

Amazon Internet Services Pvt Ltd (AWS) Feedback on NHA's UHI Consultation Paper

We are grateful to the NHA for offering stakeholders an opportunity to share their ideas and thoughts towards India's healthcare reform agenda

About AWS: AWS services are being used by healthcare, life sciences, and genomics organizations to improve patient access and care, drive innovation, advance precision medicine, and bring new therapeutics to market faster.

As you are aware, AWS' commitment to India is long term and substantive. We are empanelled by the Ministry of Electronics and Information Technology ("MeitY") for the delivery of cloud services to government agencies. We are also part of Government's Digital India and Skill India programs.

Since 2016, we have set up the first AWS Region (consisting of multiple clusters of data centers) in Mumbai and have the second AWS region coming up in Telangana. We have 17 CloudFront content delivery network locations and 6 AWS Direct Connect dedicated connectivity locations. Our offices are located across 6 Indian cities, and we also have a Technical Support Centre in India.

There are several instances where AWS teams have worked closely with Hospitals and network of hospitals, and other players in the healthcare industry, globally. For instance, we are partners of the largest health administrative network in the United States, wherein AWS's cloud technology enables processing claims, pharmacy requests, and performing other functions for more than 340,000 physicians and 60,000 pharmacies, where deployment on the cloud is used to handle millions of confidential transactions daily from its clients while maintaining with full compliance with healthcare industry regulations, including HIPAA. Such partnerships are allowing healthcare service providers develop and test new services for its customers quickly, that can scale to meet large demand while minimizing IT costs and complexity.

Digital Health: The COVID-19 pandemic has highlighted the importance of digital tools. In parallel, digital health has ensured that patients can access care during the pandemic through remote and virtual services; and countries have put in place temporary payment policies and other provisions to support such telehealth services. Policymakers should ensure that the relevant policies on virtual care remain in place even after the pandemic ends.

Patients, clinicians, public health officials, and many other organizations rely on the availability of data to inform care decisions, monitor outcomes, and reduce costs. The deployment of electronic medical records has marked a turning point in the ability to build a learning healthcare system. Increased digitization of data also opens the door to new opportunities for innovation. Policies should encourage secondary use of data, ensure appropriate access to data across borders to promote collaboration for research, and include necessary privacy safeguards to maintain the trust of patients.

Response to the UHI Consultation Paper

Section 1: Introduction and Background

1. Questions: Suggest changes to the teleconsultation policy, if any, to ensure adoption of telemedicine and e-pharmacy.

The COVID-19 pandemic risked patients forgoing medical care as they could not see healthcare providers in-person. Healthcare providers quickly scaled to support telehealth, ensuring that patients had access to clinicians and medical care.

Telehealth can also help ensure that individuals obtain the care they need—even when they live in remote areas or are unable to travel to a physician’s office. Virtual care can therefore reduce barriers to accessing health services—including those for individuals living in underserved communities or with conditions that limit mobility.

Policymakers should increasingly recognize that telehealth is a core tool in the healthcare toolbox of the future. Policies that ensured patients’ access to virtual care during the pandemic should continue and be expanded.

- 1) The teleconsultation policy acknowledges the numerous benefits of telemedicine including timely access to appropriate interventions and access to services that may not otherwise be available. Keeping in mind the rapid integration of Technology in the healthcare ecosystem, we would like to draw your attention to the following for clarifications and guidance; Please clarify the envisaged mechanism of implementing telemedicine gateways including private market players. With reference to the telemedicine guidelines, we suggest the guidelines allow and encourage
 - a) State governments to set up State-wise telemedicine gateways which will be interoperable with each other
 - b) Private sector aggregators to develop and offer telemedicine-as-a-service platforms that can on-board Governments as well as private practitioners

- 2) As per the current guidelines, ‘a Registered Medical Practitioner [RMP] is a person who is enrolled in the State Medical Register or the Indian Medical Register under the Indian Medical Council Act 1956.’ [IMC Act, 1956]¹.
 - a) The Teleconsultation guidelines should clarify if the RMPs will now be identified through the healthcare workers registry under NDHM?
 - b) Further, if RMPs are identified through core registries, would it be the sole responsibility of the Central Government to set up the core registry or would the States be allowed to set up their respective registries and integrate with the system being set up by the Central Government?

- 3) As per the current guidelines, ‘RMP may use any telemedicine tool suitable for carrying out technology-based patient consultation e.g., telephone, video, devices connected over LAN, WAN, Internet, mobile or landline phones, Chat Platforms like WhatsApp, Facebook Messenger etc., or

¹ Pg 5, <https://www.mohfw.gov.in/pdf/Telemedicine.pdf>

Mobile App or internet based digital platforms for telemedicine or data transmission systems like Skype/ email/ fax etc.’

