Azadi Ka Amrit Mahotsav

FICCI

Self-Regulatory Code of Conduct for

e-Diagnostics in India

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Self-Regulatory Code of Conduct for e-Diagnostics in India

The ubiquity of the internet and communication technology has given way to the proliferation of several technology driven models, allowing consumers to access, avail several services from any desired location. Healthcare services are also becoming increasingly tech-enabled, and digital health has the potential to transform the way our country manages its healthcare delivery. In the health sector, this has not just worked towards saving costs associated with travel but has also helped in ensuring that there is no disruption in the care rendered to the patients especially elderly and bedridden patients.

Digital technology is going to be the key enabler that will help the country achieve the vision of Universal Health Coverage. With the recent announcement of the Ayushman Bharat Digital Mission (ABDM), e Access to healthcare services will be a focus area.

With the advent of technology access to quality healthcare and making it more meaningful and making it within the reach of the people can become a reality. Adoption of technology, specifically the internet, allows for the ecosystem to increase accessibility, affordability of the services which are presented to the end users, bringing healthcare delivery to the last mile.

In the recent times, the country has witnessed an outstanding digital strategy, CoWIN, towards planning the national COVID-19 vaccination. This digital approach also helped in tracking the utilization of COVID-19 vaccination and minimizing wastage.

The medical diagnostic sector is also not untouched by this change and has seen advancements in these areas. Tech-enabled platforms have the potential to transform access to quality diagnostics and they also provide for **tracking and traceability** of the services aimed to be provisioned from over their platforms. Moreover, such platforms and services plug well into the Ayushman Bharat Digital Mission (ABDM) initiative which envisions to reshape India's digital healthcare infrastructure.

This Voluntary Code of Conduct is a self-regulatory attempt by the industry to adhere to the highest professional standards and have proper safeguards to ensure that patients' health and safety is not compromised.

Mission Statement

All members hereby commit to hold ourselves to the highest standards and voluntarily commit that our operations shall be within the following safeguards and parameters. The Code will hold the contracting bodies to a set of rules which will be instrumental in regulating their operations and ensuring compliance with the Code of Conduct and will allow the organizations to streamline their businesses and infrastructure. This Code will ensure that the members of the e-Diagnostics sector are adhering to the highest standards applicable to the industry and will ensure that the health of the consumers is not compromised.

Qualifications to submit to the Code of Conduct

All e-Diagnostic platforms have a technology platform (website, apps etc.) to take customer requests, this could be an aggregator platform for multiple medical laboratories or a technology platform for self-operated medical laboratories.

In addition, the e-Diagnostic value chain may also have any of the following three components:

I) Clinical Sample Collection and Transportation Service

a. From patient's home to the laboratory

b. From any other institution (e.g., Hospitals, Health camps) to the laboratory

ii) Clinical Sample Processing & Reporting Service

a. In-house Testing at a Medical laboratory

b. Outsourced to a reference lab

iii) Report delivery to consumer

Any entity in the area of their operations which is offering anyone, more than one, or all the above-mentioned services separately or jointly, may choose to be bound by the terms of this voluntary Self-Regulatory Code of Conduct.

Components of Code of Conduct

Components of Code of Conduct: All members commit to hold ourselves to the highest standards and voluntarily commit that our operations shall operate with the following mentioned safeguards:

1. **Responsibilities of the Technology Platform listing Medical Laboratories**
   a) **Transparent listing of laboratories on a technology platform:** Members shall provide details of the laboratories on behalf of which they are listing services, incl.
      - Registration status and accreditations of the laboratories, whichever is applicable
      - Address and contact details of the corporate office or the laboratory
      - Details of individual tests and packages incl. prices and preparations the consumers need to undertake before the test
      - Expected Time to deliver Test results

   b) **Selection of Laboratory and Audit Mechanism**
      - Members who are providing aggregation services shall have an effective documented procedure for evaluating and selecting medical laboratories

before listing any medical laboratories on their portal to ensure access to quality diagnostics

