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## Case Report

# Need for Regulation of Online Health Service Aggregators Including Medical Practice and Diagnostic Services in India: Delhi High Court

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## ABSTRACT

Issues of Patient Safety during and after COVID-19 crises came before the Delhi High Court for consideration on constitutional provisions and registration and regulation of online health service aggregators including medical practice and diagnostic services in a Public Interest Litigation and subsequently contempt petition for non-compliance of High Court order. The petitioner alleged that despite the fact that the online aggregators are not registered as labs they are functioning all over the country and collecting lab samples and submitting test reports. One example has been cited of LSS Healthcare Pvt. Ltd. (1 mg Labs) to contend that the said organization is an online aggregator and is carrying out clinical tests and submitting reports which is contrary to law. The Ld. CGSC for the Union of India submitted that the matter pertains exclusively to an Entry in the State List of the Seventh Schedule of the Constitution. However, the Court was informed that the adequate statutory scheme is not yet available under the State List, for 'registration of clinical establishments'. The extant laws deal only with regulation of Nursing Homes. This Research Paper discusses various issues related to Post COVID-19 Scenario, Role of ICMR, Role of State Govt., Role of High Court / Supreme Court, Role of NMC/ SMC, Telemedicine /Tele-consultation has been discussed in brief. This will help in understanding complexity of law and sensitivity of issues in view of patient safety, constitutional provisions, ethical and illegality issues involved by various stakeholders dealing with patient safety.

**Keywords:** Online health service aggregators, Patient safety, RTPCR test, Clinical establishment

## INTRODUCTION

The matter pertains exclusively to an Entry in the State List of the Seventh Schedule of the Constitution. However, the Court was informed that the adequate statutory scheme is not yet available under the State List for 'registration of clinical establishments' in State

of Delhi. The extant laws deal only with regulation of Nursing Homes.

It appears that the Clinical Establishment (Registration & Regulations) Act, 2010 enacted but not enforced in letter and spirit even after passage of one decade since its enactment by the Parliament. The affidavit of Indian

Council of Medical Research (ICMR) says that as of 16.08.2021, 134 labs (Government: 35, Private: 99) have been approved in Delhi for conducting test for RT-PCR, True-Nat, CBNAAT and Other M-NAT Testing Platforms.

ICMR has laid down SOP's and Standard Guidelines for setting up COVID-19 testing labs. Fourteen Mentor Institutes have been set up in India to guide the labs on implementing these SOP's and set up a testing lab. For Delhi, the Mentor Institute is AIIMS, Delhi. [Para 1]

Prior to the issuance of the approval by ICMR, a certification from the National Accreditation Board for Testing and Calibration Laboratories (NABL) is mandatory for enrolment of private labs for testing. The said laboratories certify the readiness of labs to undertake molecular testing for SARS Cov- 2 prior to ICMR granting the approval. The approved labs are expected to ensure the statutory standards for COVID-19 testing, throughout the period of their approval. [Para 2]

The petitioner complained that many online-aggregators, who are not registered as labs, are functioning all over the country collecting lab samples and submitting test reports. One such entity, which did not possess the due license and is not mentioned in the list of ICMR approved laboratories, has been identified to have offered its services in Delhi. The Department of Health, Government of NCT of Delhi ('GNCTD') sent complaints to Delhi Police and to Gurugram Police on 24.06.2021, with the request to initiate appropriate proceedings against the named entity. The GNCTD has not received any response from either police force. [Para 3]

In view of the above, Delhi Police and Gurugram Police were made respondent parties. An e-copy of the petition has been supplied to the learned counsel for the respondents.

### **Prayer in PIL**

This Public Interest Litigation has been preferred with the following prayers:

- a) Issue an appropriate writ directing the respondents for immediately banning the illegal online health service aggregators which are not registered under Clinical Establishment (Registration & Regulation) Act 2010 or under any other regulations and without any medico-legal liability for collecting and testing the patient samples for diagnosis.
- b) Direct the respondents to issue guidelines for registration & minimum standards for sample collection centers operated by online aggregators including the minimum qualification for taking samples by representatives of aggregators.
- c) Direct the respondents to ensure that these aggregators comply and register with the state pollution control board or state pollution committee for the disposal of biomedical waste.
- d) Direct the respondents to ensure the Covid-19 test reports may be duly signed by a Registered Medical practitioner with a postgraduate qualification in Pathology/ Microbiology/Biochemistry/ Laboratory medicine in terms of direction of Hon'ble Supreme court of India vide order dated 12.12.0217 in SLP (C) No. 28529 of 2010 in matter of North Gujarat Unit Association of Self-Employed Owners (paramedical) of private pathology laboratories versus North Gujarat Pathologists Associations and Others.
- e) Issue any other appropriate writ that this Hon'ble Court may deem fit and proper in the facts & circumstances of the case.

### **BACKGROUND OF THE CASE**

The instant contempt petition has been filed for non-compliance of the order dated 06.08.2020 passed by High Court in a Public Interest Litigation bearing W.P.(C) 5031/2020. High Court directed the concerned respondent authorities to initiate action, in accordance with law, against any illegal online health service aggregators operating in Delhi in violation of the applicable law,

including the Clinical Establishment (Registration and Regulations) Act, 2010, if applicable, or in violation of any rules, regulations or government policies applicable to the facts of the case after giving an adequate opportunity of being heard to the concerned parties.