- a) With different communication channels and platforms for sharing medical data being made available, the telemedicine guidelines should emphasize health data privacy and management practices. Tools like consent management as a service may be considered, both as an integral part of the platform or as standalone offering.
 - b) We further request the guidelines to clarify
 - The use of anonymization systems to utilize telemedicine data for analytics and policy-level decision making etc.
 - Sharing data from remote medical devices (e.g., remote android based sugar monitor, mobile-compatible BP monitor) etc. using AI/ML/IoT for telemedicine purposes as a part of asynchronous data transfer
 - Process of data under teleconsultation being added to the PHR of the individual
 - Acceptance of customized product that is covering all modes of teleconsultation and nature of guidelines / available sandbox applicable to such development and approvals
- 4) Other queries that need to be addressed in the telemedicine guidelines include
- a) Clarity on telemedicine application data standards and interoperability guidelines?
 - b) Process and opportunity to create a telemedicine sandbox by a private sector in partnership with NDHM.
 - c) Permissions for private sector to create service mechanisms and platforms for validating prescriptions’ authenticity.
 - d) As per the current guidelines, Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the telemedicine consultation should be retained by the RMP. Does that mean each RMP will have to become HIP and HIU? If not, are the HIS expected to be made available as a service on cloud, or separate products can be conceptualized?
 - e) Is health ID going to be mandatory for teleconsultation? If so, would the States/Private entities be able to create products and integrate with NDHM services for health ID?
 - f) Would the State Government(s) be able to create/expand on their State-level health IDs and integrate with Health ID under NDHM - that will be used for teleconsultation?
 - g) Section 1.3 - The content and the qualification of the online course requires further detailing. The course should
 - Include minimum safeguards need to be in place for a healthcare provider to safely deliver consultation and treatment planning.
 - Have modules on how the provider includes the service into their practice - dedicated teleconsult clinics, versus on demand physical vs virtual patient wait lists

- Assist the provider in setting up and monitoring and efficacy of their telemedicine capability and patient outcomes and satisfaction scores.

Additional examples from other countries include:
<https://www.lexology.com/library/detail.aspx?g=b9502a5b-6014-428e-a514-fac08ab6e529> ,
<https://www.england.nhs.uk/wp-content/uploads/2014/12/tecs-ed-telemedicine.pdf> ,
<https://www.rcophth.ac.uk/wp-content/uploads/2020/04/Overview-of-digital-technology-and-telemedicine-for-covid-090420-V3.pdf>

- 5) In Section 1.4 to 4.2, and in particular, section 3 Overview, the framework described outlines a formulaic approach to the technology and proposed use cases. But this does not help create the guidelines starting from a clinical context - Is the patient problem appropriate for the use of telemedicine?

In advertising or promoting telemedicine channels, we recommend

- Public education materials on what they can use the telemedicine services for
 - For providers, which types of clinical specialty, and which care settings can telemedicine be applied in either first consult or follow up scenarios. e.g., common sense would dictate that a collapse or road traffic accident would not be an appropriate use of telemedicine. Whereas common primary care provider ailments, such as headaches, coughs, colds, rashes may be appropriate for first consult, in primary care. And in secondary care, first consults for suspected cancer diagnoses may not be appropriate in outpatient clinic, but follow up consults for eg stable diabetics, or hypertensives may be appropriate.
- 6) Other than the section 3.7.4, and briefly covered in 3.7.2 it is not clearly documented elsewhere that practice of telemedicine still requires there to be documentary evidence of the consultation, the interacting stakeholders, a record of the interaction as well the clinical information captured, and treatment or management advice provided. We recommend guidelines to inform the healthcare providers on the necessary steps to collate, verify, validate, and publish the patient interactions through telemedicine so that other care providers, where appropriate, can see the continuity of care. (This may be a component of the PHR or other NDHM strategy). This is also a safeguard against doctor hopping - a variant of emergency room hopping, where patients visit multiple facilities either for fraudulent purposes, or because there is some condition exacerbation that does not get picked up because of the multiple centres involved.
 - 7) With the proliferation of telemedicine during pandemic, we recommend that Indian Medical Council Regulations, 2002 and the IT act, as well as any other healthcare professional regulatory body be evaluated to describe the practice of telemedicine and associated healthcare professional conduct, and these institutions should draft up to date and future provisions based on technology availability and service delivery advances.
 - 8) Section 3.7.3 - There has been a shift to value-based care delivery in countries like Singapore and Thailand for connected healthcare systems. Value-based healthcare emphasizes attaining greater value for the patient while maximizing the value for healthcare dollars spent is critical, thereby enabling equity of care through telemedicine.

