

2017 Top Markets Report **Health Information Technology** Country Case Study

India

Overall Rank

79

With a population of more than 1.3 billion people and a health infrastructure still under development, Health IT can play a significant role in addressing many unmet health care needs and accessibility issues across India. The long-term potential for U.S. Health IT companies remains positive: the sector is still at an early development stage; the information and communication infrastructure is very good; and regulations are minimal. However, Indian officials need to address many policy issues, including identifying Health IT priority areas, increasing investment, and determining which Indian ministries will take lead roles in coordinating activities for the sector. With significant regional differences in healthcare provision, the large potential market for products and services make India a long-term strong prospect for U.S. companies.

Overview of Market

India has a population of over 1.33 billion across 29 states and six Union Territories and is governed by a federal system. India is also home to the third largest smartphone market in the world, expected to reach 314 million mobile internet users by 2017, making future opportunities in the m-Health (mobile health) subsector a very lucrative possibility.

A comparatively low presence of doctors, along with limited access to full-scale health care facilities, has contributed to challenges for patients living in rural vs. urban areas. Currently, in India's three-tier, government-supported system for health care delivery, states have the primary responsibility for public health care. This results in significant disparities in quality and access to health care services between regions within states (and even cities) in India. Embracing modern technologies through health IT may help offer solutions to this lack of access, broadening health care accessibility.

On the other hand, India is technologically advanced in the Information and Communications Technology (ICT) sector and is largely self-sufficient in meeting its needs for hardware, software, connectivity and services. ICT has the potential to improve health care accessibility and affordability, especially in rural India. This success can be magnified if ICT is further integrated into existing health care delivery systems.

With 75 percent of the country's health care infrastructure concentrated in urban areas -- and more than 75 percent of the population living in rural areas¹ -- use of telemedicine (provision of telecommunications technology to provide healthcare) could help effectively bridge the gap between patients and doctors in India. For example, Devi Shetty's Narayana Health, which pioneered the concept of telemedicine, has one of the largest telemedicine networks in the world.² Further, there are 105 state-funded telemedicine centers in the country. Some Indian states have signed agreements with private players using a public-private-partnership (PPP) model. States like Rajasthan are experimenting with the PPP model in health care where private parties will run the state's Primary Health Centers (PHCs).

Current Indian Health IT Initiatives

National Health IT Authority³ ("NeHA"), the brainchild of India's Ministry of Health and Family Welfare, is an authority that is proposed to be responsible for developing an integrated health information system. It will be the nodal authority for developing this system, along with the application of telemedicine and mobile health, by collaborating with various stakeholders. NeHA would also be responsible for enforcing the laws and regulations relating to the privacy and security of a patients' health and information records. NeHA is intended to be a promotional, regulatory and standards-setting organization to guide and support India's journey in Health IT and consequently realize benefits of ICT intervention in the health sector. It also spells out the proposed functions and governance mechanism of NeHA.

At the Indian state level, the Chhattisgarh government, with the help of the Indian Space Research Organisation ("ISRO"), has linked government medical colleges at Raipur and Bilaspur with premier hospitals across the country, creating a statewide network.⁴ ISRO has also set up 30 such nodes in Karnataka. The ISRO is also deploying telemedicine nodes under the 'gramsat scheme.' Along with various state governments, the ISRO has managed to establish a vast telemedicine network that consists of 225 hospitals connected to 40 super specialty hospitals.

Additionally, India's Ministry of Health and Family Welfare is reportedly developing legislation that will address one of the critical concerns in the Health IT space – data privacy and protection of health information. The ministry has assigned the National Law School of India University with the task of preparing the first draft of the legislation, which will also formally establish NeHA, as well as health information exchanges.⁵ The proposal intends to provide regulation and standardization for electronic health records, as well as consequences for data breaches. It would also clarify areas such as the ownership of electronic health records and the transfer and access of such information.⁶

Challenges for U.S. Companies

¹ Ashok Vikhe Patil, K. V. Somasundaram and R. C. Goyal; Current Health Scenario In Rural India; available at <http://www.sas.upenn.edu/~dludden/WaterborneDisease3.pdf>

² https://en.wikipedia.org/wiki/Narayana_Health

³ https://www.nhp.gov.in/UploadFiles/microsite/635689249545690829_1.pdf

⁴ Central Bureau of Health Intelligence; Telemedicine Project, Chattisgarh; available at <http://www.cbhi-hsprod.nic.in/searum.asp?PNum=210>

⁵ Prathiba Raju, Express Healthcare; 'We are working in the direction of citizen empowerment through information dissemination'; available at: <http://www.expressbpd.com/healthcare/it-healthcare/we-are-working-in-the-direction-of-citizen-empowerment-through-information-dissemination/377474/>

⁶ <http://ehealthmasterminds.com/india-neha/>

There are hurdles in applying telemedicine practices between Indian states. Most importantly, since the objective of telemedicine is to provide medical services not restricted to the location of the patient, it is unclear whether an Indian doctor registered with a state medical council would be permitted to provide medical services to patients residing in another state, and whether such doctors would be required to obtain multiple state registrations to be entitled to practice telemedicine. Regulators may consider adopting cross-border licensing practices being followed in the United States for telemedicine. Further, cross-jurisdictional education between the United States and India could be arranged to promote the prevalence of telemedicine practice in India.