- Either the laboratory should have NABL / NABH / CAP or other relevant accreditation or else the members should include verification of trained personnel and calibration systems, and records management in their evaluation and selection process
- Arrangements with the medical laboratories shall be reviewed periodically to ensure that the medical laboratory is able to meet the requirements

2. Requirements for Safe Sample Collection and Transportation

2.1 Members shall define SOPs around patient identification, sample collection, transportation, storage, and safe disposal of material used in collection, and ensure that the concerned personnel follow them. Documented procedures and necessary instructions shall be available in a language commonly understood by the concerned personnel

2.2 Members shall employ trained phlebotomists and ensure that there is a program in place for regular training

2.3 Members shall ensure traceability of collected samples and portions of samples

2.4 Members shall ensure that the collected samples reach the laboratory within the stipulated time frame

2.5 Members shall conduct regular audits of processes and equipment to maintain quality

2.6 Members shall have a provision to handle urgent samples and recollection in case of sample rejection

2.7 Members shall send the details of the phlebotomist on the communication sent to the end user / patient for transparency, ease of identification

3. Requirements for Clinical Sample Processing & Reporting

The requirements listed below are over and above all the applicable norms, standards, and regulations for a medical laboratory which they shall strictly adhere to

3.1 Members shall ensure that the tests on the received sample are conducted within the stipulated time frame by the physical medical laboratory

3.2 Members should ensure that the report for test results shall only be generated by the physical medical laboratory engaged in sample processing irrespective of involvement of other members / players in various other processes

3.3 In addition to the standards of reporting, the members shall ensure:

- Clear identification and location of laboratory issuing the report
- Name or other unique identifiers of the requester
- Date and time of sample collection, sample receipt by laboratory, and release of report

3.4 Either the laboratory should have NABL / NABH / CAP or other relevant accreditation or else the members shall conduct regular audits of processes and equipment to maintain quality

3.5 Members shall make declarations of partnerships with collection centre / facility / source as per the applicable current guidelines

4. Requirements for Report delivery to consumer

4.1 Members taking the request from the users shall be responsible for ensuring that medical laboratory examination results and findings are provided to the users in the committed time frame

4.2 In case of any reason due to which reports are delayed due to the lab issues, the technology platform must have systems to enquire for breaches or facilitate communication between the laboratory and the user

4.3 In case reports are further delayed due to the technology platform related issues, the platform must ensure communication to the customer within 12 hours of the TAT breach

5. Customer grievances

5.1 Members shall have policies and procedures for the resolution of complaints or other feedback received from clinicians, patients, or other parties

5.2 Records of complaints and of investigations and corrective actions taken by the members shall be maintained for a minimum period of 12 months

5.3 All members should be registered with the National Consumer Helpline and try and address all issues raised there actively

6. Adherence to applicable regulatory requirements and technical specifications

6.1 All the regulatory norms, standards, and guidelines, applicable in the State of member's operation, shall be adhered to

6.2 Members shall ensure that the patient / consumer data should be processed and stored as per the applicable laws, coming into effect from time to time

