COMMENTS ON 'CONSULTATION PAPER ON HEALTH FACILITY REGISTRY'

A. OVERVIEW

The National Health Authority ("**NHA**") released a consultation paper ("**HFR Paper**") to get inputs on setting up and running a registry that will serve as a single-source of truth on all healthcare facilities that operate in the National Digital Health Mission ("**NDHM**"). Our comments are structured to provide (a) comments specific to the questions raised across sections of the HFR paper and (b) our broad comments. Our suggestions in brief are:

1. The healthcare facility registry should be backed by a robust governance framework prescribing details of the working and management of the registry and provisions, ensuring process accountability and transparency.
2. The licensing entities listed in Annexure 2 of the HFR paper should include state and local authorities tasked with licensing and monitoring under state-level shops and establishments laws.
3. The Health Facility Verifier should be appointed and trained by a standing committee to ensure their independence from the hospitals and regulators (alternative 1 proposed in the HFR paper).
4. The technology platform set up for health facility verifiers should also be independently set up (alternative 2 proposed in the HFR paper).

B. SPECIFIC QUESTIONS POSED IN THE HFR PAPER:

In this section we will answer the following questions raised in the HFR paper:[1] (1) What other licensing entities should be included in the Annexure to the HFR paper? (2) Which approach should be taken to onboard and train Health Facility Verifiers? (3) Which approach should be taken to create a technology platform for Health Facility Verifiers?

1. Other licensing entities-

In states like Maharashtra, clinical establishments that employ 10 (ten) or more persons, must comply with and get a registration certificate under the Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017.[2] Among other things, this law lays down obligations

[1] Questions listed in Para 3.3.7 ("Key Issues for Consultation"). of the Consultation Paper on Healthcare Facility Registry at p. 26.
[2] Section 2(4) "Establishment", Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, https://lj.maharashtra.gov.in/Site/Upload/Acts/H%20693.pdf.

on welfare measures for employees[3] and providing accurate information at the time of registration.[4] The Municipal Corporation of Brihan Mumbai has been tasked with enforcing this law, along with a "Facilitator" appointed by the state government.[5] A similar registration is required by clinical establishments employing more than 10 (ten) in Gujarat.[6]

Recommendation-

i. Annexure 2 to the HFR paper (which lists the various licenses and accreditation needed by healthcare facilities), should include the registration under the shops and establishment laws of each state in the "Basic Documents" and "Quality and Accreditation" sections.

ii. The NHA should coordinate with state governments to provide a technology platform capturing inputs from the municipal and state-level authorities that are involved in the registering, monitoring, and enforcement of the provisions of shops and establishment laws in the state. This will ensure that the HFR is up-to-date and that all licenses, irrespective of their location and size are listed on the HFR.

iii. The use of APIs and Digital Solutions (i.e., "third alternative")[7] proposed in the HFR paper for integrating 'HFR Organisation/Programme' will provide the flexibility needed to incorporate inputs from local authorities. Local authorities with robust digital systems can integrate with the NDHM through APIs, while the NDHM can build digital solutions for those that do not. The NHA should, therefore, opt for using "API and Digital Solutions" to integrate the licensing authorities and accreditation bodies.

iv. Additionally, by opting for the "APIs and Digital Solutions" method, the NHA can enhance the possibility of public-private partnerships. This will ensure that the National Health Authority, state governments, local authorities, licensing authorities, and accreditation bodies have the option of using the latest technology solutions as they upgrade.

[3] Chapter III ("Opening and closing hours, hours of work, interval for rest, spread-over, wages for overtime and weekly off") Chapter IV ("Leave with pay and payment of wages") and V ("Welfare Measures"), Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, https://lj.maharashtra.gov.in/Site/Upload/Acts/H%20693.pdf.
[4] Section 8, Chapter II (Registration of establishments), Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, https://lj.maharashtra.gov.in/Site/Upload/Acts/H%20693.pdf.
[5] Section 28, Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, https://lj.maharashtra.gov.in/Site/Upload/Acts/H%20693.pdf.
[6] Gujarat Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2019 https://labour.gujarat.gov.in/Portal/Document/1_204_1_SAEA.pdf.
[7] Para 3.4.3.3., ("APIs and digital solutions'), Consultation Paper on Health Facility Registry.

