Covering Letter

Karkinos Healthcare Private Limited

20 August 2021

To

Sri. Vikram Pagaria,

Joint Director (Coordination),

National Health Authority

9th Floor, Tower - 1

Jeevan Bharati Building, Connaught Place

New Delhi - 110001

https://www.nha.gov.in/

Dear Sir,

This has reference to the invitation for comments vide the **Consultation Paper on Unified Health Interface (reference: Consultation Paper 03/ 2021)**. Our team of clinicians and experts have reviewed the consultation paper and based on our deliberations have responded on each of the questions raised by the NHA via this consultation paper.

We believe the framework discussed in this paper will enable an ecosystem that will benefit the patient and the patient family in case of some really debilitating diseases. Getting the right information at the right time and closest to the citizen will help in achieving an affordable and accessible goals of a healthcare ecosystem.

We at Karkinos Healthcare look forward to provide our perspectives of a patient journey we are enabling for oncology patients in the healthcare ecosystem, we will continue to share our learnings with the community and via the open consultation process enabled by the NHA.

Kind Regards

Kumar Satyam, Deputy Chief Product Officer,

Karkinos Healthcare Private Limited

Introduction

NDHM is essential and very timely for making Digital health in India a reality. We believe NDHM UHI is a very important construct in enabling digital health services in a fair, transparent and accessible way.

Karkinos Healthcare response to the NDHM consultation paper is documented as part of this document. Karkinos Healthcare fully supports the NHA's mission and commits to play an active role in its capacity to advance the digital health adoption in the country.

Citizen/ Patient centricity and ***citizen/ patient diagnosis context*** needs to be considered as part of the NDHM UHI, in addition to the recommendations made as part of the NDHM UHI consultation paper. In addition, we believe considering specialty specific context as part of the NDHM UHI will allow specialty specific pathways to be enabled by the HSPs and EUAs.

About Karkinos

Karkinos Healthcare Pvt. Ltd. (KHPL) is a digital oncology platform focused on designing and delivering bespoke solutions for cancer care. The company is on a mission to create 'cancer centers without walls' with a unified vision to address the lack of access or the affordability in cancer care.

The core objective of Karkinos Healthcare is to create an up-to-date dynamic knowledge base in oncology and curate that knowledge to distribute, democratize, and integrate cancer care throughout the healthcare milieu. With its scalable, state-of-the-art technology platform, Karkinos Healthcare hopes to transform cancer care that can be delivered closer to a patient's home across the patient care continuum.

Feedback/suggestions on Consultation paper

Chapter 1

Question 1: Please refer to section 1.6.3. The Telemedicine Guidelines were issued by The Board of Governors of the Medical Council of India (MCI) in March 2020. Stakeholders are requested to go through them and suggest changes to the policy, if any, to ensure adoption of telemedicine and e-pharmacy. Please note that NHA will act as a coordinator and only forward these suggestions to the appropriate/concerned ministry.

KHPL Answer: Please note following comments and recommendations

1. Telemedicine guidelines need to be updated to accommodate the statement in Section 3.7 of UHI consultation paper "*Patients can sign up with Health Bots that will look at their medical history, send reminders, provide advice based on their trends*" – However, Telemedicine Guidelines say AI/ML cannot provide **"Advice"** to patients directly.
2. Section 5.4 of Telemedicine Guidelines on AI/ML-based suggestions to be made clearer. Elaboration on consent mechanism when interacting with Apps/Bot is needed.
3. Digital documentation of interactions that can be part of patient's longitudinal health records is required in-case there is offline data entry that needs to be synced with online systems within prescribed timeframe.
4. Guidelines on Group Consultation are required, as telemedicine guidelines does not explicitly mention them, however, UHI lists group consult as a use-case.
5. Guidelines on tele-trials /virtual participation in clinical trials are needed. Here, ASCO's Telemedicine Guidelines on tele-trials can be referenced (Telehealth in Oncology: ASCO Standards and Practice Recommendations | JCO Oncology Practice (ascopubs.org))
6. Drug prescription in case of follow-ups need to be relooked. A provider should be allowed to prescribe anti-cancer drugs to a chronic cancer patient doing a follow-up with the doctor. Currently anti-cancer drugs are in the '**not to be prescribed list'**.

