Dzongkhags for compliance; and
5. The MS/CMOs/MoICs/Managers of all healthcare centres for compliances.