



January 2023 Edition

This edition of the JSA Healthcare Newsletter focuses on key developments undertaken in the Indian healthcare ecosystem for the month of January.

## **‘SMART’ program for Ayurveda professionals to boost R&D in Ayurveda in the country**

The National Commission for Indian System of Medicine (“NCISM”) and the Central Council for Research in Ayurvedic Sciences (“CCRAS”), the 2 (two) institutions operating under the Ministry of Ayush for regulating medical education and conducting scientific research in India, have launched the ‘SMART’ (Scope for Mainstreaming Ayurveda Research in Teaching) program (“SMART Program”) that aims to transform clinical research in Ayurveda by boosting scientific research in priority healthcare research areas through Ayurveda colleges and hospitals. The Ministry of Ayush issued a press release on January 2, 2023 to announce the launch of the SMART Program.

The initiative has been taken to counter the underutilisation of research potential of a large community of Ayurveda teachers. Developed with an objective to identify, support and promote innovative research ideas in healthcare research areas, including, osteoarthritis, anaemia, chronic bronchitis, dyslipidaemia, rheumatoid arthritis, obesity, diabetes mellitus, psoriasis, generalised anxiety disorder and non-alcoholic fatty liver disease, the stated aim of the SMART Program is to motivate teachers for taking up projects in designated areas of research and create a large database for healthcare research in the country.

## **New system to measure and grade performance of hospitals empanelled under Ayushman Bharat PM-JAY scheme**

The NHA has introduced a new system to grade and measure the performance of hospitals enlisted under the Ayushman Bharat PM-JAY scheme (as per the press release issued by the MoHFW on January 9, 2023). The objective of the new system is to maximise health benefits by incentivizing and encouraging the healthcare providers to focus on delivering patient centric services. The rationale for introducing the new system is to shift the focus of measuring hospital performance from a ‘volume-based’ healthcare model where case-based bundled payment is made on the basis of number of services provided to a ‘value-based care’ model where payment will be outcome based and providers will be rewarded according to the quality of treatment delivered.

The new model promises a win-win situation for all the stakeholders: while patients will get cashless healthcare benefits and high-quality services at every empanelled hospital thereby receiving better health outcomes and higher satisfaction out of the spending incurred for the services, the healthcare providers stand to get better care efficiencies by being incentivised and rewarded as best performing hospitals for helping the patients to improve their health.

**Key points of the 'new value-based' system are:**

1. The performance of hospitals enlisted in Ayushman Bharat PM-JAY will be graded and measured on five performance indicators:
  - a) Beneficiary Satisfaction;
  - b) Hospital Readmission Rate;
  - c) The extent of Out-of-Pocket Expenditure;
  - d) Confirmed Grievances;
  - e) Improvement in inpatients' Health-Related Quality of Life.
2. A public dashboard displaying the performance of all hospitals as per these five indicators will be available to help the beneficiaries under the scheme to make an informed decision;
3. The new system enables the beneficiaries of the scheme to exercise cost controls; and
4. Suppliers would benefit from being able to align their products and services with positive patient outcomes and reduced cost.

In light of the introduction of the new system, NHA has also implemented some new measures which include standardizing the cost of the treatment under the scheme and adding new and advanced treatment procedures.

**MoU signed between NABH and HSSC for recognition and skilling initiatives of healthcare professionals**

The National Accreditation Board for Hospitals and Healthcare Providers ("NABH") and Healthcare Sector Skill Council ("HSSC") have signed an MoU on January 24, 2023 to recognise HSSC certification for NABH accreditation and to develop training programmes for skilling, reskilling and upskilling required for healthcare professionals.

Given that HSSC works closely with industry and academia to create a skills ecosystem in the healthcare sector, this collaboration is expected to produce skilled and work-ready professionals by facilitating them with better placement, apprenticeship opportunities and practical oriented training.

NABH and HSSC expect that their collaboration will not only make the healthcare system more accessible in India but will also help in enhancing its quality by sensitising healthcare workers about their roles and responsibilities as per the NABH accreditation standards.

**New scheme to promote the adoption of Ayushman Bharat Digital Mission ("ABDM")**

The National Health Authority ("NHA") has started the Digital Health Incentive Scheme ("DHIS") to promote digital health transactions under the ABDM (as per the press release issued by the Ministry of Health and Family Welfare ("MoHFW") on December 22, 2022). The objective of the scheme is to encourage healthcare facilities and digital solution companies to come forward and join the ABDM for providing patient-centric healthcare.

The scheme intends to provide incentives to hospitals and diagnostic labs and to providers of digital health solutions, such as, hospitals, Health Management Information Systems and the Laboratory Management Information System. The incentives can be availed by the healthcare facilities (hospitals and diagnostic labs) registered with ABDM's Health Facility Registry after fulfilling the eligibility criterion specified under the scheme. The eligible health facilities and digital solution companies under the scheme will be able to earn financial incentives of up to INR 4,00,00,000 (Indian Rupees four crore) based on the number of digital health records they create and link to Ayushman Bharat Health Account ("ABHA").

**Key points of the DHIS are:**

1. Health facilities with 10 (ten) or more beds, laboratory or radiology diagnostic centres, and digital solution companies that provide ABDM-enabled digital solutions would be eligible to avail the incentives under the DHIS.
2. The incentives will be provided on the basis of the number of ABHA-linked transactions i.e. the digital health records created and linked to ABHA.
3. Digital Solution Companies will be given an incentive of 25% of the incentive amount received by the eligible health facilities using their digital solutions.
4. For ABHA linked transactions done by facilities not eligible for direct incentives under the DHIS for example clinics / small hospitals / health lockers / teleconsultation platforms etc., an incentive would be provided to digital solution companies.

