November-December 2025 Edition

India's healthcare sector saw a continued impetus on digital integration, infrastructure expansion, and regulatory adjustments to existing schemes. The Ayushman Bharat-PM Jan Arogya Yojana (AB-PMJAY) continued to expand its footprint. As of December 2025, approximately 42.48 crore (forty two point four eight crore) Ayushman cards had been created, and over 10.98 crore (ten point nine eight crore) hospital admissions were authorised. This was an ongoing effort building on the expansion in October 2024 to cover all senior citizens aged 70 (seventy) and above, regardless of income.

This edition of the JSA healthcare Newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem during November and December 2025.

Regulatory updates

Transplantation of Human Organs and Tissues (Amendment) Rules, 2025

The Ministry of Health and Family Welfare ("**MoHFW**"), *vide* notification dated November 6, 2025, has amended the Transplantation of Human Organs and Tissues Rules, 2014. The amendment has replaced the word 'Specular' with 'Specular (optional)' in the second column for 'Corneal Transplantation Centre' entries in Form 15 of the Transplantation of Human Organs and Tissues Rules, 2014. This change removes the mandatory requirement for a specular microscope in Corneal Transplantation Centres, which is used to assess the density of corneal endothelial cells.

Draft Surrogacy (Regulation) Amendment Rules, 2025

MoHFW, *vide* notification dated November 27, 2025, has issued the Draft Surrogacy (Regulation) Amendment Rules, 2025. The draft regulations introduce specific procedures regarding the payment, utilisation of registration fees, and the detailed manner of renewing a Surrogacy Clinic's Certificate of Registration under the Surrogacy (Regulation) Rules, 2022.

Draft Medical Devices (Amendment) Rules, 2024

MoHFW, *vide* notification dated December 4, 2025, has issued the Draft Medical Devices (Amendment) Rules, 2024. The draft regulations introduce clearer qualifications for analysts and integrating the National Single Window System (NSWS) for smoother operations and creating a more supportive environment for manufacturers and importers. It aims to simplify India's medical device regulation by introducing perpetual licenses, streamlining registration for low-risk Class A devices, strengthening testing/labelling adding new forms such as Form MD-44 for data reporting,

focusing on better traceability, and enhancing patient safety within the Central Drugs Standard Control Organisation ("**CDSCO**") framework.

Requirement of license issued for procurement of medical devices by procurement agencies

CDSCO, *vide* circular dated November 17, 2025, has mandated all procurement agencies including hospitals, health institutions, etc., to obtain a CDSCO license or the license issued by the relevant State/ Union Territories Licensing Authority ("**SLA**") as part of the requirements for the procurement and sale of medical devices under the Medical Devices Rules, 2017. Other certifications required by the procurement agency will continue to apply over and above the CDSCO/ SLA Licensing Authority license, under the Medical Device Rules, 2017.

New provision for risk classification of medical devices on the CDSCO online system for medical devices

CDSCO, *vide* circular dated December 4, 2025, has issued a circular on a new risk classification module made functional on the CDSCO online system for medical devices. This facility has been provided in order to simplify the regulatory approval procedures and easing the process of risk classification of medical devices other than in-vitro diagnostic medical devices. The new Risk Classification Module has been made functional on the CDSCO Online System for Medical Devices (http://cdscomdonline.gov.in) for all stakeholders with effect from November 27, 2025.

Occupational Safety, Health and Working Conditions Code, 2020

The Ministry of Labour and Employment, *vide* notification dated November 21, 2025, fully enforced the Occupational Safety, Health and Working Conditions Code, 2020 ("**Code**"). The Code consolidates various labour laws for improved worker safety, health, and welfare across sectors, including provisions for working hours, health check-ups, and female worker safety.

Compliance of scheme of testing for packaged drinking water and mineral water

The Food Safety and Standards Authority of India ("**FSSAI**"), *vide* notification dated October 17, 2024, omitted the provision for mandatory Bureau of Indian Standards ("**BIS**") certification under the Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011. In continuation of the above omission of mandatory BIS certification, the mandatory BIS certification mark is no longer required for packaged drinking water and mineral water. Pursuant to the same, FSSAI, *vide* notification dated December 17, 2025, has notified the scheme of testing of 'Packaged Drinking Water' and 'Mineral Water'. The scheme, made to ensure safety and compliance of packaged drinking water and mineral water in the Indian market, prescribes, *inter alia*: (a) specific packing requirements in compliance with the Food Safety and Standards (Packaging) Regulations, 2018; (b) tests at various levels of control and production conformity with the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011; (c) microbiological contamination and non-conformity checks; and (d) source water testing in accordance with the Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011. All food business operators have been directed to strictly comply with the same with effect from January 1, 2026.

Case law

Supreme Court of India issues 4 (four) weeks' notice to Central Government to respond to a PIL challenging the severe lack of criminal prosecution for physicians in medical malpractice cases

The Supreme Court of India ("**Supreme Court**"), in its order dated December 20, 2025, in the case of ***Sameeksha Foundation-A Crusade Against Medical Negligence vs. Union of India and Anr.***[1], issued a 4 (four) weeks' notice to the Central Government to respond to a Public Interest Litigation ("**PIL**") seeking statutory rules for the criminal prosecution of doctors in medical negligence cases. The PIL cited the 73rd Parliamentary Standing Committee Report on Health and Family Welfare's recommendations for modifications to the Indian Medical Council (Second Amendment) Bill, 2013, widening the ambit of scrutiny of medical negligence cases to multidisciplinary committees including experts from various disciplines (such as social activists, patient's representative, etc.) in addition to medical professionals. The petitioner highlighted the 20 (twenty) year delay by the government in framing medical negligence guidelines, as previously directed by the *Jacob Mathew vs. State of Punjab* (2005) judgment, and the potentially mandatory jail time for negligence introduced by the new Bharatiya Nyaya Sanhita for enforcing ethical conduct by medical professionals.

[1] 2025 INSC 1487

Healthcare Practice

JSA provides a full range of transactional and advisory services in the healthcare sector. We represent clients in the entire spectrum of the health care system, including, hospital networks and individual hospitals, managed care organisations, health insurers, pharmaceutical and biotechnology companies, medical device manufacturers; and major financial investors in the sector. These include domestic as well multinational clients. Our clients in the sector range from start-ups to industry leaders. We also represent the leading trade associations representing these industries, namely, Centre for Scientific & Industrial Research, Centre for DNA finger printing & Diagnostics, Institute of Microbial Technology, All India Institute of Medical Science-Department of Biotechnology, National Institute of Health & Family Welfare, etc.

JSA also has substantial experience in matters relating to regulation of foods, drugs, medical devices, cosmetics, product packaging, and dangerous chemicals. Our attorneys advise manufacturers on Indian labelling questions, national rules for testing and review of new products, reporting of safety information, and proceedings relating to product withdrawals. We regularly advise clients on regulatory standards governing advertising, the distinction between advertising and labelling and the differing regulatory standards that apply to each, and the roles of the states and self-regulatory mechanisms. JSA has been actively involved in advising clients with respect to regulation of nutrition and health claims in food advertising.

We also have extensive experience in litigating cases in courts and administrative agencies in the healthcare sector.

This Newsletter has been prepared by:

Sidharrth Shankar
Partner

Achint Johri
Associate

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For more details, please contact km@jsalaw.com

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