Pharma & Healthcare Update

June 30, 2022

MID-YEAR REGULATORY UPDATE 2022: HEALTHCARE INDUSTRY IN INDIA

INTRODUCTION

Since the beginning of the pandemic, there is increased industry and regulatory focus on transformation of healthcare. The healthcare industry in India has especially benefitted from cross-industry convergence and integration of technology during this period. As healthcare delivery is moving outside the four walls of traditional health system, the Government is actively introducing new laws. Notably, the Government has proposed a new scheme for provider payments under public health insurance and a draft ethics code to govern medical practitioners is in the pipeline. In addition, women and family segment of healthcare has also received immense attention in the recent past. New laws on surrogacy and fertility clinics and banks have been enacted.

Some of the key developments that have taken place in the first half of 2022 in the healthcare sector are captured below.

CONSULATION PAPER ON PROVIDER PAYMENTS UNDER PUBLIC HEALTH INSURANCE SCHEME

The Ayushman Bharat Pradhan Mantri Jan Arogya Yojana Scheme ("**PM-JAY Scheme**") is a tax-funded health insurance scheme launched in 2018. The scheme is financed jointly by Central and state governments and provides cashless coverage for hospitalisation of up to Rs. 5,00,000 per year per person. The programme employs a case-based payment system, in which providers[3] are paid a set rate for a bundled set of services delivered in accordance with a set of Health Benefit Packages ("**HBPs**").

At the time of inception of the PM-JAY Scheme, the reimbursement rates initially included review of provider payment rates under the existing publicly financed insurance schemes, consultation with stakeholders and review of limited cost data. Subsequently, as the PM-JAY Scheme evolved, evidence on cost of healthcare was generated and used to revise the payment rates.

Presently, the PM-JAY Scheme utilises a case-based payment method for providers. Under the case-based system, patients are grouped based on different criteria such as diagnosis, procedure needed for treatment, etc. and the hospitals are paid a fixed rate per category per admission (or case treated).

Ahead of announcing the revised rates, the National Health Authority released the Consultation Paper on the Provider Payments and Price Setting under PM-JAY ("**Consultation Paper**")[4]. The Consultation Paper proposes a Diagnosis Related Group ("**DRG**") based model. Under this payment model, cases are defined or grouped according to the condition treated and the resources used for treatment. Rather than receiving payments for each specific service it provides, the healthcare provider gets paid a fixed rate for each discharged patient. This fixed rate may be calculated in a number of ways, including a single rate for a hospital, a single rate for each clinical speciality, a procedure-specific rate for each HBP or the DRG.

GUIDANCE FOR USE OF DRONES IN HEALTHCARE RELEASED BY ICMR

The Indian Council of Medical Research ("**ICMR**") has released the Guidance Document on Use of Drones in Healthcare ("**Guidance Document**") in collaboration with the Ministry of Civil Aviation. The Guidance Document has been issued in consonance with the provisions of the Drone Rules, 2021 which require Unmanned Aircraft Vehicles to be registered and carry a Unique Identification Number.

The Guidance Document is applicable to drones utilized for delivering supplies restricted to medicines, surgical materials, vaccines and temperature sensitive medical supplies. The document provides detailed guidance for drone operators in the healthcare sector seeking to undertake drone-based deliveries of such medical supplies or products. It also provides guidance on the process of obtaining regulatory approvals, selection of drones for the deliveries, type of transportation material to be used, requirement for recording of data and handling unforeseen events during drone delivery operations.

The Guidance Document is a positive step in the right direction although it fails to provide for restrictions on carriage of payload, guidance on undertaking the beyond visual line of sight operations required in deliveries of supplies/products over long distances. Additional guidance in this regard is a welcome step to ensure safety of civil population while encouraging adoption of technology to increase the efficiency of the sector and greater access to healthcare to remote areas.

