

23 August 2021

To,  
Vikram Pagaria,  
Joint Director (Coordination)  
National Health Authority,  
Ministry of Health and Welfare,  
Government of India,  
9<sup>th</sup> Floor, Tower - 1  
Jeevan Bharati Building, Connaught Place,  
New Delhi – 110001

**SUBJECT: OUR COMMENTS ON THE ‘CONSULTATION PAPER ON UNIFIED HEALTH INTERFACE’**

Dear sir,

On behalf of Ikigai Law, we would like to thank you for this opportunity to submit our comments on the Consultation Paper on Unified Health Interface. We also wish to congratulate the National Health Authority and the Ministry of Health and Family Welfare for piloting and driving the National Digital Health Mission. Achievement of the intended outcomes and uses of the National Digital Health Mission will make it a platform unlike anything the world has seen.

Ikigai Law is an award-winning policy and law firm with a deep focus on technology and innovation. We specialize in representing technology companies with new business models and work extensively with the Indian start-up ecosystem. Our comments to the Consultation Paper are informed from our experience of working with prominent technology companies and start-ups working in healthcare.

The consultation paper raises several questions on the functional and technical design of the unified health interface as well as means for increasing its adoption and governing it. Our comments highlight (i) the need for strengthening the Telemedicine Practice Guidelines, 2020; (ii) the need for passing legislation for online sale of medicines; (iii) suggested ways of mitigating risks associated with concentration of health data by periodically reviewing security of the unified health interface, using blockchain technology, and providing template consent forms/privacy notices; (iv) the use of blockchain technology to help operationalise the health information exchange envisaged in the consultation paper; (v) the need for involving medical professionals in designing of the unified health interface; and (vi) that the draft bill on personal data and ongoing discussion on non-personal data should not stymie product innovation, research (clinical/academic), and evidence-based policy making.

We are happy to meet with you and discuss our comments in detail.

Sincerely,

Shambhavi Ravishankar, Rutuja Pol, and Anirudh Rastogi

Ikigai Law



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## COMMENTS ON CONSULTATION PAPER ON 'UNIFIED HEALTH INTERFACE'

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### A. OVERVIEW:

The National Health Authority (“NHA”) released a consultation paper for getting inputs on setting up and running a new building block in the National Digital Health Mission (“NDHM”) ecosystem, namely a unified health interface (“UHI paper”). Our comments are structured to provide (a) comments specific to the questions raised across sections of the UHI paper; and (b) broad comments providing additional inputs/points for consideration by the NHA in setting up and running the UHI building block of the NDHM.

Our suggestions in brief:

1. The UHI paper has sought inputs on strengthening the Telemedicine Practice Guidelines, 2020 (“TPG 2020”) to drive the adoption of telemedicine. The TPG 2020 should be strengthened to provide greater clarity on (i) the medico-legal relationship between patients, doctors, and technology platforms offering telehealth services to patients; (ii) healthcare specialty-specific protocols; (iii) paving the way for using emerging technologies through telemedicine; and (iv) guidelines for the transfer of electronic health records (“EHR”) when a patient changes healthcare professionals on a technology platform.
2. Standards must be set to address the security risks of having an open network. This includes (i) periodic reviews of the security and vulnerability of each building block in the NDHM (including the UHI); and (ii) laying down the procedure for rapid response and incident reporting (e.g., when there is cyberattack).
3. Consider standardizing online sale of drugs and devices by laying down oversight mechanisms for the appropriate regulatory authorities through a national legislation. This is key to ensuring (i) that the list of medicines that can be prescribed on a telemedicine platform as per the TPG 2020 can be expanded; and (ii) that trust can be built in e-pharmacies that sell drugs and medical devices online.
4. The NHA must specify minimum standards or provide a privacy policy and consent notice templates for entities operating in the UHI to communicate their data privacy policies to the end user. The minimum standards and/or templates must be compliant with the forthcoming Personal Data Protection Bill, 2019. The model notices allowing the use of EHR in aggregated and anonymized form, per the report of the committee of experts on non-personal data.<sup>1</sup>

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<sup>1</sup> Report by the committee of experts on non-personal data governance framework, (December 16, 2020), [https://static.mygov.in/rest/s3fs-public/mygov\\_160922880751553221.pdf](https://static.mygov.in/rest/s3fs-public/mygov_160922880751553221.pdf)

5. The NHA should provide clarity on personal data and non-personal data ownership, management, and further use. This will ensure that requirements under the draft Personal Data Protection Bill 2019, and the report of the committee on experts on non-personal data,<sup>2</sup> do not act as disincentives to digital health innovation and healthcare delivery.
6. The NHA should consider using blockchain for EHR management and operating the health information exchange to protect patient rights while also supporting innovation, research, and evidence-based policymaking.
7. The NHA should consider having medical professionals as part of the 'Expert Committee',<sup>3</sup> to ensure that the technology protocols do not hinder the delivery of healthcare services.