- 9) In section 4.3 to 4.4, appropriate guidelines for enlisting the telemedicine support of a RMP/specialist needs to have careful consideration - appropriateness of referral, optimum care, well documented directory of providers may be required, so that referral to, or secondary opinion seeking from another provider is based on expertise, skill, specialty and also not drive “cherry picking” of patients, or inappropriate referrals, leading to delay in care, or incorrect management.
- 10) To provide guidance and confidence to the users, guidelines should outline escalation point for any complaints, arbitration, liability etc. related to the healthcare service that needs to be established to provide guidance and confidence to patients and providers. This is beyond the scope of the grievance officer appointed under the IT act by Intermediaries.

Finally, to re-iterate, the telemedicine delivery requires not only healthcare provider engagement and consent to deliver the most appropriate service possible, but also that the wider population, citizens, and patients be informed regarding the telemedicine services that are available-the benefits, limitations, costs, as well as place within the care continuum.

Section 2: Creating an Open Network for Digital Health Services

Consultation Questions:

- 1. 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.**

The concept of the open network, interoperable, open, standards mandated over a nationwide decentralized network, as supported by examples of UPI in finance and NODE by MeitY may be appropriate for highly regulated industries such as banking and IT and telecoms, and in sectors where IT standards have been universally agreed. In healthcare, the proliferation of different IT systems, multitude of standards, versions of standards, customization of some older standards means that the starting point for system providers and system owners is not all at the same foundational level. That coupled with the fact that within the systems, the naming conventions between the same specialties such as General Surgery vs General Surgery and Vascular, and the ownership of some treatments such as spinal decompression by Neurosurgeons vs spinal decompression by orthopedic surgeons leads to a question of the ability to properly provide attribution of functionality and services. This makes it difficult to develop an accurate orchestration engine allowing interconnectivity, and patient education on appropriate clinical service provider.

In the England NHS, during the Connected for Health programme in the early 2000’s, mapping of similar services facilities, clinicians rendered into directories that allowed for appropriate referrals to Choose and Book from primary care to any service. This was logistically a massive exercise in the standardisation of non-standards based convention. it was not driven by SNOMED, or HL7 or LOINC or DM&D coding, rather in the way that different hospitals and clinics had provisioned their services, naming conventions in their Administration IT systems as well as different funding mechanisms across boundaries. Despite there being a HIE called PDS and PSIS, that was meant to enable orchestration and legitimate relationship and consent documentation, the different systems required much mapping effort.

Similarly even as Singapore and Australia embarked on their National Electronic Health Record systems, mapping of services, facilities, providers, different semantic interpretation of end point user services, even configuration of the services in existing Health IT systems, significant effort was deployed to map to common data models, and setting up governance protocols to address creation, modification and retirement of health data types etc.

The open network certainly has benefits in terms of enabling IT interoperability, end user choice, creation of agile and flexible treatment networks in a federated approach, facilitating more interoperability and ability to deploy simultaneously over familiar components more rapidly. The challenge is in standardising the clinical landscape and achieving alignment between different groups, regions, and systems providers for existing information systems if the desire is to map to a standardised data model, outside of the scope of the information transmission model that FHIR can help facilitate.

Conversely a centralised single health IT ecosystem, again as demonstrated in the 5-cluster model of the UK NHS Connected for Health Programme was a massive undertaking in ripping, replacing, and deploying existing well used and familiar IT solutions. These were replaced with more modern softwares that required significant testing in a new environment with huge training, change management and IT infrastructure modifications, with a centrally managed budget, leading to waterfall and historically slow and lower performance deployments. In those same countries, learnt lessons now see a more hybrid approach - autonomy to deploy locally more aggregated capability, that interfaces into centrally managed health information exchanges. New Zealand Government in the last 2 years has announced that their national platform model will be more decentralized health information exchange, allowing local ownership and decision making on appropriate software to suit the purposes of the healthcare providers, but integrating into a standardized data model, messaging standards, agreed universally.

An observation would be that if the UHI adopts a fully open network, significant effort is required to provide the mandated data modelling and messaging standards, as well as gaining alignment throughout the whole healthcare provider network on agreed nomenclatures, so that service and care delivery are consistent when looking up the UHI services.

Further we would like to point out the following:

- 1) An implementation risk may exist with a mandate of core platforms being implemented and managed by NDHM. No core product dependency or mandate should be restricted with NDHM only. It is suggested to allow the State Governments to implement/expand their systems and ensure compliance to the standards defined under NDHM.
- 2) It is mentioned at multiple places that the system is similar to how users can use any mobile app in the UPI ecosystem to make payments to any other party. If that's the case, even core products like Health ID or Health Professionals Registry should be open (like in UPI, the same person can be ravi@oksbi and ravi@paytm and ravi@upi in different applications).
- 3) Interoperability acceptance and on-ground implementation may be a current challenge that needs to be resolved. Organizations compliant to NDHM /UHI through sandbox should be promoted/incentivized by NDHM for on-ground implementation of interoperability standards.

