

AYUSH QUALITY MARK PROGRAMME

Additional Requirements for grant of Ayush Quality Mark to Ayush Hospitals/ Daycare Centers/ Clinics

(Effective 1 Jan 2027)

0. Introduction

The hospital accreditation standards, like ISO: 7101 or ISO: 9001 or WHO EMRO standard or any ISQuaEEA accredited standards, even if for healthcare, are generic in nature; therefore there is a need for additional requirements to be prescribed for Ayush Hospitals/Daycare Centres/ Clinics under Ayush Quality Mark programme. These requirements have been drawn from the latest IPHS standards for Ayush Hospitals/ Ayushman Arogya Mandir as issued by the Ministry of Health and Family Welfare, December 2024.

1. Scope

This document specifies additional requirements for the Ayush Hospitals/Daycare centers/ Clinics to be read with the applicable standard as given in the criteria in system document.

2. Additional Requirements

2.1 Human Resources: The provision of human resources in hospitals shall be as per Annexure 1-5. The provision of human resources in Day Care Centres/Clinics shall be as per Annexure – II of Indian Public Health Standards Ayushman Arogya Mandir (AYUSH)

2.2 Compliance with Statutory norms: The following regulatory requirements shall be complied with, as applicable, for the services provided.

- i. National Commission for Indian System of Medicine Act and the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations
- ii. National Commission for Homoeopathy Act and Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations
- iii. Clinical Establishment (Registration and Regulation) Act or applicable state Act.
- iv. Drugs and Cosmetics Act and Rules/ Regulations made under it
- v. No Objection Certificate from the Fire Authority, wherever applicable by law. In other situations, fire safety measure shall follow any recognized standard like NBC Chapter 4 and a third party inspection report shall be available. The inspection agency shall demonstrate competence either by accreditation through ISO 17020 or any established fire safety inspection scheme relying on accreditation such as IFE- AHPI fire safety inspection scheme.

- vi. Air, Water and Environment protection related regulations as applicable including Authorization under the Biomedical Waste (Management and Handling Rules), noise, solid waste management etc.
- vii. Gas Cylinder Rules under Indian Explosive Act
- viii. Persons with Disability Act
- ix. Vehicle Registration Certificates for Ambulances
- x. Excise permit to store spirits
- xi. PCPNDT Act
- xii. MTP Act.
- xiii. AERB Act
- xiv. Food Safety and Standards Act.

2.3 Medication Management

2.3.1 The procedure for medication management that focuses on the availability of medication in terms of their procurement, storage, prescription and dispensing etc. by maintaining quality and safety of Ayush medicines. These factors influence the public in bringing the patient satisfaction about the medicines and services that are being provided by the Ayush healthcare facility.

2.3.2 Except Yoga & Naturopathy other Ayush systems comprises pharmacological interventions for the mitigation and management of various diseases or disorders. Qualities of "Aushadhi" (Drugs medicines) and skilled healthcare provider i.e., clinician, nursing staff etc. has also been enumerated in Ayurveda treatises. Thus, quality control and assurance of Ayush medicines/drugs have an imperative role in the effective implementation of Ayush systems of healthcare.

2.3.3 The Pharmacovigilance activity shall be as per Annexure 6.

3. Procurement of Medicines

3.1 The Ayush Hospitals/Daycare Centers/ Clinics shall procure Medicines/ Botanicals/ Herbs from licensed manufacturers/ producers for the time being but transit to procurement from manufacturers/ producers fulfilling the criteria prescribed for Medicines/ Botanicals/ Herbs under the program for grant of Ayush Quality Mark within 2 years of launch of the Program.

3.2 The supply of medicines shall be accompanied by Batch Manufacturing Records [BMR] and contaminant testing reports as per applicable Pharmacopeia with immediate effect.

4. Quality assurance of Ayush medicines

4.1 Preparation Area:

There shall be a designated preparation space for preparation of in house medicines specifically for therapies. It shall be clean and hygienically maintained.

4.2 Medicinal Plant Garden:

There shall be a medicinal plant garden in the premises or at least potted plants shall be maintained with display of their names and benefits in user-friendly language.

4.3 Yoga Sthal:

There should be a Yoga Sthal [platform] to provide a space within the facility for Yoga activities.

4.4 Patient Advocacy:

Institutional mechanism should be developed for Patient Advocacy.

5. Additional requirements applicable only in case of ISO 9001

The following additional requirements, as applicable, shall apply in case of any Hospital/ Day Care Centre/ Clinic, which has ISO 9001 Certification:

5.1 The hospital / Day Care Centre/ Clinic have systems in place to ensure hospital-wide recognition of and response to clinical deterioration.

5.2 The hospital/ Day Care Centre/ Clinic minimize use of verbal and telephone orders and transmission of results, and “read back” is practiced where verbal communication is essential.

5.3 The hospital/ Day Care Centre/ Clinic have systems in place for safe and thorough handover of patients between clinical teams and between shifts.

5.4 The hospital / Day Care Centre/ Clinic screens patients to identify those vulnerable to harm and acts to reduce risk.

5.5 The hospital / Day Care Centre/ Clinic screens patients to identify those vulnerable to falls and acts to reduce risk.

5.6 The hospital / Day Care Centre/ Clinic have a coordinated programme for all infection prevention and control (IPC) activities that involve all disciplines.

5.7 The hospital / Day Care Centre/ Clinic ensure continuous availability of essential, functioning infection prevention and control (IPC) equipment and supplies.

5.8 The hospital/ Day Care Centre/ Clinic implements recognized guidelines for hand hygiene, including WHO guidelines.

5.9 Staff are screened before employment and as best practice indicates, and afterwards for colonization and transmissible infections.

5.10 The hospital/ Day Care Centre/ Clinic acts to protect staff and volunteers from hospital-acquired infections, including provision of hepatitis B vaccination.

5.11 The hospital/ Day Care Centre/ Clinic have a surveillance system for hospital-acquired infections (HAIs).

5.12 The hospital/ Day Care Centre/ Clinic ensure legible handwriting when prescribing or writing physicians' orders.

5.13 The hospital / Day Care Centre/ Clinic have a pain management system and controls access to and storage of narcotic products according to legislation.

5.14 The hospital/ Day Care Centre/ Clinic have an implemented policy and procedures to manage medication errors.

6. The following annexures shall apply:

ANNEXURE - 1 Human Resources for 10 bedded Ayush hospital

ANNEXURE - 2 Human Resources for 30 bedded Ayush hospital

ANNEXURE - 3 Human Resources for 50 & above Bedded Ayush Hospital

ANNEXURE - 4 Qualification & experience

ANNEXURE - 5 Job responsibilities of Human Resources

ANNEXURE - 6 Reporting Form for Suspected Adverse Reactions & pharmacovigilance cases
