

Pharma & Healthcare Update

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HEALTHCARE ROUND UP: KEY DEVELOPMENTS IN 2019

INTRODUCTION

The Indian Government has had a busy 2019 so far with respect to healthcare regulation. From passing the controversial National Medical Commission Act, 2019 through Parliament to releasing a digital health blueprint, the Indian Government has had a very clear vision for the future of healthcare in India. That vision largely focuses on health services being controlled and administered centrally, with states playing supporting roles in this process. The Government is also encouraging and regulating alternative forms of medicine such as Ayurveda and Homoeopathy.

NATIONAL MEDICAL COMMISSION ACT WILL SOON COME INTO FORCE

The National Medical Commission Act, 2019 ("NMC 2019") has received Presidential Assent and will soon come into force once it is notified by the Government.¹ The NMC 2019 was passed in the Indian Parliament amid strong opposition from both the Parliament (including a walkout by some opposition parties) and the medical fraternity.² The NMC 2019 seeks repeal the Indian Medical Council Act, 1956 ("IMC Act") which comprises the current regulatory framework governing medical colleges and the medical practice in India.³ The NMC 2019 will also establish the National Medical Commission to replace the Medical Council of India ("MCI")- the current body regulating the medical profession in India. Legislation to replace the MCI was first introduced in the Lok Sabha in 2017 through the National Medical Commission Bill, 2017 ("NMC 2017"). The NMC 2017 was however referred to a Parliamentary Standing Committee following stiff opposition from the Indian Medical Association ("IMA") against a provision in the NMC 2017 which would allow practitioners of Ayurveda, Siddha, Unani and Homoeopathy to practice modern medicine after undertaking a bridge course ("Bridge Course Provision").⁴ The Bridge Course Provision has been omitted from the NMC 2019.

Some of the key provisions in and differences between the IMC Act and the MCI 2019 are as follows.

Criteria	IMC Act	NMC 2019
Governing Body	Medical Council of India	National Medical Commission
Appointment of governing body	Most MCI members are elected from within the medical fraternity.	The Central Government appoints all members of the NMC.
Composition of Governing Body	<ul style="list-style-type: none"> One member from each state other than a union territory is nominated by the Central Government in consultation with the State concerned. One member from each university (having medical faculty) elected by such university. One member from each state elected by persons eligible to practice medicine in the respective state. Seven members elected by persons eligible to practice medicine in any Indian State. Eight members nominated by the Central Government. 	<ul style="list-style-type: none"> Chairperson appointed by the Central Government. President of the Under-Graduate Medical Examination Board. President of the Post-Graduate Medical Examination Board. President of the Medical Assessment and Rating Board. President of the Ethics and Medical Registration Board. The Director General of Health Services. The Director General of the Indian Council for Medical Research. A Director of any of the All India Institutes of Medical Sciences. Two persons from amongst the Directors of some prominent medical colleges. One person to represent the Ministry of Health and Family Welfare. 14 part time members.
Recognition of Medical Colleges	Any person wishing to establish a medical college in India must obtain approval from the Central Government for doing so. The Central medical college and determine the procedure	The Medical Assessment and Rating Board will grant permission for establishing a new

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	Government grant permission based on the recommendation made by the MCI in this regard.	for assessing and rating existing medical institutions.
Regulation of Medical Qualifications	Establishment of a uniform entrance examination to all medical institutions at undergraduate and postgraduate level.	Under-graduate admissions will happen on the basis of a National Eligibility-cum-Entrance Test (“ NEET ”). All final year undergraduate students will have to appear for the National Exit Test (“ NEXT ”) shall be held for granting license to practice medicine. The NEXT will also be the basis for admission to post-graduate courses and serve as a qualifying test for persons possessing foreign medical qualifications to practice in India.

Currently, there is still considerable tension in the medical fraternity over the provisions relating to Community Healthcare Providers (“**CHP Provision**”). The CHP Provision empowers the NMC to grant a limited license to practice medicine to persons connected with the modern scientific medical profession.⁵ The IMA believes that the CHP Provision will encourage and legitimize quackery in the medical profession.⁶ The medical fraternity has also objected to a provision in the NMC 2019 which allows the Central Government to completely override the NMC at will.⁷

After the passage of the NMC 2019 in Lok Sabha (the lower house of India's Parliament) the IMA had called for a 24-hour withdrawal of non-essential services.⁸ After the passage of the NMC 2019 in the Rajya Sabha (the upper house of India's Parliament) protests only intensified.⁹ Doctors have called off the strike after meeting with the Health Minister of India Dr. Harsh Vardhan who assured them their concerns would be addressed. Nonetheless, skepticism over the NMC 2019 remains.