Delhi High Court was informed that the testing laboratories operating in Delhi have been certified by Indian Council of Medical Research ('ICMR'), as a corollary they would meet the required standards. [Para 2] The petitioner refuted the same and submitted that the comprehensive regime as envisaged in law, especially in view of the orders of the Supreme Court, [R] is non-existent. [Para 3]

The petitioner submitted that despite the fact that the online aggregators are not registered as labs they are functioning all over the country and collecting lab samples and submitting test reports.

One example has been cited of LSS Healthcare Pvt. Ltd. (1 mg Labs) to contend that the said organization is an online aggregator and is carrying out clinical tests and submitting reports which is contrary to law. [Para 2]

### **Duty of Central Govt./State Govt.- Constitutional Provisions**

The Ld. CGSC for Union of India submitted that the matter pertains exclusively to an Entry in the State List of the Seventh Schedule of the Constitution. However, the Court was informed that the adequate statutory scheme is not yet available under the State List for 'registration of clinical establishments' in State of Delhi. The extant laws deal only with regulation of Nursing Homes <sup>[1-4]</sup>.

### **Duty of State Government**

There is no mechanism of oversight by the State Government, apropos who collects blood samples etc. in Delhi apropos such tests or services. It would be in the fitness of things that a re-assurance to the residents of Delhi, if the GNCTD were to formulate and operationalize

a regime for surprise checks, inspections and audits as may be appropriate. This should be done to ensure that:

- The services are being rendered by persons qualified to collect the samples.
- The samples collected are properly stored.
- The samples reach the laboratories within the stipulated time.
- The tests are then conducted within the stipulated time.
- The test report is then promptly disseminated to the parties concerned.

In view of the exigent circumstances, this timeline and methodology could well be formulated by the GNCTD under through its executive powers including under the National Disaster Management Act, 2005. [Para 2]

### **Stand of State of Haryana**

The Ld. Senior Additional Advocate General for the State of Haryana submits that the enquiry was done apropos the complaint/ communication received from the GNCTD, regarding one entity, which is stated to have been rendering such services in Delhi, allegedly without due authority/ license. [Para 4]

He submitted that the matter was looked into and the response has been submitted to the GNCTD to the effect, that the said entity has all the requisite permissions and its testing laboratory is as per requisite parameters set and approved by National Accreditation Board for Testing and Calibration Laboratories (NABL).

### **Duty of ICMR /GNCTD: Need for publishing SOPs**

The petitioner submitted that there is no clarification apropos any standards as to the collection of such sample and requisite quantum of the blood that should be drawn for the tests to be conducted. Let the GNCTD in consultation with the Indian Council of Medical Research (ICMR) publish the requisite standards within one week.

[Para 5] The ICMR will highlight, on its website, as to how much blood sample, etc. is permitted to be collected for conducting the Covid related tests. [Para 6]

Delhi High Court observed that having heard the Ld. Counsel for both the sides and looking to the facts and circumstances <sup>[5,6]</sup> of the case, it appears that there are allegations about operations of illegal online health service aggregators which are not registered under any law, including the Clinical Establishment (Registration and Regulations) Act, 2010. [Para 2]

Delhi High Court further observed that much has been argued out by the counsel for the petitioner relying on several annexure including Annexure-P1, that there are several non-registered online health service aggregators operating in the field in Delhi and that their activities must be stopped by the respondents in accordance with law. [Para 3]

### Observations of Delhi High Court

Delhi High Court observed that having heard the learned counsel for both the sides and looking to the facts and circumstances of the case, it appears **that there are allegations about operations of illegal online health service aggregators which are not registered under any law, including the Clinical Establishment (Registration and Regulations) Act, 2010.** [Para 2]

Delhi High Court further observed that much has been argued out by the counsel for the petitioner relying on several annexure **that there are several non-registered online health service aggregators operating in the field in Delhi and that their activities must be stopped by the respondents in accordance with law.** [Para 3]

### Directions for Violations by Delhi High Court

Delhi High Court observed that having heard the counsel for both the sides and looking to the facts and circumstances of the case, we hereby direct the concerned respondent authorities to initiate action, in accordance with law, against any illegal online health

service aggregators operating in Delhi in violation of the applicable law, including the Clinical Establishment (Registration and Regulations) Act, 2010, if applicable, or in violation of any rules, regulations or government policies applicable to the facts of the case.

Action will be initiated in accordance with law against such violators of the law as expeditiously as possible and practicable, after giving an adequate opportunity of being heard to the concerned parties. [Para 4]

**Several examples** have been given in this writ petition about such alleged violators. Since they are not joined as party respondents, High Court is not observing anything against any of the parties or so-called violators of the law, as pointed out in the writ petition. It is open for the respondents to take action against any such violators of the law as stated hereinabove, after giving an adequate opportunity of being heard to the concerned parties. [Para 5] With these observations, the writ petition was disposed of. [Para 6]

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