Besides the challenge of cross-state consultations, there are other considerations with popularizing Health IT in India, including drug prescription and other location-based issues.

On drug prescription, doctors must exercise caution while prescribing drugs through a telemedicine platform. Apart from the Information Technology Act, 2000 (“IT Act”) requirements relating to the validity of a prescription (referenced below), Indian courts have stated that prescriptions should not ordinarily be given to a patient without actual examination and observed that the tendency to give prescriptions over the telephone should be avoided, except in cases of emergency.⁷ As a result, the worldwide trend of increasingly submitting prescription requests online (whether as an offshoot of a physical pharmacy or totally on the Internet) has so far bypassed India.

Resolving potential disputes may also present jurisdictional challenges. Since Health IT services are not location-specific, service recipients are distributed around India. This could become an issue in case of an adverse event, leading to filing a suit in a civil, criminal or consumer court. The plaintiff – in this situation an aggrieved patient – is entitled to institute a suit at a local court, requiring the service provider to have to travel to the location in which the suit has been filed. This also acts as a deterrent for practitioners who are on the fence regarding the adoption of Health IT services in their practice, as there is an ongoing risk of having to travel to any part of India to appear before the relevant forum if a case is instituted.

Last but not least, foreign businesses must be aware that regulatory approvals in India on Health IT can take from three to nine months on average.

Opportunities for U.S. Companies

When considering the Health IT sector’s potential in India, there may be opportunities for U.S. companies to invest in the market. Laws governing this area include the Foreign Exchange Management Act, 1999 (“FEMA”), rules and regulations made by the Reserve Bank of India (“RBI”), and the Industrial Policy and Procedures issued by the Ministry of Commerce and Industry through the Secretariat for Industrial Assistance, Department of Industrial Policy and Promotion (“DIPP”). While the DIPP issues policy guidelines and press releases from time to time regarding foreign investment into India, it also issues an annual consolidated FDI policy (the most recent edition was published in 2016). There are no restrictions prescribed for Health IT investments. Therefore, FDI up to 100 percent should be permitted without government approval.⁸

⁷ Martin F. D’Souza v. Mohd. Ishfaq; (2009) 3 SCC 1

⁸ Press Note 5 of 2016, available at: http://dipp.gov.in/sites/default/files/Press_Note_5_2016.pdf

Government of India Oversight of Health IT Sector

In a broader scope, several laws appear below that cover Health IT services in India:

- The Information Technology Act, 2000 (“IT Act”), The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (“Data Protection Rules”) and the Information Technology (Intermediaries Guidelines) Rules, 2011 (“Intermediary Guidelines”): Health IT involves a constant exchange of information between the patient and the service provider.
- Other Service Providers Regulations under the New Telecom Policy 1999 (“OSP Regulations”): Service providers who render “Application Services” -- including telemedicine services – using telecom resources provided by telecom service providers, are required to be registered as an ‘Other Service Provider’ (“OSP”) with the Department of Telecommunications.
- The Drugs and Cosmetics Act, 1940 (“D&C Act”) and Drugs and Cosmetics Rules, 1945 (“D&C Rules”): The D&C Act and D&C Rules regulate the manufacture, sale, import and distribution of drugs in India, and it is important to note that medical devices are currently regulated as drugs.
- The Indian Medical Council Act, 1956 (“MCI Act”) and The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (“MCI Code”): The MCI Act provides that only those persons who have a recognized degree in medicine, and are registered with one of the state medical councils have the right to practice medicine in India. The MCI Code lays down professional and ethical standards of interaction of doctors with patients.
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 (“DMRA”).
- Unsolicited Commercial Communications Regulations, 2007 (“UCC Regulations”) and Telecom Commercial Communication Customer Preference Regulations, 2010 (“TCCP Regulations”).
- The Clinical Establishments (Registration and Regulation) Act, 2010 (“Clinical Establishments Act”).

As a rule of thumb, the laws above, along with rules and regulations are governed by multiple ministries in India, including the Ministry of Commerce and Industry (MOCI), Ministry of Health and Family Welfare (MHFW), and the Department of Pharmaceuticals (DOP). Due to the fragmentation of oversight regarding the health care sector in India, it’s critical for American companies operating in India to have local partners who are familiar with navigating the system and to help explore commercial opportunities.

To date, most Indian Health IT opportunities appear to lie in telemedicine, but it is possible that opportunities in other subsectors will develop in the future, such as Self-Monitoring Healthcare Devices, with monitors and sensors being integrated into wearables, which allow it to detect various physiological changes in the body. These smart devices are capable of tracking weight, sleep patterns, posture, diet and exercise.⁹ The raw data collected can be used to self-monitor by detecting various health symptoms and alert the user in case of potential issues. Another could be Electronic Health Records (“EHRs”). With

⁹ Geoff Appelboom, Elvis Camacho, Mickey E Abraham; Smart wearable body sensors for patient self-assessment and monitoring; available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166023/>

EHRs, doctors can view their patient's complete medical history even if they are treating the patient for the first time.

Telemedicine, together with self-monitoring health care devices and electronic health records, appear to be the areas with promising development potential in India's Health IT market. Though the market potential is significant, navigating India's convoluted and fragmented regulatory approval system can be challenging, and for a company interested in venturing into India, a long-term viewpoint may be prudent, with further market intelligence needed before making any business decisions.