The incentives for public sector facilities will be added to the funds under the Rogi Kalyan Samiti. The estimated financial outlay of the scheme is set to be INR 50,00,00,000 (Indian Rupees fifty crore) for a duration of 6 (six) months from January 1, 2023.

## Consultation Paper on Operationalising Unified Health Interface (UHI) in India

The NHA has released a consultation paper titled 'Operationalising Unified Health Interface (UHI) in India' (as per the press release issued by the MoHFW on December 14, 2022). UHI is envisioned as a foundational layer of the ABDM and aims to enable interoperability in health services in India through open protocols.

The consultation paper focuses on the different elements of UHI network and the market rules that will govern them. These include guidelines that will govern the way search & discovery will take place in a fair and transparent manner, payment & settlement processes, rules around cancellation & rescheduling, and grievance redressal mechanism, to meet the objective of ABDM.

**Key points of the consultation paper with respect to operationalising UHI are:**

1. **Search and Discovery.** The UHI network enables Health Service Provider Applications ("HSPAs") to declare the digital health services they want to offer on the network, and the end users can discover these health services, their pricing and service availability using any End User Applications ("EUAs").
2. **Service Booking.** Users can select the Health Service Provider ("HSP") of their choice from the results on the EUA. After selection of the service and as part of the booking confirmation, the transacting EUA and HSPA enter into a binding transaction level contract, which sets out the rights and obligations of both the participants.
3. **Service Fulfilment.** Once a service is booked, HSP is required to deliver the services in accordance with the parameters of the booking. To fulfil a teleconsultation between a patient and HSPA, UHI also offers Web Real-Time Communication as a video solution. However, platforms are not mandated to utilize this mechanism for service fulfilment. In case there is any rescheduling, cancellation or no-show, the refund to the user should be processed as per the terms and conditions of the booking.
4. **Payment and Settlement.** There are 2 (two) payment and settlement flows proposed, and in both cases the collector (who will be receiving the payment) will hold the amount in a nodal-like account until the amount is settled.
5. **Reschedule & Cancellation.** HSPAs have the responsibility for providing policies for rescheduling and cancellations, which are communicated to the transacting EUA during the confirmation of booking.
6. **Grievance Redressal.** Grievance may be raised by the user or HSP based on the following four-level grievance redressal mechanism:
  - a) Internal grievance redressal mechanism;

- b) Resolution through grievance redressal officers;
- c) Resolution through online dispute resolution (ODR); and
- d) Resolution through other legal remedies.

The stakeholders were required to submit their comments by January 13, 2023.

## Case Law Review

### Removal of condition of a magistrate's approval in the process of living wills

In its 2018 judgment in *Common Cause v Union of India*<sup>1</sup>, the Supreme Court had, while recognising the legality of passive euthanasia, framed certain guidelines in relation to living wills/advance medical directives. One of the guidelines required the living will to be attested to by 2 (two) independent witnesses, and a Judicial Magistrate, First Class.

By its order dated January 24, 2023, the court, whilst recognising the cumbersome nature of the said guidelines, has removed the requirement of the attestation by the magistrate, and has instead indicated that the living will could be attested by a notary, or a gazette officer.

### Variation in the standards of the qualifications required of medical practitioners in rural areas is unconstitutional

The Supreme Court in the case of *Baharul Islam and Ors. v. Indian Medical Association and Ors.*<sup>2</sup> held that any variation in the standards of the qualifications required of medical practitioners who render services in rural areas vis-à-vis those rendering services in urban and metropolitan areas is violative of the constitutional values of substantive equality and non-discrimination. Further, the Supreme Court struck down the Assam Rural Health Regulatory Authority Act, 2004, which permitted diploma holders in Medicine and Rural Health Care to treat certain common diseases, perform minor procedures, and prescribe certain drugs.

### Medical termination at an advanced stage of pregnancy

In the case of *ABC v. State of Maharashtra*<sup>3</sup>, the Bombay High Court allowed a married woman to terminate her 32 (thirty two) week pregnancy after the foetus was detected with severe abnormalities, stating that in cases of severe foetal abnormality the length of the pregnancy does not matter and that a woman has a right to choose whether to continue her pregnancy or not, as refusing termination solely on the basis of delay would be denial of her right to dignity, and her reproductive and decisional autonomy. The court further held that, "it is the woman alone who is the ultimate decision-maker on the question of whether she wants to undergo an abortion once the conditions in the statute are met".

### National Commission and Professional Council for Physiotherapists

Vide its order dated January 24, 2023, in the case of *Haider Khalid v Union of India (WP(C) 7588/2016)*<sup>4</sup> and in the case of *The Indian Association of Physiotherapists (IAP) v. Union of India*<sup>5</sup>, the Delhi High Court directed the MoHFW to establish a National Commission and Professional Council for Physiotherapists. The direction has been issued in response to a request from several physiotherapists who wanted the Government of India to take steps in

<sup>1</sup> WP (C) No. 215 OF 2005 (Supreme Court)

<sup>2</sup> SLP(C) No. 32592-32593/2015 (Supreme Court)

<sup>3</sup> WP (ST) No. 1357/2023 (Bombay HC)

<sup>4</sup> WP(C) 7588/2016 (New Delhi HC)

<sup>5</sup> WP (C) 8322/2017 & C.M. No. 41667/2017

recognising physiotherapy as a separate and independent profession, establishing a separate regulatory body to oversee them, and rewriting the standards established for the profession.

## 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.

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24 Ranked Lawyers



16 Practices and  
11 Ranked Lawyers



7 Practices and  
2 Ranked Lawyers



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