## **B. SPECIFIC QUESTIONS POSED IN THE UHI PAPER:**

In this section we provide inputs for the following specific questions posed in the UHI paper: (1) strengthening the Telemedicine Practice Guidelines 2020 (“**TPG 2020**”);<sup>4</sup> and (2) risks of adopting an open network approach to digital health.<sup>5</sup>

### 1. Strengthening the Telemedicine Practice Guidelines 2020:

The TPG 2020 was released to ensure continuity of care during the COVID-19 pandemic and to enhance access to healthcare in India.<sup>6</sup> It was a much-needed step in clarifying the dos and don'ts for doctors (i.e., registered medical practitioners) and for laying down some basic requirements for technology platforms offering telemedicine. Since then, however, there have been discussions on what the TPG 2020 does not provide clarity on. Some of these issues include:

- i. Other healthcare professionals: The TPG 2020 does not provide inputs on what healthcare professionals other than doctors can do in a telehealth/telemedicine setting. To tackle this, the TPG 2020 could be strengthened to include protocols for each healthcare specialty.<sup>7</sup> Take, for example, a mental health counsellor or a physiotherapist. Both professionals provide healthcare,

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<sup>2</sup> Report by the committee of experts on non-personal data governance framework, (December 16, 2020), [https://static.mygov.in/rest/s3fs-public/mygov\\_160922880751553221.pdf](https://static.mygov.in/rest/s3fs-public/mygov_160922880751553221.pdf)

<sup>3</sup> Para 6.1.2, Chapter 6, UHI development, governance, and management, Consultation paper on unified health interface.

<sup>4</sup> Para 1.7., Questions for consultation. Consultation paper on unified health interface, at p.13

<sup>5</sup> Para 2.4, Questions for consultation. Consultation paper on unified health interface, at p.18

<sup>6</sup> Background, Telemedicine Practice Guidelines, 2020, <https://www.mohfw.gov.in/pdf/Telemedicine.pdf>, at p. 7.

<sup>7</sup> For example, Singapore's National Telemedicine Guidelines recommends healthcare professionals adhere to healthcare specialty-specific guidelines for providing services through telemedicine. These guidelines give the example of relying on the Tele-radiology Guidelines 2007 as documented by the College of Radiologists in Singapore. (See: para 4.4., National Telemedicine Guidelines, 2015, [https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06\\_2015\\_30jan15\\_telemedicine-guidelines-rev.pdf](https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06_2015_30jan15_telemedicine-guidelines-rev.pdf), at. p. 24).

but the TPG 2020 does not lay down clear protocols on what they can do through a telemedicine platform.<sup>8</sup> The following illustration demonstrates why this lack of clarity is problematic. During the COVID-19 pandemic, many patients received their physiotherapy through video chats. Physiotherapy is not just a hands-on type of treatment. It also involves the physiotherapist carefully observing a person's movements – to pinpoint areas of pain or awkward movement.<sup>9</sup> To do this in a virtual setting requires protocols to ensure that the physiotherapist can assess a patient's progress properly. Good lighting, for example, could play a big role in this regard.<sup>10</sup> Similarly, there may be instances where a patient may not be eligible for telemedicine-based physiotherapy sessions. The Australian Physiotherapy Association released a set of guidelines on how physiotherapy should work through telemedicine. These guidelines include assessing whether a patient's condition is stable enough to do the session virtually or whether an in-person session would be more appropriate.<sup>11</sup> It also recommends that any pre-existing conditions be taken into consideration (e.g., a disability) when assessing the safety of telemedicine for physiotherapy for a patient.<sup>12</sup> Relying on healthcare specialty-specific guidelines will boost the growth of telemedicine by ensuring that more types of healthcare services can safely be offered through telemedicine. This also means that irrespective of whether a patient lives in a big metropolitan city or a remote town, they can get good quality care even on complex aspects of health care, like physiotherapy.