Telemedicine Guidelines is silent on consent required by Health worker working with a patient. Consent guidelines for health worker accessing patient health information for counselling and other interactions need to be added.

Chapter 2

Question 2: As a stakeholder in the health ecosystem, what benefits and risks do you see if an open network approach to digital health services is implemented? Please respond with details.

KHPL Answer: An Open network approach will enable benefits for the health ecosystem. It can bring about parity in the ecosystem and it also opens up options for all players in the ecosystem, specifically the citizen/ patient and the providers. However, it will increase the IT burden for individual and small providers to get on UHI network, there needs to be some form of incentive to enable the participation from all stakeholders of the healthcare ecosystem.

Chapter 3

Question 3: The primary stakeholders in the UHI ecosystem are mentioned in section 3.3. While the list is more indicative than exhaustive, are there any other primary or secondary stakeholders that should be considered while building the interface? If yes, please outline their role in the UHI ecosystem.

KHPL Answer: Please note following comments and recommendations:

1) Following stakeholders are important
    a. Insurance & Payers. Payers can be insurance, govt., corporates, or third parties.
    b. Regulators play an important role in shaping up and governing the open network.

Question 4: The proposed objectives of UHI and UHI Network have been detailed in sector 3.4. Please share your comments on the comprehensiveness of these objectives, methods to ensure these objectives are adhered to. Please comment if there are other objectives which must be included in section 3.4.

KHPL Answer: *Patient Centricity:* UHI should ensure that the patient's interests are always at the forefront of the UHI's objectives, while we see the HSP and the technology enablement has been thought through in great detail, patient centricity will provide an additional level of context to each of the objectives of UHI Network. We propose this should be an additional objective ingrained into the objectives of the UHI Network.

Fair Discoverability: Enabling patient centricity in this context should not stop the EUA from showing the patient *"context"* specific HSPs. For instance, for an oncology patient, they would want to know which pharmacies in their vicinity stock oncology medicines. The EUA should be allowed to include patient context in enabling each of the objectives of the UHI Network.

Question 5: UHI will support a range of digital health services and is expected to evolve with time. What digital health services should the initial version of UHI focus on?

KHPL Answer: In addition to the list of digital health services between patients and health service providers (HSPs), UHI should first focus on enabling the following services which also have a focus on speciality like oncology services:

1. E-Pharmacies: Automatic sending of prescription to a pharmacy of patient's choice to fulfil the prescription.
2. Enable the discovery of lab and diagnostic services based on qualifying attributes like speciality (e.g., whether the laboratory handles histopathology samples, biobanks, genetic laboratories, etc or diagnostic services such as Radiotherapy Centres)

Chapter 4

Question 6: Have all incentives / disincentives for various stakeholders to participate been covered in chapter 4? If not, please provide the list and mention the role and description of the stakeholder.

KHPL Answer: For HSPs of individual practitioners and small clinics, there will be an upfront cost of joining the UHI network in terms of an IT Infrastructure that would be required to connect to the UHI Network.

For large hospital groups, and network hospitals, they will be competing the smaller practices who can offer the services at the fraction of the cost and have an equal level of discoverability. For instance, a cardiologist in a tier 1 hospital versus a cardiologist in the neighbourhood clinic will be displayed on the EUA based on the fair discoverability principles. But the cost and the fee structure may vary significantly.

Question 7: For the disincentives mentioned in chapter 4 and as an answer to Question 1 of chapter 4, please provide possible mitigating measures that may be taken to minimize the impact of said disincentives.

KHPL Answer: For the HSP of individual practitioners and small clinics, they should be incentivised for adopting the UHI Network, both financial and technical incentives should be considered.

The price band for similar services should be moderated and all the operators on the network should comply. Certain exclusion criteria should be made for social and non-profit organisations adopting the UHI Network guidelines.

Chapter 5

Question 8: In the proposed discovery model in section 5.1.3.1 EUAs are expected to present all responses returned by the Gateway to the user and allow the user to choose the HSP. Should any alternate models be allowed? If yes, provide details.

KHPL Answer: As mentioned in our earlier response, to the question 4, including a **patient centric** and **context aware** model for service discovery will go a long way in helping chronic care patients avail of services.