2. The 'Health Facility Verifier' and 'Health Facility Verifier Platform'-

The Health Data Management Policy of the NDHM requires health facilities operating in the National Digital Health Ecosystem to *"deploy health facility auditors to verify"* the information they provide while registering for the NDHM.[8] The responsibilities of the Health Facility Verifier appear to be the same as the duties of the auditors verifying information provided by the health facilities. This means that the health facility auditors referenced in the Health Data Management Policy are the same as the Health Facility Verifier proposed in the HFR paper. If this is indeed the case, then requiring health facilities to bear the costs of the audit or verification, as provided in the HFR paper,[9] will disincentivise clinical establishments from signing up to the NDHM. Additionally, it is important to lay down standards for the independence and operations of the Health Facility Verifiers. This is because both have a direct impact on the reliability of the hospital information in the health facility registry. Data reliability is paramount for a database like a health facility registry because it has larger implications on people's access to healthcare[10] and the government's ability to operate a platform of interaction between healthcare professionals, patients, clinical establishments, policymakers, and other relevant entities (i.e., a health information exchange).[11]

Recommendation-

i. Health facilities must not be forced to bear the cost of the audit/verification process as it would be a barrier to more entities signing up to provide healthcare services through the NDHM. This would add to the independence of the Health Facility Verifiers.

ii. For managing the onboarding of Health Facility Verifiers, the NHA should onboard and train Health Facility Verifiers through a standing committee ("Alternative 1" proposed in the HFR paper).[12] Alternative 1 will create an independent set of professionals responsible for verifying the details provided by health facilities.

iii. For the Health Facility Verifier Platform, the NHA should opt for an independent health facility verifier platform ("Alternative 2" proposed in the HFR paper).[13] This will allow the NHA to rely on emerging technologies like geospatial data mapping done by unmanned aerial vehicles, to verify

[8] Para 24.2 ("Health facility registry"), National Digital Health Mission, Health Data Management Policy, https://ndhm.gov.in/health_management_policy.
[9] Para 3.3.2., ("Role and Responsibilities of a Health Facility Verifier"), Consultation Paper on Health Facility Registry.
[10] Mpango, J., & Nabukenya, J. (2020). A Qualitative Study to Examine Approaches used to Manage Data about Health Facilities and their Challenges: A Case of Uganda. *AMIA ... Annual Symposium proceedings. AMIA Symposium*, *2019*, 1157–1166. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153096/ - A qualitative study conducted on Uganda's master facility list, demonstrated the hazards of not having reliable data in the list. One participant in the study stated that the lack of accurate information on the availability of health specialties in a hospital, led to loss of life.
[11] Jennifer Bresnick, How Health Information Exchange Models Impact Data Analytics, (February 19, 2015), https://healthitanalytics.com/news/how-health-information-exchange-models-impact-data-analytics.
[12] Para 3.3.3., ("Selection and Onboarding of Health Facility Verifier"), Consultation Paper on Health Facility Registry.
[13] Para 3.3.4., ("Health Facility Verifier Technology Platform"), Consultation Paper on Health Facility Registry.

the information provided by the health facilities (e.g., information on their location and infrastructure). The individual organisations interested in providing a platform for Health Facility Verifiers should be made to comply with standards set by the independent standing committee[14] that is tasked with onboarding Health Facility Verifiers.

