



Ayushman Bharat Digital Mission

Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Personal Health Records Apps

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1 Summary

The Ayushman Bharat Digital Mission (ABDM) formerly known as the National Digital Health Mission (NDHM) is working on bringing interoperability for digital health data in India. National Health Authority (NHA) will manage the ABDM's foundational digital building blocks that need to be adopted by all healthcare providers in the country.

Any healthcare provider who is creating health data (diagnostic reports, discharge summaries, prescriptions, etc.) digitally, should participate in ABDM. This will enable them to share these records with their patients and fetch records issued by other providers with patients' consent.

To avail these benefits from ABDM, the hospital / lab information management system or electronic medical record software that is being used by the healthcare provider must be upgraded to become ABDM compliant. The software being used by the provider must integrate with the digital building blocks of ABDM and comply with the guidelines outlined in this document. Healthcare providers are required to check with their vendor or inhouse software team and ensure they are operating with ABDM compliant software.

The ABDM sandbox has been setup to enable any software to integrate with the digital building blocks and test their compliance with the guidelines and digital health standards. The sandbox offers all open APIs available under ABDM. Healthcare software developers are required to apply on the sandbox website (https://sandbox.abdm.gov.in/) for access. Full documentation on the Open APIs, a discussion forum for support, a hosted environment containing the digital building blocks and a test harness that will check for compliance is available at the sandbox. Please visit 'ABDM Sandbox Integration and Exit process' section on the sandbox website as this section offers step-by-step guidance for the integrators.

NHA requires the software to be certified for compliance and it will notify the agencies who are empaneled to certify that the software is compliant to ABDM requirements. This is required to ensure correct capture and linking of Ayushman Bharat Health Account (ABHA), secure storage of health data, use of standards in data exchange, etc.

Once the software provider has made their solution ABDM compliant, they will be added to the ABDM registry. They will receive a set of digital keys that need to be configured in their ABDM compliant software. These keys will provide access to the ABDM production APIs.

Healthcare providers can choose to adopt any ABDM compliant software at their facility. Providers will need to first sign up with the Health Facility Registry. With the approval of their facility and adoption of an ABDM compliant software, the healthcare provider will be able to register and issue ABHA numbers, issue health records digitally to patients and request and view patient's medical history with their consent.

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2 ABDM Functional Landscape

ABDM has been conceptualized as a set of 'digital building blocks. Each building block is seen as a 'digital public good' that can be used by any entity in the digital health ecosystem and provides key capabilities that enable the ABDM vision.

Ayushman Bharat Health Account (ABHA): To standardize the process of identification of an individual across healthcare ecosystem, every patient who wishes to have their health records available digitally may avail the facility to create a ABHA number. The ABHA can be obtained via self-registration at abha.abdm.gov.in from a PHR mobile application or at any participating healthcare provider. ABHA numbers will be issued only after verifying individual's identity with a KYC document. Users can either use Aadhaar or other documents such as Driving license, PAN or any other KYC doc as notified by NHA from time to time, to create their ABHA numbers. Each individual will possess only one ABHA number and the system will perform appropriate checks to ensure users do not accidentally obtain multiple numbers. ABHA will support multiple authentication methods such as Aadhaar biometric authorization or OTP authorization with linked mobile.

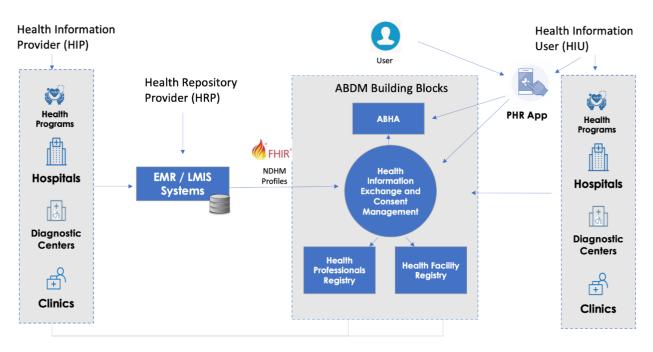
Healthcare Professionals Registry (HPR): NHA maintains the national directory of all Healthcare professionals and enables them to participate in the digital health ecosystem. All doctors and other health professionals at healthcare providers that are participating in ABDM are required to enroll with HPR (hpr.abdm.gov.in). The HPR will be an integrated data set from data maintained by various medical councils, nursing councils and paramedical boards. HPR will help in standardizing healthcare Professionals' data and offer APIs that can be used by various stakeholders in the ecosystem who wish to use the HPR data.