- ii. Procedure when the assigned healthcare professional is changed: There is a lack of clarity on the procedure when a patient changes their doctor on a technology platform, regarding their healthcare and health records thus far. For example, will the patient have to provide consent again to share their records with the new doctor? Or in a case where a technology platform does not have the provision for patients and doctors to make such EHR (e.g., in data entry fields or fields to upload PDFs/image files)? In the second instance, it may be more difficult to manage consent and transfer EHR to the new doctor, because the doctor may have taken notes on paper.

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<sup>8</sup> Damodharan Dinakaran, Narayana Manjunatha, Channaveerachari Naveen Kumar, Suresh Bada Math, Telemedicine practice guidelines of India, 2020: Implications and challenges, (15 February 2021), <https://www.indianjpsychiatry.org/article.asp?issn=0019-5545;year=2021;volume=63;issue=1;spage=97;epage=101;aulast=Dinakaran>,

<sup>9</sup> Abby Ellin, Telemedicine for physical therapy: how it works, (May 19, 2020), <https://www.everydayhealth.com/pain-management/telemedicine-for-physical-therapy-it-works/>.

<sup>10</sup> Abby Ellin, Telemedicine for physical therapy: how it works, (May 19, 2020), <https://www.everydayhealth.com/pain-management/telemedicine-for-physical-therapy-it-works/>.

<sup>11</sup> Australian Physiotherapy Association, Telehealth guidelines, (March 2020), <https://australian.physio/sites/default/files/APATelehealthGuidelinesCOVID190420FA.pdf>, at p.9

<sup>12</sup> Australian Physiotherapy Association, Telehealth guidelines, (March 2020), <https://australian.physio/sites/default/files/APATelehealthGuidelinesCOVID190420FA.pdf>, at p.10

The consent process under the TPG 2020 could be strengthened by suggesting options for providing consent for the new doctor to access EHR (e.g., OTP authentication before each access).

- iii. Addressing medico-legal liability: The TPG 2020 also does not discuss aspects of medico-legal liability of technology platforms or doctors providing care through a technology platform.<sup>13</sup> Consider a situation where the doctor is providing guidance on proper use of an insulin pen. Insulin pens typically have dials to ensure that patients inject the right quantity of insulin into themselves.<sup>14</sup> The patient must rotate the dial to the dosage prescribed to them (e.g., 5 units), so that only that amount gets injected.<sup>15</sup> While the doctor is providing information on how to rotate the dial, the technology platform glitches, and the patient injects more than her prescribed dose. This leads to insulin shock (too much insulin in the body)<sup>16</sup> and dizziness which causes the patient to hit their head and lose consciousness. In such a situation, who will be liable? The technology platform or the doctor? While it may be the case that this fact scenario does not rise to the level of medical negligence under current laws and cases, it is useful in demonstrating the need to consider the implications of technology use on patient safety. With such a consideration, protocols and guard rails can be set in place to protect all parties concerned, i.e., doctors, technology platforms, and patients. This fact scenario also throws light on the importance of involving medical professionals in the decision-making process on what technology tools are used to provide the NDHM ecosystem and how. It also reveals the relevance of annual reviews of the functioning of the NDHM and its various moving parts, including entities operating in the UHI. This is because technology evolution is fast paced, and the risks and benefits of each new technology must not be discussed in a purely technological sense. The discussions must frequently reference the mission of increasing access to quality and affordable healthcare. Singapore's 'National Telemedicine Guidelines'<sup>17</sup> for example, call for training healthcare

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<sup>13</sup> DIAL A DOCTOR- A look at the Telemedicine Practice Guidelines, 2020, (April 17, 2020), <https://www.cyrilshroff.com/dial-a-doctor-a-look-at-the-telemedicine-practice-guidelines-2020/>.

<sup>14</sup> Mayo Clinic, How to use an insulin pen, (14 June 2014), <https://www.youtube.com/watch?v=fCqEIn7ccA>.

<sup>15</sup> Mayo Clinic, How to use an insulin pen, (14 June 2014), <https://www.youtube.com/watch?v=fCqEIn7ccA>.

<sup>16</sup> Warning signs and treatment options for insulin shock, (June 05, 2020), <https://www.healthline.com/health/diabetes/insulin-shock>.

