

Pharma & Healthcare Update

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REGULATORY UPDATE 2023: HEALTHCARE INDUSTRY IN INDIA

INTRODUCTION

The first half of 2023 has brought about some significant developments for the Indian healthcare industry. The trend has been to regulate previously unregulated or under-regulated activities, enactment of new regimes for healthcare professionals, and operationalizing laws that were notified in the past few years. There have been significant developments for both the medical and dental fraternity; the laws that govern fertility services and surrogacy have been fully operationalised; the state-level Allied and Healthcare Councils that have been envisaged under the National Commission for Allied and Healthcare Professions Act, 2021 ("NCAHP Act") are in the process of being established by the end of this year. There have also been discussions about bringing hair transplant centres and cosmetology clinics under the ambit of the Clinical Establishments Act.

Some of the key developments that have taken place in the first half of 2023 in the healthcare industry in India have been captured below.

NEW CODE OF CONDUCT FOR DOCTORS IN INDIA

The National Medical Commission ("NMC") has notified the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 ("NMC Code") to supersede the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 ("MCI Code") issued by the erstwhile Medical Council of India. The Professional Conduct Regulations were notified on August 9, 2023, and were subsequently put in abeyance on August 23, 2023, pursuant to representations made by various stakeholders.

The NMC Code is applicable to medical practitioners registered to practice medicine in India in accordance with the National Medical Commission Act, 2019 ("Registered Medical Practitioners / RMPs") and regulates their conduct as part of the profession. The NMC Code has tightened the noose around the interactions between RMPs and the industry. Among other compliances applicable to the RMPs, specifically with respect to interactions with the industry, the NMC Code lays down as follows:

- RMPs are required to prescribe drugs with their generic names in line with the Generic Drugs and Prescription Guidelines laid down under the NMC Code.
- RMPs and their families are prohibited from receiving any gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation from pharmaceutical companies or their representatives, commercial healthcare establishments, medical device companies, or corporate hospitals under any pretext. However, RMPs may receive salaries and benefits in the capacity of employees of such organizations.
- RMPs are prohibited from participating in any third-party educational activity like continuing professional development programmes, seminar, workshop, symposia, conference, etc., which involves direct or indirect sponsorships from pharmaceutical companies or the allied health sector.

Non-compliance with the above requirements trigger penalties for RMPs under the NMC Code. The penalties range from suspension of the RMP from practicing medicine for a specified period to permanent debarment of the RMP. While the NMC Code does not prescribe a direct penalty on pharmaceutical and medical device companies, there would be tax implications in terms of non-allowance of tax deductions for expenses incurred towards marketing activities directed at RMPs which are non-compliant with the NMC Code.

NATIONAL MEDICAL REGISTER ESTABLISHED

The NMC has issued the Registration of Medical Practitioners and License to Practice Medicine Regulations, 2023 ("RMP Regulations¹") under which the National Medical Register ("NMR") is being set up² to replace the existing Indian Medical Register which was maintained by the erstwhile Medical Council of India. The NMR will be maintained by the Ethics & Medical Registration Board.

The NMR will contain the names of all medical practitioners registered with the state medical councils and will display the following information: registration number, name, fathers name, date of registration, name of hospital or institutes where they work, medical qualifications including additional medical qualifications, specialty, year of passing, university and names of the institute(s) where qualifications were obtained.

The RMP Regulation also specifies the process of obtaining a license to practice medicine. Upon granting registration (or, in case of RMPs who are already licensed to practice medicine, upon updating their information on the portal) the Ethics & Medical Registration Board will generate a Unique Identification Number ("UIN"). The UIN combined with the code of the state or union territory where the person will be practising as a suffix would constitute

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the registration number.

The NMR will provide data on the number of active medical professionals in India and their regional distribution across India.

LEGAL FRAMEWORK FOR DENTISTS REFORMED

The National Dental Commission Act, 2023 ("**NDC Act**") was notified on August 11, 2023.³ The provisions of the NDC Act are still to come into force, once effective, the NDC Act will replace the erstwhile Dentists Act, 1948 ("**Dentists Act**") in governing both dental practice and education in India.

The NDC Act broadens the definition for 'dentistry' and includes science, practice and research in dental and oral health within its ambit. Dentists registered in the national or state dental registers are eligible to practice dentistry in India. In order to register as a dentist in India, the individual should hold a dental education degree recognized under the NDC Act and qualify the National Exit Test (Dental), introduced under the NDC Act. The NDC Act also enables foreign dentists who have qualified the National Exit Test (Dental) and enrolled in the state/national dental registry to practice in India. In addition, it also recognizes and regulates 'dental auxiliary' which includes dental hygienists, dental mechanic and dental operating room assistants. Such professionals are also required to be registered with the national or state registers in India.

The NDC Act establishes the National Dental Commission ("**Commission**")- an autonomous body to oversee education, practice, and ethics of dentists. The Commission shall be supported by the Dental Advisory Council. Further, there are State Dental Councils established at a state level for the implementation of the NDC Act.

Separately, the NDC Act also enables the Government to set-up Autonomous Boards under the supervision of the Commission, which include- Under-Graduate and Post-Graduate Dental Education Board, Dental Assessment and Rating Board and the Ethics and Dental Registration Board to cater to the aim of standardization of dental education and for the implementation of the objectives of the NDC Act.

