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Complex regulatory structure creating compliance bottlenecks for healthcare sector: NATHEALTH

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Whitepaper lays out short-, medium- and long-term recommendations to make Indiaâ??s regulatory ecosystem more cost-efficient



Healthcare Federation of India, in collaboration with EY India, has released a landmark whitepaper titled '**Streamlining Compliance in the Indian Healthcare Sector."** Formally submitted to NITI Aayog, the whitepaper presents a practical, future-facing roadmap for regulatory reform, grounded in extensive engagement with healthcare stakeholders across the country.

The whitepaper makes a compelling case for a sector-wide overhaul of India's fragmented and resource-intensive compliance landscape. It presents a positive, industry-backed vision that aligns with the government's priorities on Ease of Doing Business, digital transformation, and healthcare access focusing on how simplified, harmonised regulation can drive quality, innovation and growth.

India's healthcare sector is subject to a complex and ever-evolving network of regulations spanning 10–12 ministries and three tiers of governance (central, state, and municipal). NATHEALTH has benchmarked healthcare's regulatory intensity against other industries including BFSI, mining and IT, where healthcare emerges among the top three sectors in terms of compliance burden. A single facility is required to manage hundreds of tasks annually, many of which are duplicative or unclear.

The whitepaper identifies 85 key compliance challenges across hospitals, diagnostic centres, and MedTech companies. Of these, 44 were flagged by industry as particularly onerous, either due to duplication, lack of clarity, or administrative inefficiency.

Segment-Specific Challenges Highlighted in the Whitepaper:

- Diagnostics: Clinical Establishment registration, physical vs. digital signatures on reports, PNDT Act compliance, dual maintenance of physical and electronic records
- MedTech: BIS certifications, labelling norms, marketing codes, and licensing under Medical Device Rules
- Hospitals: Blood bank licensing, practitioner registration overlaps, building codes and Fire Officer's NOCs

By digitising, centralising and streamlining healthcare compliance, NATHEALTH seeks to support the government's vision of a high-performing, technology-enabled healthcare system that delivers value across the board for patients, providers, and the broader economy.