<sup>17</sup> Singapore, National Telemedicine Guidelines, 2015, [https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06\\_2015\\_30jan15\\_telemedicine-guidelines-rev.pdf](https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06_2015_30jan15_telemedicine-guidelines-rev.pdf).

professionals in technology use, adding that where technical or environmental issues affect the quality of the session, it must be rescheduled.<sup>18</sup>

- iv. Telemedicine can involve more than mere digital communication: Today, telemedicine largely involves doctors and patients communicating virtually with each other for a patient's healthcare needs. However, as technology advances, more healthcare options will be available to patients through telemedicine. The TPG 2020, in its current form, may be a barrier to incorporating such advancements. The TPG 2020 must adequately address how such advancements can fit into the healthcare delivery process. The following examples illustrate the need for opening up healthcare delivery options through the TPG 2020. Currently, the TPG 2020 does not allow prescription of drugs and provision of<sup>19</sup> AI/ML-based tools, if incorporated on a technology platform, can be used in different ways. An AI/ML tool can read the diagnostic scans (e.g., an X-ray) and provide options to the doctor or healthcare professional. Before including the tool in the platform, it should be evaluated and deemed safe and efficacious for human use. The tool would then be a 'software as medical device'<sup>20</sup> resulting in the appropriate evaluation mechanism being the Medical Devices Rules, 2017<sup>21</sup> A patient's safety (and medico-legal liability of the technology platform and doctor) will come into question if the TPG 2020 does not provide a link to relevant regulatory compliances. Another example is the use of robotics.<sup>22</sup>

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<sup>18</sup>Para 1.3(a) (i) and (ii), National Telemedicine Guidelines, 2015, [https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06\\_2015\\_30jan15\\_telemedicine-guidelines-rev.pdf](https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/guidelines/moh-cir-06_2015_30jan15_telemedicine-guidelines-rev.pdf) at p. 13.

<sup>19</sup> Para 5.4., Telemedicine Practice Guidelines, 2020, <https://www.mohfw.gov.in/pdf/Telemedicine.pdf> at p. 33.

<sup>20</sup> See: US Food and Drug Administration, Software as a medical device, <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>; European Union, Medical Device Coordination Group Document, (October 2019), Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, [https://ec.europa.eu/health/sites/default/files/md\\_topics-interest/docs/md\\_mdcg\\_2019\\_11\\_guidance\\_en.pdf](https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_mdcg_2019_11_guidance_en.pdf); See also: <https://www.med-technews.com/medtech-insights/medtech-regulatory-insights/software-as-a-medical-device-demystifying-eu-mdr/>.

<sup>21</sup> See: Ikigai Law, Regulation for rigorous clinical investigation of medical devices: the missing link of the Atma-nirbhar drive in healthcare, <https://www.ikigailaw.com/regulation-for-rigorous-clinical-investigation-of-medical-devices-the-missing-link-of-the-atma-nirbhar-drive-in-healthcare/>; See also: Ikigai Law, De-coding the Clinical Investigation process under the Medical Device Rules, 2017, <https://www.ikigailaw.com/de-coding-the-clinical-investigation-process-under-the-medical-device-rules-2017/>.

<sup>22</sup> Lovo Grona, S., Bath, B., Bustamante, L., & Mendez, I. (2017). Case Report: Using a Remote Presence Robot to Improve Access to Physical Therapy for People with Chronic Back Disorders in an Underserved Community. *Physiotherapy Canada*. *Physiotherapie Canada*, 69(1), 14–19. <https://doi.org/10.3138/ptc.2015-77> - "An RPR allows a physical therapist to easily move around a patient, and it has a high-quality zoom camera and sensitive audio, which captures sound in front of and behind it. Screen-sharing capabilities can facilitate patient education, enabling a physical therapist in one location to show the patient in another location pictures and photographs of anatomy, pathology, recommended lumbar ergonomic postures, and exercises; they also enable the physical therapist to highlight objects on the screen to focus the patient's attention. The physical therapist uses this function to show the

Using robotics in telemedicine will also need standards that account for patient safety and medico-legal liability. The growth of telemedicine could be bolstered by the TPG 2020 laying down guardrails such as requiring technology platforms to incorporate such tools after they have been appropriately evaluated for safety and clinical efficacy by the regulators.

