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JSA Newsletter Healthcare

January-February 2025 Edition

Healthcare is one of the key focus areas of the Government of India and this year in the Union Budget 2025-26. The finance minister announced some of the following key initiatives to boost the Indian healthcare sector.

1. The gig workers of online platforms will be provided healthcare under PM Jan Arogya Yojana. This measure is likely to assist nearly 1,00,00,000 (one crore) gig-workers.
2. Government has added almost 1,10,000 (one lakh ten thousand) undergraduate and postgraduate medical education seats in 10 (ten) years, an increase of 130%. In the next year, 10,000 (ten thousand) additional seats will be added in medical colleges and hospitals, towards the goal of adding 75,000 (seventy five) seats in the next 5 (five) years.
3. The Government proposed to facilitate setting up of day care cancer centres in all district hospitals in the next 3 (three) years. 200 (two hundred) centres will be established in 2025-26.
4. Medical tourism and 'Heal in India' will be promoted in partnership with the private sector along with capacity building and easier visa norms.
5. To provide relief to patients, particularly those suffering from cancer, rare diseases and other severe chronic diseases, 36 (thirty six) lifesaving drugs and medicines will be added to the list of medicines fully exempted from basic customs duty. Further, 6 (six) lifesaving medicines will be added to the list attracting concessional customs duty of 5%. Full exemption and concessional duty will also respectively apply on the bulk drugs for manufacture of the above.
6. Specified drugs and medicines under patient assistance programmes run by pharmaceutical companies are fully exempt from basic customs duty, provided the medicines are supplied free of cost to patients and 37 (thirty seven) more medicines along with 13 (thirteen) new patient assistance programmes will be added.

This edition of the JSA healthcare newsletter focuses on the key developments undertaken in the Indian healthcare ecosystem in January and February 2025.

Regulatory updates

Compliance of the provisions of Para 24 and 25 of Drugs (Prices Control) Order, 2013

On February 4, 2025, the Department of Pharmaceuticals issued an [office memorandum](#) directing all the retailers and dealers including online pharmacies carrying on business of purchase or sale of drugs through physical mode as well as online mode i.e., through website/online portal/mobile app/e-commerce platforms or any other online mode are required to display the current price list issued by manufacturer/marketer to ensure compliance to Para 24 and 25 of

Drugs (Prices Control) Order, 2013 (“**DPCO, 2013**”). Further, it may be noted that violation of Para 24 and 25 of DPCO, 2013 is punishable under Section 7 of the Essential Commodities Act, 1955.

Drugs Amendment Rules, 2025

On February 11, 2025, the Ministry of Health and Family Welfare notified the [Drugs Amendment Rules, 2025](#), allowing small and medium manufacturers (having turnover ≤ 250 crores) to seek extension of time to comply with the revised Schedule M (*Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products*) of the Drugs Rules, 1945. Small and medium manufacturers with turnover less than INR 250 crore (Indian rupees two hundred fifty crores) may seek an extension of the timeline for compliance by making an application to the Central Licence Approving Authority in Form ‘A’, within a period of 3 (three) months from the date of publication of this notification (*i.e., February 11, 2025*), along with a plan of upgradation. If approved, the deadline for compliance will be extended to December 31, 2025 (*earlier this was December 28, 2024*).

One-time mandate for blocking the amount towards premium through unified payments interface for issuance of life and health insurance policies

On February 18, 2025, the Insurance Regulatory and Development Authority of India, issued a [circular](#) to facilitate smooth transactions of payment of premium, a facility of the unified payments interface one time mandate is enabled to be used by insurers. This feature allows users to block funds in their bank accounts for specific transactions, ensuring availability of funds while deferring actual payments. Insurers are mandated to offer Bima Applications Supported by Blocked Amount (“**Bima – ASBA**”) facility to its prospects for life and health insurance policies. At present, the facility of Bima-ASBA is extended to individual policyholders. All insurers must go live and offer Bima-ASBA facility to the prospect or customer on or before March 1, 2025.

Adherence to National Accreditation Board for Testing and Calibration Laboratories scope of accreditation for testing of referral samples

On February 25, 2025, the Food Safety and Standards Authority of India, has issued an [advisory](#) to all the referral laboratories stating that they must strictly adhere to their National Accreditation Board for Testing and Calibration Laboratories (“**NABL**”) scope of accreditation as per ISO 17025, while testing referral samples. The laboratories must test food products and parameters explicitly covered under their NABL scope of accreditation to ensure compliance with quality and regulatory standards. In this regard, all the FSSAI notified referral laboratories under 43(2) of Food Safety and Standards Act, 2006 are also hereby informed and instructed to test only the test parameters specified by the designated officers/authorised officers in Form VIA.