Health Facility Registry (HFR): NHA maintains the national directory of all healthcare facilities. Any participating facility needs to sign up in the health facility registry at facility.abdm.gov.in This ensures that they are a valid facility which is authorized to issue health records in the ecosystem. HFR consists of information for each healthcare facility in the country – hospitals, clinics, diagnostic centers, pharmacies etc., across all systems of medicine and covering both public and private health facilities. HFR offers APIs that can be used by various stakeholders in the ecosystem.

Health Information Exchange and Consent Manager (HIE-CM): The HIE-CM enables exchange of personal health data with consent as per the Health Data Management Policy issued by NHA. Users who would like to link their health records at various health facilities, share their data with consent, etc must sign up with the HIE-CM and obtain an ABHA address. Users can use their ABHA number and the authentication methods to obtain the ABHA address. ABHA Address will also include a QR code that can be scanned to enable seamless patient registration at health facilities. While NHA manages and runs one HIE-CM, multiple HIE-CMs are expected to be available in the ecosystem over time.

Each PHR application will be associated with at least one HIE-CM to enable consent and data exchange for the individual. The Individual and the associated HIE-CM can be identified by the full ABHA address which would look like <username>@HIE-CM (e.g.: xyz@abc), and each HIE-CM will be assigned a "domain" which looks like @abdm or @abc.

The diagram below captures the above building blocks and how they interact with stakeholders in the ecosystem.



Consequently, there are several entities in the healthcare ecosystem that can integrate with above building blocks:

- A. **Health Information Provider** (**HIP**) Any healthcare provider who creates, stores, or distributes health information in the context of providing healthcare related service to a patient and agrees to share the same digitally with the patient using the consent framework adopted by ABDM is a Health Information Provider (HIP). All hospitals, diagnostic centers, clinics, public health programs, telemedicine players, etc. are encouraged to become HIP. HIPs use an ABDM compliant software that implements the HIP software specifications. The specifications are published at the ABDM Sandbox website, available at https://sandbox.ndhm.gov.in/docs/build hip.
- B. **Health Information User (HIU)** Any permitted entity that would like to access health records of an individual with their informed consent is called a Health Information User. This would include hospitals / doctors who would like to view medical history of patients, mobile applications that want to display health data to users including Personal Health Record applications etc. HIUs use an ABDM compliant software that implements the HIU software specifications published at the ABDM Sandbox website, available at https://sandbox.ndhm.gov.in/docs/build_hiu.
- C. **Health Repository Provider (HRP)** Health Repository Providers are software service providers who offer ABDM compliant software and long-term record storage to hospitals, diagnostic centers and clinics. The HRP service enables healthcare providers to become HIPs or HIUs and meet their obligations of sharing and securely maintaining health records of patients digitally. HRPs offer long term storage of health records on behalf of a HIP. For example, a hosted Lab Information Management System (LIMS) provider may update their software to become a ABDM compatible HRP. Any lab using this LIMS software can rapidly become a HIP by adopting the software.

D. **Personal Health Record Apps (PHR Apps)** – PHR Apps are software service providers which offer front ends to Individuals and enable them to create a ABHA address, discover & link health records from various HIPs, allow users to view their records, offer long term storage of records, upload users health records and share records on the ABDM network. Every PHR App works closely with one HIE-CM. PHR Apps provide a front end for HIE-CM actions like viewing and granting consents. The specifications are published at the ABDM Sandbox website, available at https://sandbox.abdm.gov.in/docs/build_PHR_App.

A large hospital or a public health program like Reproductive and Child Health Programme (RCH) could hold the records of patients in long term storage on premises or in the cloud as per policies/guidelines issued by NHA. The hospitals will play the role of HIP and the software they use will be the HRP in the ecosystem.

Smaller diagnostic centers / clinics may use a specialized Health Repository Provider (HRP) who provides software solutions to help issue health records to patients and hold the same in long term storage. The software provider plays only the role of the HRP and supports the healthcare provider to become a HIP and participate in the ABDM ecosystem.