## 2. Risks of adopting open networks for digital health:

Over the past few years there have been numerous reports of health data breaches in India,<sup>23</sup> including the health data of COVID-19 patients being sold on the dark web.<sup>24</sup> Reports have shown how mobile health applications leak health data through APIs.<sup>25</sup> Open APIs run the risk of attacks on one entity in the network, subsequently impacting many other entities in that network.<sup>26</sup> Similarly, the UHI could be a system that has multiple fault lines, i.e., areas where hackers can exploit weakness or piggyback on existing algorithms to enter the system. To tackle this:

- i. Consider setting standards for conducting periodic reviews of security protocols. For example, a quarterly or bi-annual review of the security of the NDHM ecosystem and each building block (including the UHI) is necessary to ensure that faults and weaknesses in the algorithms are identified and plugged.
- ii. Similarly, the standards set could include a reporting mechanism for breaches and protocols for fast response to such breaches.<sup>27</sup> Automated controls for identifying breaches and emergency response should also be considered.<sup>28</sup>

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*patient an image on the therapist's end (e.g., a photograph of anatomy). The therapist can also draw on or highlight something in the picture so that the patient can focus directly on the structure that the therapist is discussing (e.g., the therapist might draw a circle around a disc to show the patient where the problem is located in his or her spine)."*

<sup>23</sup> Observer Research Foundation, Oomen C. Kurien, Data, Privacy, Pandemic: India just had the Biggest Medical Records Breach Ever, (January 2021), <https://www.orfonline.org/expert-speak/data-privacy-pandemic-india-just-had-the-biggest-medical-records-breach-ever/>.

<sup>24</sup> Devina Sengupta, Covid-19 patients' health data being sold on dark web, (May 13, 2021), <https://telecom.economictimes.indiatimes.com/news/privacy-fears-around-patients-health-data-breach-amid-covid-surge/82600300>.

<sup>25</sup> Brian T. Horowitz, Mobile health apps leak sensitive data through APIs, report finds, (Feb 2021), <https://www.fiercehealthcare.com/tech/mobile-health-apps-leak-sensitive-data-through-apis-report-finds>

<sup>26</sup> KPMG, Jackie Hennessy, Managing risk in a connected ecosystem, <https://home.kpmg/xx/en/home/insights/2020/11/managing-risk-in-a-connected-ecosystem.html>.

<sup>27</sup> Mohit Chawdhry, Challenges to digital ecosystems, (April 25, 2020), <https://www.dailypioneer.com/2020/columnists/challenges-to-digital-ecosystems.html>.

<sup>28</sup> Capitol Technology University, How can automation be used in cybersecurity incident response? (April 2020), <https://www.captechu.edu/blog/automation-in-cybersecurity-incident-response>.

### C. **BROAD COMMENTS:**

In this section, we provide comments for the NHA's consideration while setting up and running the UHI, based on discussions found in the UHI paper.

1. Need for clarity on personal data and non-personal data ownership, management, and further use:

The NDHM involves entities operating in the ecosystem, interacting with building blocks (i.e., health IDs for patients and registries for healthcare professionals and facilities) to provide (i) greater access to healthcare and (ii) data-driven insights for clinical and academic research, and policy interventions.<sup>29</sup> The NDHM 'Strategy Overview' indicated that a federated architecture will be opted for health data (EHR), meaning that EHR will be stored closest to where it was created.<sup>30</sup>

With the creation of an additional UHI layer, clarity is needed on patient's EHR storage, security, processing, and sharing. Technology platforms use aggregated and anonymized EHR to (i) improve their platform, and (ii) for research and development (e.g., clinical research).<sup>31</sup> Clarity is therefore needed on:

- i. EHR storage, management, and further use: The UHI paper should allow technology platforms to continue to use EHR for research and development in the aggregated and anonymized form for patients treated through the UHI layer.
- ii. Non-personal data: The revised report of the committee of experts on non-personal data indicates that certain data sets will be considered 'high-value data sets' and can be requested by the government (i.e., a 'data trustee') for 'public good'.<sup>32</sup> The NHA could conceivably use such a power to mandatorily require 'end user applications' or 'technology service providers' operating in the UHI layer to share aggregated and anonymized data sets with the NHA. While this report is not law yet, its approach may be discouraging to technology platforms, especially those that provide advanced healthcare services (e.g., AI/ML-based tools that help doctors diagnose patients during a telehealth consultation). The kinds of medical data points that such platforms collect may lead to the discovery of how their technology tools work.
- iii. Personal and sensitive personal data: The draft Personal Data Protection Bill, 2019, under its data localisation provision, requires that sensitive personal data (which includes health data

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<sup>29</sup> About NDHM, <https://ndhm.gov.in/home/ndhm>.