GOVERNMENT TAKES STEPS TOWARDS REGULATING ALLIED HEALTHCARE PROFESSIONALS

The National Commission for Allied and Healthcare Professions Act, 2021 ("**NCAHP Act**") came into force on May 25,

Research Papers

M&A In The Indian Technology Sector
February 19, 2025

Unlocking Capital
February 11, 2025

Fintech
January 28, 2025

Research Articles

Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?
February 04, 2025

INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals
January 15, 2025

Key changes to Model Concession Agreements in the Road Sector
January 03, 2025

Audio

CCI's Deal Value Test
February 22, 2025

Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice
December 18, 2024

Digital Lending - Part 1 - What's New with NBFC P2Ps
November 19, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

Click here to view Hotline archives.

Video

Arbitration Amendment Bill 2024: A Few Suggestions | Legally Speaking With Tarun Nangia | NewsX
February 12, 2025

2021. The NCAHP Act is intended to provide standards for education and services performed by allied and healthcare professions such as ophthalmic science professionals, behavioural health sciences professional, scanning professionals to name a few. Individuals with recognised qualifications in respect of the allied and healthcare professions listed in the schedule to the NCAHP Act are required to enrol themselves with the state councils constituted under the NCAHP Act and subsequently, be register under the Central Register of Allied and Healthcare Professions.

To facilitate this, the NCAHP Act provides for the creation of a National Commission for Allied and Healthcare Professions ("**NCAHP**") at central level. As per the NCAHP Act, within sixty days from the date of enactment, an interim NCAHP was required to be constituted for a period of three years. Subsequently, the National Commission for Allied and Healthcare Professions 1st (Removal of Difficulties) Order, 2021[5] was passed to extend this timeline to 6 months. After subsequent delays, on June 10, 2022, the Government has notified the formation of the interim NCAHP.[6]

At the state level, the NCAHP Act requires every state government to constitute a State Council to be called the State Allied and Healthcare Council ("**State Councils**") for exercising the powers and discharging the duties as laid down under the NCAHP Act, within six months from the date of commencement of the Act. However, due to challenges posed by the pandemic, state governments sought relaxation in the constitution of State Councils. In pursuance of which, the National Commission for Allied and Healthcare Professions 2nd (Removal of Difficulties) Order, 2021[7] was issued on November 24, 2021 extending the timeline to constitute State Councils until May 25, 2022 (one year from the date of enactment of NCAHP Act). In the latest order, i.e. the National Commission for Allied and Healthcare Professions 3rd (Removal of Difficulties) Order, 2022[8], the Central Government has further extended the timeline to constitute State Councils until November 25, 2022 (one year and six months from the date of enactment of NCAHP Act).

NEW SURROGACY LAW INTRODUCED

The Surrogacy (Regulation) Act, 2021 ("**Surrogacy Act**")[9] was notified in late 2021 to regulate the practice of surrogacy in India. Through the passage of this legislation, commercial surrogacy in India has been prohibited. The Surrogacy Act permits 'legally married Indian couple'[10] or an 'intending woman'[11] to avail altruistic surrogacy. It also introduces registration requirements for surrogacy clinics and prescribes certain eligibility requirements for surrogate Indian mothers and intending couples/woman.

In June 2022, the Surrogacy (Regulation) Rules, 2022 with provisions on minimum requirements of staff and their qualifications at a registered surrogacy clinic, and the application and other procedures at the surrogacy clinic. It also lays down the procedure for a clinic to obtain a registration certificate.

NEW LAW INTRODUCED TO REGULATE FERTILITY CLINICS AND BANKS

The Assisted Reproductive Technology (Regulation) Act, 2021 **("ART Act")** was notified in late 2021 to regulate fertility clinics and banks in India. The ART Act lays down the framework for safe and ethical practice for addressing the issues of reproductive health where assisted reproductive technology is required for becoming a parent or for freezing gametes, embryos, embryonic tissues for further use due to infertility, disease or social or medical concerns. Under the ART Act, every assisted reproductive technology clinic and bank must be registered.

In June 2022, Assisted Reproductive Technology (Regulation) Rules, 2022 was notified. This provides for the levels of clinics which may carry out the procedures envisaged under the ART Act. It also lays down minimum requirements of staff and their qualifications and the procedure for registration.

