

COVID-19 – Healthcare Measures for Delivery of Drugs and Telemedicine

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Availability of healthcare services and essential goods such as drugs to consumers has been a paramount concern of the Central Government during the country-wide lockdown imposed to prevent the spread of COVID-19. To this end, the Government has introduced certain measures such as regulated sale of retail drugs through door-step delivery to consumers and guidelines to regulate the provision of telemedicine services to enable the remote screening and diagnosis of patients.

1. **Door-step Delivery of Drugs:** The Ministry of Health and Family Welfare issued a notification on 26 March 2020 recognising that persons holding requisite licenses under the Drugs and Cosmetics Rules, 1945 (**Rules**) may sell permitted drugs through door-step delivery. Schedule H drugs however will continue to be sold only with a prescription that may be provided physically or via email. Doorstep delivery is not permitted for narcotics, psychotropics and controlled substances, as well as drugs specified in Schedule H1 & Schedule X of the Rules.

With the spread of COVID-19 in India and the consequent lockdown, the Central Government has taken various steps to ensure availability of drugs and accessibility of healthcare services through measures such as door-step delivery of drugs and introduction of telemedicine guidelines.

Some other conditions that need to be met to engage in door-step delivery are as follows:

- to receive prescriptions for Schedule H drugs via email, the licensee will need to register an email-ID with the licensing authority;
- drugs can only be supplied at the door-step of patients who are located within the same revenue district as the licensee;
- for chronic and acute diseases, prescription must be presented to the licensee within 30 days and 7 days of issue, respectively; and
- the licensee must send the bill by email and maintain records of all transactions

While several entities have already been home delivering drugs, this notification goes on to recognise this activity and lays down the appropriate compliances.

2. **Telemedicine Practice Guidelines:** The Indian Medical Council issued the Telemedicine Practice Guidelines (**Guidelines**) on 25 March 2020 as an appendix to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (**Regulations**). The Guidelines have been issued to prevent exposure of staff and patients to viruses and infections and to reduce any unnecessary and avoidable exposure to COVID-19 in India, as well as to provide access to medical practitioners who may not be immediately available in person.

The Guidelines permit only Registered Medical Practitioners (**RMP**) to provide telemedicine consultations through mediums such as video (apps, Skype/Facetime etc.), audio (phone, VOIP, apps etc.) and text-based (chat-based

apps and platforms such as WhatsApp, general messaging, or through email/fax). They also regulate the provision of telemedicine services and detail the compliances involved such as, (a) the requirement for the identity of both the patient and the RMP to be verified, (b) consent of the patient to be obtained in certain cases, (c) age verification for issuing prescription, (d) retention of appropriate patient records by the RMP, and (e) confidentiality and secrecy obligations of the RMP. The Guidelines require all RMPs to adhere to the confidentiality obligations under the Regulations and data protection obligations under the Information Technology Act, 2000 and do not specify any additional standards in this regard.

The medicines that may be prescribed by the RMP are also classified in the Guidelines. The Guidelines create a prohibited list of drugs that cannot be prescribed based on a telemedicine consultation. Presently, this list contains drugs listed in Schedule X of Drugs and Cosmetics Act, 1940 or any narcotic or psychotropic substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985. Further, the Guidelines prescribe the process flows for various kinds of telemedicine consultations such as the manner of obtaining patient consent, types of consultations, patient management, manner of prescribing medication etc.

The Guidelines also regulate previously unregulated technology platforms, such as mobile apps and websites that provide telemedicine services to consumers. Such platforms are now required to comply with certain requirements such as ensuring that the consumers are consulting only with RMPs and conducting due diligence before listing any RMP on its online portal. They are also required to ensure that there is a proper mechanism in place to address any queries or grievances that the end-customer may have. While technology platforms can provide tools such as artificial intelligence and machine learning to be used by RMPs for support and assistance, the final prescription and counselling must be conducted only by the RMP. These technologies may be used only to support and assist the RMP. Given their business models, it stands to reason that a large portion of the above-mentioned compliances imposed on RMPs would have to be in effect operationalised by the platforms themselves and therefore, the Guidelines may require technology platforms to modify their existing operations to comply with the due diligence and technology-related compliances. Any non-compliance with the guidelines may lead to blacklisting of the technology platform, and no RMP may then use that platform to provide telemedicine.

The measures will hopefully provide much needed support to the healthcare sector in India to enable it to respond nimbly to the challenges brought about by the COVID-19 outbreak and beyond.

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