<sup>30</sup> Para 2.2.4., NDHM Strategy Overview, Chapter 2: Scope of the mission, [https://ndhm.gov.in/documents/ndhm\\_strategy\\_overview](https://ndhm.gov.in/documents/ndhm_strategy_overview),

<sup>31</sup> Mfine Privacy Policy, Clause 5(14) <https://www.mfine.co/privacy-policy/>; Practo, privacy policy, Clause 3.1.3. <https://www.practo.com/company/privacy>.

<sup>32</sup> Paragraph 7.7. and Paragraph 8 of the Report by the committee of experts on non-personal data governance framework, (December 16, 2020), [https://static.mygov.in/rest/s3fs-public/mygov\\_160922880751553221.pdf](https://static.mygov.in/rest/s3fs-public/mygov_160922880751553221.pdf).

and genetic data)<sup>33</sup> be stored in India.<sup>34</sup> This is important because the NHDH's Health Data Management Policy also references the need to apply to all existing laws, including those on data privacy (i.e., the draft Personal Data Protection Bill, 2019).<sup>35</sup> Therefore, the data localization requirement will become applicable to EHR created through the NDHM. Localisation of data is contrary to the principles of open networks and could also increase the risks of cyberattacks and loss of data privacy for patients in India. This is because all their data would be concentrated in a few data centres in India, leaving them extremely vulnerable to attack.<sup>36</sup> This kind of concentration of EHR in a few data centres means that hackers will know exactly where to find the data. Over time hackers will be able to identify entry points into the centrally maintained building blocks of the NDHM and the servers where EHR is stored across the country. One way to counter this threat is by using blockchain technology, which is discussed later in these comments.

2. Need for standards of operation, model privacy policies, and consent notices for 'end user applications' and 'technology service providers':

The NDHM has a model data privacy notice<sup>37</sup> and a model consent form<sup>38</sup> for entities participating in the NDHM ecosystem to communicate users' rights to them before they sign on. It has also released model data privacy notices specific for health information users,<sup>39</sup> health locker provider,<sup>40</sup> and health information provider.<sup>41</sup> Specific model documents may be released for 'technology service providers' and 'end user applications' that align with the requirements of the Personal Data Protection Bill 2019 such as informed consent, purpose limitation, and privacy by design. This will be useful for not only small start-ups entering the NDHM ecosystem, but also for bigger companies, because it will help ensure that the industry adheres

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<sup>33</sup> Clause 3(36), Personal Data Protection Bill, 2019, [https://prsindia.org/files/bills\\_acts/bills\\_parliament/Personal%20Data%20Protection%20Bill,%202019.pdf](https://prsindia.org/files/bills_acts/bills_parliament/Personal%20Data%20Protection%20Bill,%202019.pdf).

<sup>34</sup> Clause 33(1), Personal Data Protection Bill, 2019, [https://prsindia.org/files/bills\\_acts/bills\\_parliament/Personal%20Data%20Protection%20Bill,%202019.pdf](https://prsindia.org/files/bills_acts/bills_parliament/Personal%20Data%20Protection%20Bill,%202019.pdf).

<sup>35</sup> Para 5.3., NDHM Health Data Management Policy, [https://ndhm.gov.in/health\\_management\\_policy](https://ndhm.gov.in/health_management_policy).

<sup>36</sup> #DataProtectionTop10: Data Localisation, a threat to free and open internet,

<https://internetfreedom.in/dataprotectiontop10-data-localisation-a-threat-to-free-and-open-internet/>.

<sup>37</sup> National Digital Health Mission, Model data privacy notice, <https://ndhm.gov.in/documents/hdmpolicy/privacynotice>.

<sup>38</sup> National Digital Health Mission, Model consent form, <https://ndhm.gov.in/documents/hdmpolicy/consentform>.

<sup>39</sup> National Digital Health Mission, Model data privacy notice for HIUs, [https://ndhm.gov.in/documents/Model\\_Data\\_Privacy\\_Notice\\_by\\_HIU](https://ndhm.gov.in/documents/Model_Data_Privacy_Notice_by_HIU).

<sup>40</sup> National Digital Health Mission, Model data privacy notice for HLPs, [https://ndhm.gov.in/documents/Model\\_Data\\_Privacy\\_Notice\\_by\\_Health\\_Locker\\_Provider](https://ndhm.gov.in/documents/Model_Data_Privacy_Notice_by_Health_Locker_Provider).