C. BROAD COMMENTS

1. Need for a robust governance framework:

The Health Facility Registry proposed in the HFR paper needs a robust governance framework. The World Health Organization released a toolkit with modules to help countries launch and maintain a *'master facility list'*.[15] A *'functional'* master facility list has a structure that performs oversight and management of the list. The toolkit recommends: (i) A steering committee should perform these functions, in addition to periodically engaging with relevant stakeholders (e.g., other government departments; policymakers; NGOs, national health programs, etc.); (ii) the master facility should be governed by a policy specific to the management of the master facility list (e.g., the National Health Data Blueprint, the Health Data Management Policy) that assigns responsibilities, and provides ways to ensure accountability of all relevant entities, including the steering committee;[16] and (iii) housing the master facility list under one entity or institution (e.g., the NHA to ensure that the list is maintained properly over time.[17]The Health Data Management Policy of the NDHM states that the governance structure of the National Digital Health Ecosystem will be decided by the NDHM (housed under the National Health Authority).[18] The Health Data Management Policy also states that the governance structure will include all persons, authorities, and committees necessary to implement the NDHM; adding that the Ministry of Electronics and Information Technology will provide "overall guidance" on "relevant aspects".[19]

Additionally, public health and sanitation, hospitals and dispensaries is a state subject,[20] while legal, medical and other professionals are a concurrent subject[21] (i.e., both the centre and state government can

[14] Para 3.3.3., ("Selection and Onboarding of Health Facility Verifier"), Consultation Paper on Health Facility Registry.
[15] World Health Organization and USAID, MASTER FACILITY LIST RESOURCE PACKAGE: Guidance for countries wanting to strengthen their MFL, https://www.who.int/healthinfo/MFL_Resource_Package_Jan2018.pdf at MFL Module on Good Governance (p. 35-49) and MFL Module on "Maintaining the MFL" (p. 103-121).
[16] Para 3.3., ("Policy Environment"), World Health Organization and USAID, MASTER FACILITY LIST RESOURCE PACKAGE: Guidance for countries wanting to strengthen their MFL, https://www.who.int/healthinfo/MFL_Resource_Package_Jan2018.pdf at p. 45.
[17] Para 3.4., ("Institutionalization and Sustainability"), World Health Organization and USAID, MASTER FACILITY LIST RESOURCE PACKAGE: Guidance for countries wanting to strengthen their MFL, https://www.who.int/healthinfo/MFL_Resource_Package_Jan2018.pdf at p. 46.
[18] Clause 6, ("Governance Structure"), Health Data Management Policy, National Digital Health Mission, https://ndhm.gov.in/health_management_policy.
[19] Clause 6, ("Governance Structure"), Health Data Management Policy, National Digital Health Mission, https://ndhm.gov.in/health_management_policy.
[20] Entry 6, List II, Seventh Schedule, Constitution of India, https://www.mea.gov.in/Images/pdf1/S7.pdf.
[21] Entry 26, List III, Seventh Schedule, Constitution of India, https://www.mea.gov.in/Images/pdf1/S7.pdf.

legislate on the subject. However, the central law will prevail in the case the state and central laws are "fully inconsistent and absolutely irreconcilable"[22]). The NHA should therefore, accommodate India's federal structure by ensuring state and local authorities are adequately represented in the steering committee.

Recommendation- The health facility registry requires proper management for accomplishing the goals of the NDHM. The NHA should establish a governance framework and steering committee through law. The steering committee should have relevant subject-matter experts (e.g., professionals from the medical, legal-regulatory, and technology sectors), and representatives from licensing authorities, state governments, and other ministries (like the Ministry of Electronics and Information Technology). The NHA should also lay down guidelines for appointment, tenure, renewal, and removal of the subject-matter experts. For instance, the United Kingdom's Health and Social Care Information Centre (i.e., NHS Digital) has taken a similar approach, and has different types of board members (i.e., permanent, non-permanent, associate, clinical),[23] and committees.[24] NHS Digital was set up under and is governed by the Health and Social Care Act, 2012.[25] This law details the size, appointment, remuneration, and removal of members of the board and committees.[26] both of which incorporates the inputs of subject-matter experts. It also publishes minutes of meetings and board meeting dates of board meetings. Additionally, the NHS Digital's functioning is reviewed by the Secretary of State for Health,[27] who is obligated to present an annual report to the Parliament.[28]

2. **Importance of updating the registry periodically:**

The HFR paper highlights the study done of two existing registries in India, namely- the Registry of Hospitals in Network of Insurers ("ROHINI") and National Health Resource Repository ("NHRR").[29] ROHINI is a portal where the public can only see lists of which facilities' registrations are up for renewal, and allows these facilities to check the status of their registration.[30] The NHRR was set up after conducting a census to enumerate all public and private healthcare facilities and their specifications.[31] The NHRR list was intended to support policy making and government intervention in public health. The HFR paper also