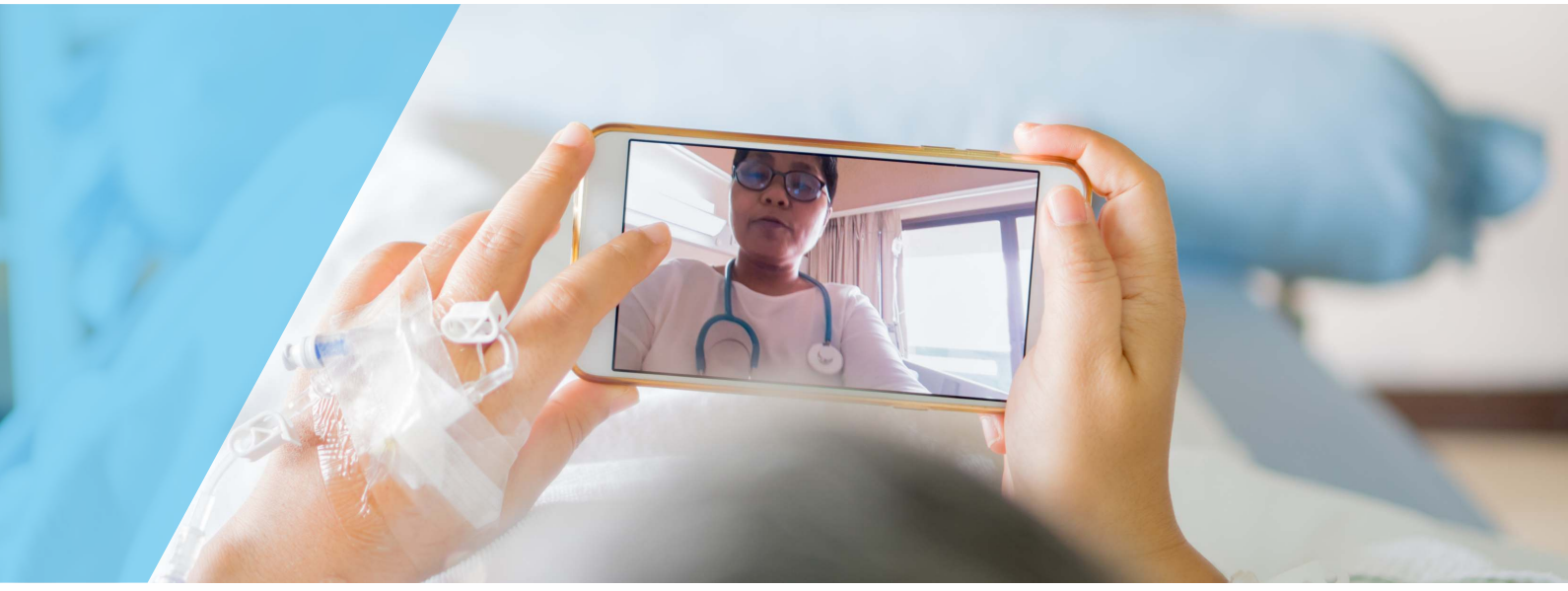
6.3 All the technical equipment used in operations shall meet the required standards

6.4 All personnel carrying out various operations shall be duly qualified for and properly trained in their respective roles.

7. Public Health Initiatives of Government of India

Members shall support Government's various public health initiatives coming into effect from time to time.

Annexure: Benefits of e-Diagnostics



- **Accessibility:** Recent reports reveal that the diagnostics penetration in India is only thirty-nine diagnostic labs per million people compared to 418 labs per million people in the US and sixty labs per million people in Brazil. Further only a small fraction of these labs is accredited by National Accreditation Board of Laboratories (NABL) and / or College of American Pathologists (CAP). This is where the technology driven models can transform the access through their vast network of accredited and reputed labs, a professionally trained phlebotomist workforce, and collection centres.
- **Convenience:** The technology driven access models makes the entire process of getting medical test very convenient for the patients and their family members / attendants. This can be of immense benefits to elderly citizens, and patients of chronic diseases who face mobility challenges or are bedridden. Unlike the past when one would need to book a test, travel to the lab, and spend a lot of time and effort in getting the test done, now it takes very little time and effort as the samples are collected from home and there is no need for all those hassles.
- **Affordability:** Despite the various health coverage schemes, the diagnostic testing is predominantly an out-of-pocket expense in India and the existing insurance schemes hardly cover any of them. Thus, the cost of tests becomes a major factor for the patients. Technology can make the testing more affordable by allowing the patients to compare between products and services offered by different labs. It gives the patients

greater ability to make well informed choices and they avoid getting overcharged by unorganized local labs.

- **Optimization of existing lab resources:** The usage of technology leads to greater optimization of resources in the labs. This brings out greater resource utilization and efficiency in the entire system.
- **Key element of digital health outreach programs such as ABDM:** The e-Diagnostics industry has an enormous potential of enabling the digital health ecosystem in the country.

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About FICCI

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states. FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.