<sup>41</sup> National Digital Health Mission, Model data privacy notice for HIPs, [https://ndhm.gov.in/documents/Model\\_Data\\_Privacy\\_Notice\\_by\\_HIP](https://ndhm.gov.in/documents/Model_Data_Privacy_Notice_by_HIP).

to some minimum standards of management and securing patients' data. It is important to clarify that the model notices and forms are not binding.

The NHA should also ensure that the model notices and forms contain clauses on how aggregated and anonymized data (i.e., non-personal data) may be used by entities operating in the UHI layer of the NDHM. For example, entities may use such non-personal data for research and development of their platform or for clinical/academic research purposes.

### 3. Using blockchain for EHR management and operating a health information exchange:

The NHA should consider allowing the use of blockchain technology for secure storage and strict access controls for EHRs. Blockchain technology can also play a big role in operating a health information exchange,<sup>42</sup> which is what the UHI layer will facilitate.<sup>43</sup> In brief, blockchain involves a system where all data and transactions (e.g., entities accessing EHR of a patient) are recorded and stored in a distributed 'ledger' that cannot be tampered with. This means that<sup>44</sup> (i) patients' EHR is incorruptible; (ii) access to the EHR on the blocks requires appropriate permissions; (iii) every entity which accesses a patient's EHR will be recorded in a 'digital ledger' each time they access the patient's EHR; and (iv) entries in this digital ledger cannot be modified or erased.

With blockchain technology, patients, healthcare professionals, hospitals, technology platforms, and the government can securely create/aggregate and manage access to the various health data sets under the numerous public health schemes and government departments.<sup>45</sup> It is important to note that security comes from the fact that some of the 'blocks' in the blockchain are distributed (i.e., they are not centralised to one server or data centre and can be outside India). Therefore, data localization requirements are also contrary to how blockchain would work.<sup>46</sup>

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<sup>42</sup> PwC, Reimagining health information exchange in India using blockchain, (April 2019), <https://www.pwc.in/assets/pdfs/consulting/technology/it-function-transformation/insights/reimagining-health-information-exchange-in-india-using-blockchain.pdf>.

<sup>43</sup> Para 1.4.4., Chapter 1, Introduction and Background, Consultation paper on unified health interface, at p. 8.

<sup>44</sup> Deloitte, Blockchain: Opportunities for health care, <https://www2.deloitte.com/us/en/pages/public-sector/articles/blockchain-opportunities-for-health-care.html>.

<sup>45</sup> PwC, Reimagining health information exchange in India using blockchain, (April 2019), <https://www.pwc.in/assets/pdfs/consulting/technology/it-function-transformation/insights/reimagining-health-information-exchange-in-india-using-blockchain.pdf> at p. 19.

<sup>46</sup> Advait Papepu, National Blockchain Strategy At Odds With Data Localisation And Privacy Says Ikigai Law, (February 23, 2021), <https://www.medianama.com/2021/02/223-blockchain-government-ikigai-data-privacy/>.

Blockchain can help overcome the barriers to operating a health information exchange.<sup>47</sup> As described earlier, peer-to-peer transactions (i.e., each time an EHR is created, accessed, shared, or deleted) on the blocks are recorded in the digital ledger, only a person with appropriate permissions (i.e., through public or private access keys) has access to the blocks.<sup>48</sup> This means that information can securely be accessed and used for clinical or academic research, or evidence-based policy making, without the EHR being tampered with or erased.

#### 4. Need to pass the 'Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018':

India's journey to passing legislation on the online sale of drugs began as early as 2016.<sup>49</sup> A draft bill amending the Drugs and Cosmetics Rules, 1945, ("**Draft Bill**") was released in 2018 to provide clarity on how online sale of drugs would work.<sup>50</sup> The Draft Bill is still awaiting passage three years later, despite the COVID-19 pandemic. The government did, however, notify guidelines for entities with the appropriate licenses to engage in the online sale of drugs;<sup>51</sup> a much-needed step to ensure access to drugs during the pandemic induced lockdowns. Online sale of drugs and devices will have an impact on the ability of telehealth to truly revolutionise healthcare delivery in India, a fact that the TPG 2020 acknowledges by containing a list of drugs that can be prescribed in a virtual setting.<sup>52</sup> The role played by e-pharmacies during the COVID-19 pandemic<sup>53</sup> demonstrates their potential in ensuring continued access to healthcare.