Case law

Karnataka High Court: Right to health and right to medical-care is a fundamental right, which stands enforced through corresponding Constitutional obligation on part of the State to create medical facilities

The Karnataka High Court, in the case of [The Registrar General vs. Union of India](#)¹, has stated that when right to health and right to medical-care is treated as fundamental right, it stands enforced only with corresponding Constitutional obligation on part of the State to create medical facilities. Further, the court stated that for effective enjoyment of this right, the creation of medical cadre, adequate medical personnel, setting up of infrastructure, availability of medicines in sufficient quantity and without interruption, as also establishment of primary health

¹ Writ Petition No. 797 Of 2024 (Gm-Res-Pil)

centres in the rural area, are the concomitants as they become inseparable necessities for enjoyment of right to health and right to medicare at all levels from urban to semi-urban to rural areas of the State, the medical facility, medical infrastructure and medical personnel have to be made available by the welfare state. The court has issued the following directions:

1. The Department of Health and Family Welfare, State of Karnataka, must constitute a 3 (three) member committee headed by the Secretary, Department of Health, to continuously oversee and implement the mechanism to ensure the providence of medical facility and medical infrastructure including the medical and para-medical personnel at all levels-city, district and rural.
2. The Committee as above must every 6 (six) months collect and assess the relevant details from deterrent districts about the number of vacancies of medical staff in different categories, the need for upgrading or further extending the medical infrastructure and medical facilities including medicines to the various government hospitals and primary health centres run by the Government.
3. The committee must gather the information about the medical staff vacancies in the Government Hospitals and Primary Health Centres and take steps for filling up the vacant posts. This exercise shall be undertaken every six months.
4. The committees at the district level for the above purposes, must be constituted under the headship of collector/deputy commissioner which must collect the details relating to the medical staff vacancies, medical infrastructure and medical facilities at district and taluka levels to provide such details to the committee as prescribed above, every 6 (six) months and must function in aid and in coordination.
5. The State Government must periodically and preferably every 6 (six) months undertake the survey of the primary health centres in the rural areas of the State for the purpose of upgradation of such centres in terms of medical facilities to be catered by them and also decide about establishing additional primary health centres on need basis in the villages.
6. The Health and Family Welfare Department must evolve and set up a mechanism to see that there is proper co-ordination and supervision in implementing different health schemes of the Central Government and the State Government, as also the health-related strategies.
7. The budgeting provision for the purpose must be properly and adequately made and there must be ensured purpose-serving spending of the budgetary allocations.

Interesting Reads

The Central Drugs Standard Control Organisation has signed agreements or memorandum of understandings on regulatory cooperation with other international agencies

The Press Information Bureau *vide* [press release](#) dated February 4, 2025, has announced that the Central Drugs Standard Control Organisation has signed agreements or memorandum of understandings on regulatory cooperation with other international agencies, including with such agencies in Afghanistan, Argentina, Brazil, Denmark, Dominican Republic, Ecuador, Germany, Guyana, Japan, Netherlands, Russian Federation, Suriname, Sweden, Ukraine, United Kingdom and United States of America and the Drug Regulatory Authority of BRICS.

Steps taken to Strengthen Healthcare access under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana

The Press Information Bureau *vide* [press release](#) dated February 4, 2025, has announced that the Government of India has developed specific guidelines for the empanelment of hospitals under the Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana ("AB-PMJAY") which mandates a physical verification of hospital at the time of empanelment. As per

empanelment guidelines, public hospitals with inpatient services are deemed empanelled. Further, the National Health Authority has launched an improved version of the Hospital Engagement Module (“**HEM 2.0**”) which mandates physical verification for private hospitals. HEM 2.0 has also introduced a feature that allows for periodic reviews to ensure that hospital information remains accurate. As per the terms and conditions of empanelment, hospitals are mandated to provide the services to eligible beneficiaries under AB-PMJAY. In case services under the scheme are not provided by the empanelled hospital, beneficiaries can lodge grievances.

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



Prakriti Jaiswal
Partner

		
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For more details, please contact km@jsalaw.com

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