- 4) The current systems refer to service delivery alone and requires an effective and reliable grievance redressal process. It is not clear how would grievance redressal on healthcare direct benefits transfers be managed under UHI? We recommend a clear escalation mechanism be established, as the resident grievance redressal officer appointed under the IT Act will not be equipped to respond to service delivery.
- 5) Clinical Decision Support and Standard Treatment Workflows must be added.

Section 3: Creating an Open Network for Services in NDHM

Consultation Questions:

- 1. 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.**

We suggest the following stakeholders be considered,

- 1) Private sandboxes for UHI – They will enable, augment and expand players’ readiness for NDHM enabled digital health ecosystem.
 - 2) There are a significant number of stakeholders who take ownership of components required for UHI, such as administration managers, owning outpatient and clinic timetables, ward and bed management, ambulance and emergency services, allied health therapies, such as physio, occupational health, rehab, speech and language, radiology, oncology, dialysis, residential, nursing home, community hospital, primary care clinics, ASHA and ANW administrators. This list also needs to include the Operating theatre functions, Sterile services, day surgery, as well as medical device manufacturers, pharmaceutical and biotech suppliers etc.
- 2. 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.**

We suggest including Key Performance Indicators (KPIs) - what improvements are we expecting, or predicting by adopting the UHI; how does it make a difference to patients, or disease incidence, patient experience or provider experience; does the UHI allow for better overview and therefore service planning of future services, funding and policy making

- 3. UHI will support a range of digital health services and is expected to evolve with time. How should the digital health services be phased in the upcoming versions of UHI?**

The phasing of the UHI needs to be properly architected against a business case of the benefits for the India healthcare delivery such as What are the biggest deficit areas? Which are the easiest services to deploy, how much population or disease does that impact, if at all?

The Authority can decide low hanging fruit against minimal return, versus, longer term success, but less short-term projects. Depending on the architecture approach, and the willingness of the authorities to program manage multiple projects, change management, care delivery disruption as SME is required to

volunteer time to help design, build, configure, test and deploy capability, taking them away from their normal duties, the demand on the care system will be great.

Section 4: Ecosystem Adoption

Questions for Consultation

- 1. 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.**

NDHM should allow private sector to build reference apps. Please see response for Question/Answer Section 2 -2, Section 3 - 1b. Also to identify incentives and disincentives, the additional stakeholders identified in Question/Answer Section 3 - 1b would have different perspectives from purely medical perspectives.

- 2. For the disincentives mentioned in chapter 4 and the ones provided as an answer to the question above, please provide details on possible mitigating measures that may be taken to minimize the impact of said disincentives.**

Disincentives may not be purely monetary - additional workload, liability, clinical safety, concerns over continuity of care, plus for aggregators, challenges of size, scale, adoption, no guaranteed return on investment. Disincentives for other stakeholders may also need to be elucidated through consultation exercises with those indicates in Question/Answer Section 3- 1b.

Section 5: Unified Health Interface in Depth

Questions for Consultation

- 1. 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.**

NDHM should allow multiple UHI gateways.

- 1) The Service Discovery is a 3 tier process - Application to, validation of, and then publication of services. This will include availability of services, real time updating and confirmation of remaining or retirement of services to prevent duplicate booking.
- 2) The Service Discovery should also cover services not just medical, but also nursing and allied Health professional delivered. Constraints on service provision and patient equity is not just limited to seeing a doctor.

- 2. 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.**

Please refer to Question / Answer Section 1 - 6. This will be driven by the expectations of the user.

If the expectation is that the UHI will be able to provide, for instance, the cheapest, then how is service rated, success rates? Alternately, the service has a high success rate and therefore could be priced higher.

Section 6: UHI Development, Governance and Management

Questions for Consultation

- 1. What approaches, other than the ones mentioned in chapter 6, should be considered for managing and governing the UHI gateway? Please provide details.**
- 2. What should the UHI Gateway charge in the initial few years of operation? How can this model evolve over time?**
- 3. 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.**

We recommend that NDHM should be flexible and open from the start, with the private sector allowed to undertake development of UHI gateway as per the compliance standards defined by NDHM, in addition to NDHM's efforts. This will offer a choice of UHI gateway to the Healthcare service providers defined by NDHM. Subsequent choice will be of HSPAs to decide if they want to onboard with the Government UHI gateway or one of the options of a feature rich private sector built UHI gateway. The purpose of standardization and