If a Hospital / Clinic wants to access the medical history of a patient, they need to become a HIU and comply with policies/guidelines issued by NHA for the same. Individuals can use the PHR mobile applications to view their health records and also manage their consent. These applications also need to comply with the policies/guidelines issued by NHA.

3 ABDM IT Landscape

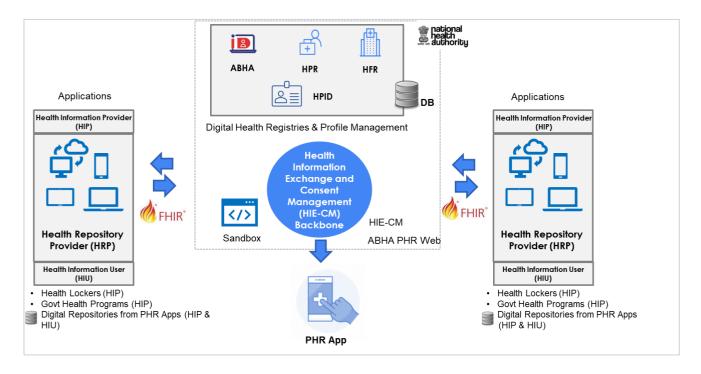


Figure 1: ABDM IT Landscape

The Ayushman Bharat Digital Mission (ABDM) IT Landscape (Figure 1) has been categorized under the following:

a) NHA managed ABDM Building Blocks

The ABDM building blocks which are developed, hosted and managed by National Health Authority (NHA) and NHA is the sole custodian for these building blocks. The ABDM building blocks are:

- A. Digital Health Registries & Profile Management
 - I. ABHA
 - II. Healthcare Professional Registry (HPR)
 - III. Healthcare Professional ID (HPID)
 - IV. Health Facility Registry (HFR)
- B. HIE-CM Backbone:
 - I. HIE-CM APIs
 - II. ABHA PHR Web Application
- C. Sandbox

These building blocks are accessible through database, web application and APIs listed on: https://sandbox.abdm.gov.in/docs/building_blocks.

b) Partner ecosystem managed ABDM Compliant Applications

The ABDM Compliant Applications which are developed, hosted and managed by the ABDM Partner ecosystem and are the sole custodian for these building blocks. One of the pre-requisite is that the applications must be integrated with ABDM ecosystem i.e. integration at M1 (ABHA ID Creation and Linkages) /M2 (Health Information Provider-HIP) /M3 (Health Information User – HIU) milestones

through the available APIs (https://sandbox.abdm.gov.in/). The ABDM Applications managed by the partner ecosystem are:

- Citizen Facing Apps: Patient Health Record (PHR) App
- Health Repository Applications (HIP & HIU): HMIS/LMIS used by Health Facilities (HIP & HIU), Health Lockers (HIP), Government Health Programs (HIP) and Digital Repositories from PHR Apps (HIP & HIU)

3.1 NHA managed ABDM Building Blocks

- 1) Digital Health Registries & Profile Management:
 - a. **Ayushman Bharat Health Account (ABHA):** The 14 digital Ayushman Bharat Health Account (ABHA) ID is assigned for every patient as unique Health ID for patient records with the aim of universal health coverage. It is used for linking health records across multiple systems. HRPs will be able to locate a patient health record by searching using the ABHA ID, along with the appropriate consent provided by the Patient using HIE-CM. The HRP system which is integrated with ABDM at minimum M1 milestone can both create and link ABHA ID in its system.

The modes to access ABHA ID repository are through following systems/services:

- ABHA Web Portal which is accessible at: https://healthid.abdm.gov.in/
- ABHA APIs which are available at: https://app.swaggerhub.com/apis-docs/abdm.abha/abha-service/1.0.

Some of the nature of ABHA Services APIs are related to Authentication, create ABHA number from various modes, forget ABHA number, login with mobile number etc.

b. **Healthcare Professional Registry (HPR):** NHA maintains the national repository of all Healthcare professionals and enables them to participate in the digital health ecosystem. The HPR is an integrated data set from data maintained by various medical councils, nursing councils and paramedical boards. The unique identifier which is used in HPR is 14 digit Healthcare Professional ID (HPID). HPR will help in standardizing healthcare Professionals' data and offer APIs that can be used by various stakeholders in the ecosystem who wish to use the HPR data.