REGISTRATION OF FERTILITY AND SURROGACY CLINICS MANDATORY

The Assisted Reproductive Technology (Regulation) Act, 2021 ("**ART Act**")⁴ and Surrogacy (Regulation) Act, 2021 ("**Surrogacy Act**")⁵ were notified in December 2021 and subsequently operationalised with the publication of the rules issued under the respective laws in June 2022. As per the law, every clinic and bank that offers assistive reproductive technology ("**ART**") or surrogacy, either exclusively or amongst other services, is required to be registered with the appropriate assisted reproductive technology and surrogacy authority ("**Appropriate Authority**") for the location in which the clinic or bank is situated.

On January 24, 2023, the Ministry of Health and Family Welfare ("**Ministry**") issued a circular⁶ directing all clinics providing ART and surrogacy services and gamete banks that had either not applied for registration, or whose applications had been found to be incomplete or deficient, or whose applications had been rejected to cease all procedures and counselling pertaining to ART and surrogacy after March 31, 2023. Thereby indicating on the mandatory registration requirement for clinics or banks offering services under the ART Act and the Surrogacy Act.

EXTENSION GRANTED TO STATE GOVERNMENTS TO CONSTITUTE STATE ALLIED AND HEALTHCARE COUNCILS

The NCAHP Act came into force in May 2021 and intends to provide standards for the education and services provided by allied healthcare professionals which include behavioural health professionals (mental health counsellors excluding clinical psychologists). To practise their profession, allied healthcare professionals are required to be registered under the state and national registers. Foreign-qualified behavioural health professionals holding a recognized qualification (under the Indian Law) are permitted to register as well.

The NCAHP Act provides for the setting up of a National Commission for Allied and Healthcare Professions at central level. An interim national commission has been notified by the Government in June 2022.⁷

At the state level, the NCAHP Act requires every state government to constitute a State Allied and Healthcare Council ("**State Council**") for exercising the powers and discharging the duties laid down under the NCAHP Act, within six months from the date of commencement of the NCAHP Act. However, owing to administrative difficulties, the state governments have been delayed in setting up the State Councils and sought relaxations from the Government. Numerous orders were issued to extend the timeline for constituting the State Councils including National Commission for Allied and Healthcare Professions 2nd (Removal of Difficulties) Order, 2021 which extended the initial timeline by one year from the date of commencement of the NCAHP Act.⁸ In the latest order, i.e. the National Commission for Allied and Healthcare Professions 5th (Removal of Difficulties) Order, 2023,⁹ the Government has further extended the timeline to constitute the State Councils until November 2023 (two years and six months from the date of commencement of the NCAHP Act.)

ACCESSIBILITY STANDARDS FOR HEALTHCARE FACILITIES NOTIFIED

The Ministry has notified the 'Accessibility Standard for Healthcare'¹⁰, a set of guidelines specifying standards for ensuring barrier-free access to healthcare facilities to persons with disabilities. The standards are applicable to public and private hospitals, nursing homes, private clinics and public health centres.

The Rights of Persons with Disabilities Act, 2016 ("**PwD Act**") empowers the central government to formulate standards of accessibility for persons with disabilities, which all establishments are required to comply with. Such standards are specified in the Rights of Persons with Disabilities Rules, 2017 ("**PwD Rules**").¹¹ Failure to comply with the PwD Act and Rules may be punishable with a fine which may extend to INR 10,000 for the first contravention and may extend to INR 5,00,000 for subsequent contraventions.

Separately, during the meeting of the National Council for Clinical Establishments that was held on March 16, 2023¹², the National Council recommended that accessibility for specially-abled persons be included as a

mandatory requirement under the minimum standards for hospitals that are prescribed under the Clinical Establishments Act, 2010. The law is yet to be amended to reflect this recommendation.

CONCLUSION

As indicated by the developments from the first half of 2023, the focus remains on ensuring patient welfare and safety. Not only are healthcare professionals being brought under either revised or entirely new legal regimes, but the past few years have also seen a shift towards regulating clinical establishments that offer specific categories of healthcare services.

In addition to issuing the NMC Code, the NMC has also been actively reforming the regulatory framework for medical education in India, with the aim of ensuing more holistic and competent medical professionals in the future, which will improve the overall healthcare delivery system in India.

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You can direct your queries or comments to the authors.

¹ Accessible at: https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/DOC-20230514-WA0038_230514_120545.pdf

² Accessible at: <https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Advisory%20Dt%2009.08.2023.pdf>

³ Accessible at: <https://main.mohfw.gov.in/sites/default/files/gazette%20notification%20of%20NDC%20Act.pdf>

⁴ Accessible at: <https://dhr.gov.in/document/acts-circulars/assisted-reproductive-technology-regulation-act-2021>

⁵ Accessible at: <https://dhr.gov.in/sites/default/files/Surrogacy%20Regulation%20ACT%202021.pdf>

⁶ Accessible at: <https://artsurrogacy.gov.in/NationalArtSurrogacy/faces/HomePage.xhtml#>

⁷ Accessible at: <https://egazette.nic.in/WriteReadData/2022/236462.pdf>

⁸ Accessible at: <https://egazette.nic.in/WriteReadData/2021/231347.pdf>

⁹ Accessible at: [https://egazette.gov.in/\(S\(hg0mex02wjekw41jt0ljhdn\)\)/SearchMinistry.aspx?id=206117](https://egazette.gov.in/(S(hg0mex02wjekw41jt0ljhdn))/SearchMinistry.aspx?id=206117)

¹⁰ Accessible at: <https://egazette.gov.in/WriteReadData/2023/245810.pdf>

¹¹ Available at: <https://egazette.gov.in/WriteReadData/2023/248011.pdf>

¹² Minutes of Meeting available at: <http://www.clinicalestablishments.gov.in/WriteReadData/9631.pdf>

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