INDIAN COURTS SPUR GOVERNMENT TO TAKE ACTION ON RARE DISEASE POLICY

The Delhi High Court, in *Mohd. Kalim v. Employees State Insurance Corporation & Ors*¹⁰, (“**Delhi HC Case**”) has directed the Ministry of Health and Family Welfare (“**Health Ministry**”) to frame policy for the treatment of rare diseases. The Delhi HC Case was disposed of in April 2019 as the Petitioners received the treatment required during the pendency of the Delhi HC Case. However, in earlier hearings the Delhi High Court did direct the Health Ministry to come up with a permanent policy to provide financial assistance to persons suffering from rare diseases.

Currently India does not have a rare disease policy in place.¹¹ The Health Ministry had published a policy titled the National Policy on Treatment of Rare Diseases 2017 (“**NPTRD/Policy**”) which was subsequently withdrawn.¹² The NPTRD promised a corpus of INR 1 billion for the treatment of patients with rare genetic diseases, many of them children. According to the Health Ministry the NPTRD is in abeyance as the Policy was being handled by the Public Health Division which is a state body. The Health Ministry has since transferred all matters relating to rare/genetic diseases to the National Health Mission.¹³

The Health Ministry has stated before the Delhi High Court that it is in process of framing a new policy dealing with rare diseases and is looking at foreign legislations such as the United States of America's Orphan Drug Act, 1983, the European Union's Orphan Medicinal Product Regulation, 1999¹⁴ as well as legislations and policies prevalent in Japan, Australia and Israel.

In the past, the Delhi High Court in *Mohd. Ahmed (Minor) v. Union of India*¹⁵ formally recognized the constitutional obligation of the Government to ensure access to life saving medicines. Additionally, the Delhi High Court also directed the Delhi Government to provide enzyme replacement therapy worth INR 600,000 per month free-of-cost for the treatment of the rare disease gaucher to the patient in question. Currently, India has a one-time financial assistance program in place for treatment of rare diseases.

INDIA INVITES PUBLIC COMMENTS ON THE DRAFT NATIONAL DIGITAL HEALTH BLUEPRINT REPORT

The Health Ministry has released the draft National Digital Health Blueprint Report (“**Digital Health Report**”) inviting comments from the public.¹⁶ The Digital Health Report was prepared in pursuance of National Health Policy 2017 which identifies the extensive deployment of digital tools and technology to enhance health system performance as one of its goals. One of the corner stones of the Digital Health Report is the establishment of state-of-the-art system in order to manage core digital health data along with the infrastructure to share the data seamlessly. The Digital Health Report also proposes the creation of the state-of-the-art National Digital Health Eco-System (“**NDHE**”) to help avoid some of the pitfalls experienced by the developed countries when they were first implementing digital health. The NDHE also aims to support universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, through provision of a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensuring the security, confidentiality and privacy of health-related personal information.

Part of the NDHE is the creation of a National Health Stack (“**NHS**”) as recommended by the NITI Aayog, which is a policy think tank of the Government of India. The NHS is a set of core building blocks to be “built as a common public good” that helps avoid duplication of efforts and achieve convergence among the IT systems of the diverse stake holders such as the Governments, the Payers, the Providers and the Citizens. The NHS prioritizes data safety, privacy and confidentiality and aims to establish a mechanism to incorporate these elements ab-initio into the architecture.

INDIA ESTABLISHES DRAFT MINIMUM STANDARDS FOR CLINICAL ESTABLISHMENTS

The Health Ministry has released a draft notification proposing to amend the Clinical Establishment (Central Government) Rules, 2012 (“**Draft Notification**”) framed under the Clinical Establishments (Registration and Regulation) Act, 2010 (“**CERA Act**”) which govern the formation of and establish standards for clinical establishments in the country.¹⁷ The Draft Notification aims to revise the minimum standards for allopathy and Ayurveda, Yoga, Siddha, Unani, Homoeopathy, Naturopathy and Sowa Rigpa (“**AYUSH**”) clinics in India.

For allopathy clinics, the Draft Notification sets standards for general clinical establishments as well as super-specialty clinical departments. The general clinical establishments covered under the Draft Notification are:

1. Clinic or Polyclinic: only consultation, with dispensary, with diagnostic support and with observation facility;
2. Mobile clinic: only consultation, with procedures and dental mobile;
3. Hospitals;
4. Health check-up centre;
5. Dental lab;
6. Physiotherapy;
7. Dietetics; and
8. Integrated Counseling Centre.

The Draft Notification also identifies over 35 super-specialty clinics such as anesthesiology, pediatrics, cardiology, dermatology, gastroenterology, psychiatry services, radiology and endocrinology among others.