DRAFT REGULATIONS PUBLISHED FOR REGULATING PROFESSIONAL CONDUCT OF DOCTORS

The National Medical Commission ("**NMC**") released the draft Registered Medical Practitioner (Professional Conduct) Regulations, 2022 ("**Draft Regulations**")[1] under the National Medical Commission Act, 2019 ("**NMC Act**").The Draft Regulations aim at circumscribing the contours of professional conduct of Registered Medical Practitioners ("**RMPs**") through specified norms and guidelines. The Draft Regulations upon notification will supersede the erstwhile Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 ("**MCI Code**").[2]

Key features of the Draft Regulations are provided below:

- Absolute prohibition on RMPs from receiving gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation from pharmaceutical companies, commercial healthcare establishments, medical device companies, or corporate hospitals;
- RMPs permitted to receive salaries/benefits in capacity of employees only;
- No allowance for professional engagements or medical research;
- RMPs prohibited from involvement (as participants and speakers) in any third-party educational activities (seminar, workshop, conferences, etc.) involving direct or indirect sponsorships from the industry;
- RMPs to prescribe using generic/non-proprietary/pharmacological names only;
- 30 hours of mandatory Continuous Professional Development ("**CPD**") training to be undertaken every five years from recognized medical colleges and health institutions under the NMC Act. This is proposed as a mandatory requirement for the renewal of license of the RMP. Additionally, CPD trainings mandated for RMPs practicing telemedicine;
- Prohibition on solicitation of patients independently or through institutions/organizations/hospitals/nursing homes/corporate hospitals, etc.;
- Comprehensive guidelines for social media engagement of RMPs on social media issued;
- Revised telemedicine guidelines appended to the Draft Regulations;

What India's Transition to New Data Protection Law Means for Global Businesses
January 23, 2025

India 2025: The Emerging Powerhouse for Private Equity and M&A Deals
January 16, 2025

- Monetary penalties have been omitted and all violations to be treated as professional misconduct under the NMC Act.

We have analysed the Draft Regulations in detail here.

CONCLUSION

With the shift of focus to the healthcare delivery, it has been realized that there are vast opportunities in the healthcare industry beyond the pharmaceutical segment. As a result, previously neglected and unregulated activities in this sector are being recognized and actively regulated. Given the extent of regulatory activity in this space witnessed in just the first half of the year, 2022 is likely to be a significant year for the industry and public alike.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

[1] Accessible at at https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/NMC%20RMP%20REGULATIONS%202022%20Draft%20Final%20YM.pdf (Last accessed on June 29, 2022).

[2] Accessible at: https://wbconsumers.gov.in/writereaddata/ACT%20&%20RULES/Relevant%20Act%20&%20Rules/Code%20of%20Medical%20Ethics%20Regulations.pdf (Last accessed on June 29, 2022).

[3] Providers of healthcare, which includes public and private hospitals empanelled under PM-JAY Scheme.

[4] Accessible at: https://pmjay.gov.in/sites/default/files/2022-03/AB%20PM-JAY%20Price%20Consultation%20Paper_25.03.2022.pdf (Last accessed on June 29, 2022).

[5] Accessible at: https://egazette.nic.in/WriteReadData/2021/228702.pdf (Last accessed on June 29, 2022).

[6] Accessible at: https://egazette.nic.in/WriteReadData/2022/236462.pdf (Last accessed on June 29, 2022).

[7] Accessible at: https://egazette.nic.in/WriteReadData/2021/231347.pdf (Last accessed on June 29, 2022).

[8] Accessible at: https://egazette.nic.in/WriteReadData/2022/235974.pdf (Last accessed on June 29, 2022).

[9] Accessible at: https://egazette.nic.in/WriteReadData/2021/232118.pdf (Last accessed on June 29, 2022).

[10] The Surrogacy Act permits surrogacy for legally married Indian man and woman above the age of 21 years and 18 years respectively.

[11] The Surrogacy Act defines an 'intending woman' as "*an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy.*"