The modes to access HPR repository are through following systems/services:

- HPR Web Portal which is accessible at: https://hpr.abdm.gov.in/
- Some of the nature of HPR APIs are related to Enroll Doctors, Search Doctors, Get Doctor Profile and Master Data
- c. **Healthcare Professional ID (HPID):** Healthcare Professional ID (HPID) is a unique 14 digit identification number that would be provided to all healthcare professionals who enroll in the Healthcare Professionals Registry. The HPID will be the professional's primary identifier in the National Digital Health Ecosystem and can be used in a variety of healthcare transactions. Various categories of healthcare professionals either directly or indirectly providing health services across modern and traditional systems of medicine can enroll on Healthcare Professional ID. Applications for enrolment in the registry will be verified by the appropriate authorities. The Healthcare Professional ID would be used for the purposes of uniquely identifying persons, authenticating them, and threading their health records (only

with the informed consent of the patient) across multiple systems and stakeholders.

The modes to access the HPID are through following system/services:

- HPID Web Portal which is accessible at: https://hprid.abdm.gov.in/
- Some of the nature of HPID APIs are (https://hpridbeta.ndhm.gov.in/api/swagger-ui.html) related to Authentication, Forget HPID, Profile etc.
- d. **Health Facilities Registry (HFR):** NHA maintains the repository of all healthcare facilities. HFR consists of information for each healthcare facility in the country hospitals, clinics, diagnostic centers, pharmacies etc., across all systems of medicine and covering both public and private health facilities. The 12 digit unique Facility gets assigned to the registered Health Facility. HFR offers APIs that can be used by various stakeholders in the ecosystem.

The modes to access HFR repository are through following systems/services:

- HFR Web Portal which is accessible at: https://facility.abdm.gov.in/
- HFR APIs which are available at: https://sandbox.abdm.gov.in/docs/hfr
 Some of the nature of HFR APIs are related to Search API, On-Boarding Facility, Master Data, Facility type etc.

2) HIE-CM Backbone

The HIE-CM enables exchange of personal health data with consent as per the Health Data Management Policy issued by NHA. Health data exchange and consent services are provided solely by ABDM through a 'Consent Manager & Gateway'. The ABHA ID and Consent Manager are tightly integrated in the current system and every ABHA ID is associated with a ABHA consent manager. Each PHR application is associated with at least one HIE-CM to enable consent and data exchange for the individual. The Individual and the associated HIE-CM can be identified by the full ABHA address, and each HIE-CM will be assigned a "domain" which looks like @abdm or @abc. All HRPs (HIU) requests the consent from the patient through HIE-CM backbone to pull patient health records from other HRP (HIP). NHA is not storing any patient health record data. The patient health record data is available at respective HIP only.

The HIE-CM Backbone building block is categorized under three components:

a. **HIE-CM APIs:**

i) Consent Manager

The set of APIs to enable the entity which provides health information aggregation services to customers of health care services. It enables customers to fetch their health information from one or more Health Information Providers (e.g., Hospitals, Diagnostic Labs, Medical Device Companies), based on their explicit Consent and to share such aggregated information with Health Information Users i.e. entities in need of such data (e.g., Insurers, Doctors, Medical Researchers).

Some of the nature of Health Data Consent Manager APIs are (https://sandbox.abdm.gov.in/swagger/ndhm-cm.yaml) related to User Authentication, Identification, Profile, Discovery, HIP Facing, HIU Facing etc.

ii) Health Information Exchange (Gateway)

HIE Gateway is a NHA cloud-hosted software system that enables HIPs, HIUs, and CMs in the ABDM ecosystem to connect with each other and exchange information and will act as hub of information exchange in the ABDM ecosystem. It is the hub that routes/orchestrates the interaction between consent managers and API bridges. There are 5 categories of APIs; discovery, link, consent flow, data flow and monitoring.