The Draft Notification is unique in making provisions for patient rights and responsibilities when prescribing standards for clinical establishments. Some of the patient rights are:

1. To obtain adequate, relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
2. Rate of services;
3. Access to a copy of case papers;
4. To choose alternative treatments if options are available;
5. Confidentiality, human dignity and privacy;
6. To seek a second opinion; and
7. To have a female person present during physical examination of a female patient by a male practitioner.

At present, minimum standards are available only for medical diagnostic labs which were notified in May 2018.¹⁸ However, enforcement of the CERA Act differs from state to state as the subject of health can be legislated upon only by the States as per the Constitution of India. Therefore, healthcare cannot be legislated upon by the Central Government. Currently, the States of Arunachal Pradesh, Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Himachal Pradesh, Mizoram, Sikkim and all Union Territories except the National Capital Territory of Delhi are governed under the CERA Act.

CONCLUSION

From the developments of 2019 so far, the Central Government has shown a keen inclination to regulate the healthcare sector despite facing some resistance at the state level. Currently, healthcare regulation in India varies from state to state which can make compliance and implementation complex. However, a unifying force in the form of central model legislation and policy to guide states in regulating the healthcare sector can make all the difference.

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You can direct your queries or comments to the authors

¹ NMC Act 2019, available at: <http://egazette.nic.in/WriteReadData/2019/210357.pdf> (Last Accessed August 15, 2019).

² News article on 'Lok Sabha Passes National Medical Commission Bill, available at: <https://www.indiatoday.in/india/story/lok-sabha-passes-national-medical-commission-bill-1574946-2019-07-29> (Last Accessed August 15, 2019).

³ News article on 'Lok Sabha Passes National Medical Commission Bill, available at: <https://www.indiatoday.in/india/story/lok-sabha-passes-national-medical-commission-bill-1574946-2019-07-29> (Last Accessed August 15, 2019).

⁴ News article on 'Government Plans to Re-introduce National Medical Commission Bill', available at: <https://www.thehindubusinessline.com/news/govt-plans-to-re-introduce-national-medical-commission-bill/article27762134.ece> (Last Accessed August 15, 2019).

⁵ S.32 NMC 2019.

⁶ News article on 'Indian Medical Association calls for strike' available at: <https://www.livemint.com/news/india/indian-medical-association-calls-strike-on-8-august-to-protest-against-nmc-bill-1565006894181.html> (Last Accessed August 15, 2019).

⁷ S.45 NMC 2019.

⁸ News article on 'IMA calls country-wide strike' available at: <https://www.theweek.in/news/india/2019/07/30/IMA-calls-countrywide-strike-on-July-31-against-passage-of-NMC-Bill-in-Lok-Sabha.html> (Last Accessed August 15, 2019).

⁹ News article on 'IMC calls Indian Medical Association Calls Strike on 8 August to protest against NMC Bill, available at: <https://www.livemint.com/news/india/indian-medical-association-calls-strike-on-8-august-to-protest-against-nmc-bill-1565006894181.html> (Last Accessed August 15, 2019).

¹⁰ W.P.(C) 8445/2014.

¹¹ News article on 'India's Rare Disease Policy Hangs in the Balance', available at: <https://www.downtoearth.org.in/news/health/india-s-rare-diseases-policy-hangs-in-balance-62611> (Last Accessed August 15, 2019).

¹² Notification dated December 18, 2018 by the Health Ministry keeping the National Policy on Treatment of Rare Diseases in abeyance, available at: <https://mohfw.gov.in/sites/default/files/National-policy-for-Treatment-of-Rare-Diseases.pdf> (Last Accessed August 15, 2019).

¹³ Office Memorandum dated August 01, 2018 by Ministry of Health and Family Welfare transferring rare disease matters to the NHM division, available at: <https://mohfw.gov.in/sites/default/files/OMdatedAug2018.pdf> (Last Accessed August 15, 2019).

¹⁴ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

¹⁵ W.P.(C) No 7279 of 2013.

¹⁶ National Digital Health Blueprint Report, available at: https://mohfw.gov.in/sites/default/files/National_Digital_Health_Blueprint_Report_comments_invited.pdf (Last Accessed August 15, 2019).

¹⁷ Draft notification amending the Clinical Establishment Rules, available at: <https://mohfw.gov.in/newshighlights/draft-notification-clinical-establishment-central-government-third-amendment-rules> (Last Accessed August 15, 2019).

¹⁸ News article on 'Health Ministry Proposes Minimum Standards for Clinical Establishments', available at: https://www.business-standard.com/article/pti-stories/health-ministry-proposes-minimum-standards-for-clinical-establishments-119072100291_1.html (Last Accessed August 15, 2019).

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