[22] M. Karunanidhi v. Union of India, 1979 SCR (3) 254, https://indiankanoon.org/doc/1716282/
[23] https://digital.nhs.uk/about-nhs-digital/our-organisation/nhs-digital-board/board-members.
[24] https://digital.nhs.uk/about-nhs-digital/our-organisation/executive-membership-of-the-board-and-attendance-at-board-committees#committees.
[25] Section 252, Health and Social Care Act, 2012, https://www.legislation.gov.uk/ukpga/2012/7/contents/enacted.
[26] Schedule 18, the Health and Social Care Act, 2012, https://www.legislation.gov.uk/ukpga/2012/7/schedule/18.
[27] Section 52, Health and Social Care Information Act, 2012 https://www.legislation.gov.uk/ukpga/2012/7/section/52/enacted.
[28] Section 247D, Health and Social Care Act 2012, https://www.legislation.gov.uk/ukpga/2012/7/section/53/enacted
[29] Para 2.1. Consultation Paper on Healthcare Facility Registry at p. 12.
[30] ROHINI website: https://rohini.iib.gov.in.
[31] Arun Sreenivasan, Govt launches nationwide census to create India's first registry of healthcare facilities; 4,000 enumerators out to collect data, http://www.pharmabiz.com/ArticleDetails.aspx?aid=112231&sid=1; NHRR website: https://www.cbhidghs.nic.in/index7.php?lang=1&level=0&linkid=1088&lid=1109&color=4.

cites the registries from two developing countries, namely- Tanzania and Nigeria.[32] On close examination, it becomes evident that these four registries' public portals are not updated regularly. The Health Facility Registry of Tanzania for example, is a static list of hospitals and some information about their location and facilities.[33] It is unclear when the list was last updated. The Nigerian registry's website appears to follow a similar practice (i.e., a static but searchable list).[34]

Recommendation:

The stated goal of the NHA is to ensure that the HFR is a single source of truth of all health facilities operating in the NDHM. Additionally, the HFR will play a larger role in the NDHM ecosystem by connecting to the other building blocks of the NDHM. The accuracy of the health facility registry will thus impact other aspects of the NDHM. To ensure its reliability:

i. The overarching governance framework should include provisions or mechanisms for ensuring that facilities are (a) periodically audited for changes in their facilities, including their management, departments, beds, technologies and capacities; and (b) health facilities are obligated to update their profiles on the registry annually. This should include requiring the updating of the facility's account when a healthcare professional is not working in their facility anymore, where the Health Facility Registry and Healthcare Professionals Registry are linked.[35] Where there are no significant changes, the facility should submit declarations or select checkboxes on the registry portal to indicate the lack of changes. The Health Facility Verifier can be tasked with checking whether facilities have kept their accounts up-to-date.

ii. The governance framework should obligate the head of the steering committee to provide an annual report to the NHA on this status of each facility in the registry. This report should be available publicly.

iii. The date of last update should be made public on the registry portal to give people and all stakeholders in the NDHM ecosystem, an accurate representation of the health facility. Similarly, the public should be able to see if health facilities have not provided mandatory documents or information listed in Annexure 1 and 2 of the HFR paper.

iv. The registry should be accessible for persons with disabilities and ensure that there are separate categories or tabs for each type of health facility. This will make the registry easier to navigate.

[32] Paras 2.3.3. and 2.3.4., Consultation Paper on Healthcare Facility Registry at p. 15-16.
[33] http://hfrportal.moh.go.tz/index.php?r=facilities/summaryAndTables.
[34] https://hfr.health.gov.ng/facilities/hospitals-list?page=3.
[35] Consultation Paper on Healthcare Professionals Registry, https://ndhm.gov.in/assets/uploads/consultation_papersDocs/Consultation-Paper-on-Healthcare-Professionals-Registry.pdf.