Streamlining Compliance for Hospitals, Diagnostic Centres and MedTech

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RECOMMENDATIONS BY NATHEALTH & EY

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Executive Summary

Complex regulatory structure creating compliance bottlenecks for the healthcare sector and preventing ease of doing business

Regulatory landscape for the healthcare sector

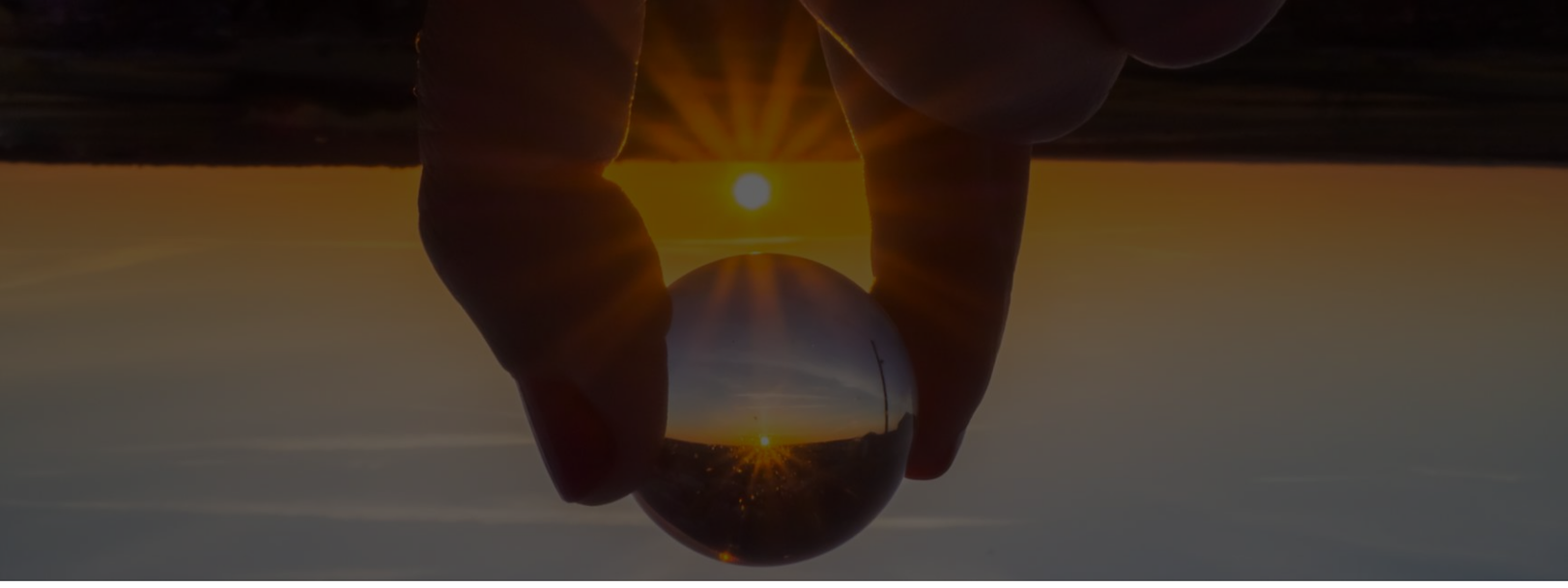
- Healthcare industry is one of **the top three regulated sectors in India. ~24% of regulations** applicable to the industry are healthcare specific
- **~60% of regulations applicable to healthcare industry are decentralized** – leading to complexity of compliance due to lack of standardization
- **~25-30% of compliances undergo change every year** leading to a dynamic and complex regulatory structure
- **29000+ annual compliance tasks triggering** for a healthcare organization with operations pan-India
- **1400+ compliance tasks pertain to licenses/approvals/registrations** to be obtained by the healthcare sector

Key compliance challenges faced by the industry

- **Highly dynamic and changing regulatory landscape** with little/no transition time
- **Multiplicity of regulators** and enforcement agencies
- Dated regulations resulting in **delayed approvals**, project completion, ability to expand
- **High number of industry specific regulations** impacting day-to-day operations
- **Multiple/ numerous licensing** requirements
- **High frequency of compliance reporting** / high number of compliance requirements

Key recommendations

- **Single window clearance**
- **Self-certification or touchless certification** to increase transparency
- Stringent penalties to **increase accountability** on industry to self-certify
- **Digitization** of processes and records
- Need for collaborative discussions and **consultations with industry** prior to implementing regulatory changes



Top 12 compliance challenges identified by industry	
Hospitals	➢ Restriction on hospital building heights leading to reduced number of beds in hospitals and lack of clarity of definition of "critical patients" leading to ambiguity in occupancy permissible in hospitals beyond the 30m height ➢ State registrations for medical practitioners leading to multiple UIN generations and administrative burden ➢ Licensing of blood banks required for central and state licensing authorities leading to delays
MedTech	➢ Mandated BIS certifications and compliance with multiple QCOs leading to delays in medical device registrations and approvals ➢ Different licensing authorities based on activity and class of device leading to multiple registrations and complex procedures and high response time by authorities to grant approvals ➢ Multiple regulations governing medical device labelling ➢ No defined timelines or guidance on seeking approvals for HCPs travelling for an event
Diagnostics	➢ Lack of standardization in clinical establishment regulations across states ➢ Digital signatures are not accepted on lab reports and physical presence of doctors is mandated while signing of lab reports ➢ Lack of timelines defined to approval ultrasound devices under PCPNDT Act, and lack of clarity on the list of devices to be registered under the Act
Industry Agnostics	➢ Lack of clarity on rejection reasons for lift licenses, and lack of transparency in timelines for issuance of lift licenses ➢ Lack of standardization or defined processes to obtain consent from State PCBs and stringent penalties imposed in case of failure to obtain / renew consent in a timely manner

Key recommendations	
Short term	• Permit usage of digital signatures • Centralize registrations for medical practitioners • Leverage ABHA to digitize health records • Rely on international certifications like ISO for QCO compliance
Medium term	• Increase transparency around license approval response times • Rely on approvals from international regulators for granting approvals • Allow deemed approvals on licenses for establishment set-up • Decriminalize non-safety related compliance • Eliminate dual licensing authorities • Extend hospital building height limits
Long term	• Enhancement to NSWS to include all statutory approvals • Bring uniformity in state requirements pertaining to establishment set-up • Adopt specific regulations for medical devices