The Draft Bill contains several provisions that can play a big role in building consumer trust. For example, one way that e-pharmacies will be monitored is through 'transaction audits' that involve the central licensing authority to match the prescription and drug dispensed.<sup>54</sup> Another example is that e-pharmacies'

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<sup>47</sup> Blockchain: The New Model for Health Information Exchanges (HIE), (Jan 4, 2021), <https://www.intellectsoft.net/blog/blockchain-health-information-exchanges/>.

<sup>48</sup> Boris Shiklo, How Blockchain Can Improve The Health Information Exchange, (June 27, 2017), <https://www.forbes.com/sites/forbestechcouncil/2017/06/27/how-blockchain-can-improve-the-health-information-exchange/?sh=42c35198f05b>.

<sup>49</sup> Ikigai Law, The e-pharmacy story, (November 2020), [https://www.ikigailaw.com/the-e-pharmacy-story-in-india/#\\_ftn3](https://www.ikigailaw.com/the-e-pharmacy-story-in-india/#_ftn3).

<sup>50</sup> Ministry of Health and Family Welfare, Draft of the Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018, [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTkzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==)

<sup>51</sup> Ministry of Health and Family Welfare notification, (March 26, 2020), <https://www.mohfw.gov.in/pdf/Doorstepdelivery26B.pdf>.

<sup>52</sup> Ikigai Law, Telemedicine and access to drugs in the time of corona virus, (March 28, 2020), <https://www.ikigailaw.com/telemedicine-and-access-to-drugs-in-the-time-of-coronavirus/>.

<sup>53</sup> FICCI, e-pharmacies at the COVID-19 frontline, (August 2020), <https://ficci.in/spdocument/23316/FICCI-ePharmacy-Whitepaper.pdf>.

<sup>54</sup> Rule 67V, Monitoring of e-pharmacy, Draft of the Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018, [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTkzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==)

registrations are valid for three years,<sup>55</sup> after which the registration must be renewed to continue operations.<sup>56</sup> To get a registration, e-pharmacies must provide (among other things) details of their logistics service provider.<sup>57</sup> These points will demonstrate to consumers that there is periodic regulatory oversight, meaning the e-pharmacy can be trusted. Consumer trust is key if we are to see e-pharmacies and logistical advancements like drone delivery<sup>58</sup> increase access to drugs and devices.

5. Need for clear guidelines on the operation of the 'specification committee' and the 'expert committee':

The UHI paper envisages the creation of two committees that will be part of devising open protocols for the UHI layer.<sup>59</sup> The NHA should consider including medical professionals in the expert committee. This is because the protocols put in place based on the suggestions of the expert committee will ultimately have an impact on the quality of healthcare a patient receives. As mentioned earlier in the discussion on strengthening the TPG 2020, digital health must not be viewed purely in the technological sense, but also through the lens of safeguarding the quality of healthcare patients can get through the UHI layer. This is a practice that many digital health companies currently follow.<sup>60</sup> Medical professionals know the realities of healthcare delivery in the country and their insights would thus be invaluable in developing these protocols.

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<sup>55</sup> Rule 67Q, Validity of registration of e-pharmacy, Draft of the Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018,

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTkzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==)

<sup>56</sup> Rule 67R, Renewal of registration of e-pharmacy, Draft of the Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018,

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTkzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==)

<sup>57</sup> Rule 67N(6)(iv), Conditions of registration of e-pharmacy, Draft of the Drugs and Cosmetics (\_\_\_\_ Amendment) Rules, 2018,

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTkzOQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==)

<sup>58</sup> We have also seen examples of drone delivery of medicines and COVID-29 supplies, with Telangana's "Medicine-from-the-sky project. See: Manju Lal Kalanidhi, Medicine From The Sky: Telangana becomes first state to deploy drones in diagnostic and healthcare, (May 2021),

<https://www.newindianexpress.com/lifestyle/tech/2021/may/30/medicine-from-the-sky-telangana-becomes-first-state-to-deploy-drones-in-diagnostic-and-healthcare-2308467.html>.

<sup>59</sup> Para 6.1., Chapter 6, UHI development, governance, and management, Consultation paper on unified health interface. at p. 38

<sup>60</sup> MDisrupt, Ruby Gadelrab, 3 leadership roles doctors can play in healthtech companies, (September 22, 2020), <https://mdisrupt.com/blog/healthcare/healthtech-leadership-roles/>; See also: The role of doctors in digital health startups, (March 31, 2021), <https://thehbiz.com/160-the-role-of-doctors-at-digital-health-startups-with-sven-jungmann/>.