Question 9: Are there any challenges to the proposed approach to pricing of services detailed in section 5.1.3.2? Please suggest other alternate pricing models that must be supported by the Gateway.

KHPL Answer: As shown earlier, by the adoption of UPI in bringing down the cost of financial transactions, UHI should not impose any UHI Gateway charges for the first 5 years, as it will take at a minimum 5 years for the ecosystem to adopt to these transformational changes to the way a citizen avails of healthcare services.

Question 10: Are there any other areas that must be supported by the Gateway for service fulfilment in section 5.1.3.3? If yes, provide details.

KHPL Answer: The gateway should lay down SLAs for HSPs and EUAs participating in providing a service and it should ensure each of the participating entities meet the SLA requirements for service fulfilment. Non-adherence to the SLAs should be factored in defining the rating of the HSP and EUA. The SLAs defined by the Gateway should be a technical SLA definition that provides a quantitative value as a service fulfilment feedback mechanism. For instance, if an HSP or an EUA has 'n' number of incomplete transactions and is unable to fulfil outstanding service requests, the gateway should, for a duration of time, stop displaying that HSPs or EUAs services for a duration of time. Therefore, allowing the HSP or EUA to resolve their issues.

The Gateway should enable **service portability** in case the service cannot be fulfilled by the EUA or the HSP when the payment has been made.

Question 11: Post-fulfilment, as described in section 5.1.3.5, covers ratings and grievances. Are there any other areas that must be supported by the Gateway for post service fulfilment in section 5.1.3.5? If yes, provide details.

KHPL Answer: In addition to the technical SLA mentioned in the response to question 10, the gateway rating and grievance redressal mechanism should be based on technical SLAs defined for HSPs and EUAs by the UHI Gateway.

Question 12: The proposed approach for allowing users to share ratings for the HSPs as well as EUAs has been laid out in 5.1.3.5. Please comment on the same and share any other approach that might be adopted.

KHPL Answer: Instead of only user-based feedback and ratings, the Post fulfilment Reputation management on the gateway should be based on a Technical SLA defined while onboarding every HSP and EUA. This will ensure service delivery levels on the UHI Gateway is more quantitative and provides a more trust-oriented framework driven by the centrally defined metrics of service offerings.

Chapter 6

Question 13: What approaches, other than the ones mentioned in chapter 6, should be considered for managing and governing the UHI gateway? Please provide details.

KHPL Answer: Establishing a managing and governing body will go a long way in enabling the ecosystem to adopt the UHI Gateway by the ecosystem stakeholders. We propose setting up of an arbitrator or ombudsman for helping resolve any payment related queries for the transactions for the patient/ citizen, this will help in adoption and change management towards UHI Gateway by all the healthcare ecosystem partners.

Question 14: What should the UHI Gateway charge in the initial few years of operation? How can this model evolve over time?

KHPL Answer: In addition to the response to question 9, we propose the following:

As has been shown by the adoption of UPI in bringing down the cost of financial transactions, UHI should not impose any UHI Gateway charges for the first 5 years, as it will take at a minimum 5 years (or more) for the ecosystem to adopt these transformational changes to the way a citizen avails of healthcare services.

In addition, an incentive should be provided to the early adopters of the UHI Network. This approach has been validated across multiple countries in ensuring rapid adoption of digital health initiatives.

Question 15: Please share your views on the duration for which NDHM should manage and govern the UHI gateway, and if NDHM should open the path to multiple gateways. Please provide details on the benefits and risks of the options.

KHPL Answer: Yes, NDHM should eventually enable multiple gateways that will allow greater manageability and localization as required. A similar model to DNS systems can be considered to make the UHI system robust and fault tolerant.

Additional KH comments/feedback

1) Provide guidelines on data retention and usage policy for EUAs.
2) It is not clear if specific NDHM registries can be used without leveraging the UHI?
3) Clear and detailed guidelines on TSPs are required.
4) HIE term is referred in the Consultation Note but is not explained anywhere. Does it refer to the PHR network of NDHM?
5) UHI document is silent on what standards will be used to build APIs. Globally HL7 FHIR Healthcare APIs specifications and IHE specifications are used to build open APIs.