Some of the nature of Health Information Exchange (Gateway) APIs are (https://sandbox.abdm.gov.in/swagger/ndhm-gateway.yaml) related to User Authentication, Consent Flow, Consent Manager Facing, HIU Facing, HIP Facing etc.

b. ABHA PHR Web Application

The PHR Web Application facilitates the user to create ABHA Address and manage his/her profile. The ABHA Address can be created through Mobile Number, ABHA Number or Email ID. Some of the profile details which can be updated using ABHA PHR Web Application are: Email Address and Current Address. The user can also link/unlink their ABHA number and can also update the password. The ABHA card using the QR code can also be downloaded through this PHR web application.

To access ABHA PHR Web Application: https://phr.abdm.gov.in/.

3) Sandbox

The ABDM Sandbox environment is a framework developed by the NHA to allow technologies or innovative products to be tested in a contained environment in compliance with the ABDM standards. This will help organizations intending to be a part of the ABDM Ecosystem, become a Health Information Provider (HIP) or Health Information User (HIU), and Health Locker for

efficiently linking with other building blocks of the ABDM. The environment allows both alpha as well as beta testing of the products. The sandbox can be accessible from the link: https://sandbox.abdm.gov.in/

The Sandbox hosts all the ABDM building blocks for integration and testing. They can be used by anyone to comply with the HIP, HRP, HIU, UHI, and Locker guidelines. Unrestricted access to the sandbox is available upon request. Upon request approved, an integrator will get access to the sandbox to build and/or expand products in the healthcare / health-tech industry. Such a product management approach provides an integrator with the chance to partner with the ABDM, by enabling and empowering products within the core building blocks of the ABDM.

To integrate with the ABDM ecosystem, there are three levels of integration which are also called "milestones":

- <u>Milestone 1 (M1)</u>: ABHA Number creation and capture & verification for seamless patient registration.
- <u>Milestone 2 (M2)</u>: Building Health Information Provider (HIP) services to share digital records via Personal Health Records (ABHA) app.

• <u>Milestone 3 (M3)</u>: Developing Health Information User (HIU) services to provide view of patient's medical history to authorized healthcare workers with complete consent

More details are available at: https://sandbox.abdm.gov.in/docs/integration_and_exit_process
The Complete list of APIs are available in Sandbox: https://sandbox.abdm.gov.in/docs/apis

3.2 Partner ecosystem managed ABDM Compliant Applications

1) Citizen Facing Applications

PHR Apps: PHR Apps are software service providers which offer front ends to Individuals and enable them to create a ABHA address, discover & link health records from various HIPs, allow users to view their records, offer long term storage of records, upload users health records and share records on the ABDM network. Every PHR App works closely with one HIE-CM. PHR Apps provide a front end for HIE-CM actions like viewing and granting consents.

The PHR Application launched by NHA: ABHA Mobile application provides the individuals with a longitudinal view of health records with an option to link and share post user consent through ABDM network of different health facilities and providers. Existing & New Functionalities (with all new simple & intuitive UI design)

- Create an easy to remember ABHA Address (username@abdm) with mobile number, email ID or ABHA number.
- Link ABHA address with 14digit ABHA number to become KYC verified and utilize benefits of government health programs.
- Discover health facilities to link, view and manage health records by citizens
- Access health records such as lab reports, prescriptions, CoWIN vaccination certificates etc.
- Share health records with registered doctors, health facilities or health programs.
- Own and Control access of your health records in terms of who can access, what type of health information can be accessed and for what duration.
- Option to revoke consent to stop sharing of your health records after granting consent.
- Option to Edit Profile details including address and update the mobile no or email with respective OTP validation.
- Scan QR code at the counter of the ABDM compliant facility for express registration.

2) Health Repository Applications (HIP & HIU)

Health Repository Providers Applications are software applications which offer ABDM compliant services and long-term record storage to hospitals, diagnostic centers and clinics. The HRP service enables healthcare providers to become HIPs or HIUs and meet their obligations of sharing and securely maintaining health records of patients digitally.

a. HMIS/LMIS used by Health Facilities (HIP & HIU)

The HMIS/LMIS interacts with the ABDM ecosystem as HRP (HUI or HIP) using FHIR exchange standards. The HMIS/LMIS needs to be ABDM compliant and shall be compliant with at least M2 milestone of ABDM Integration i.e. HIP. In M3 ABDM integration, the HMIS/LMIS acts as a HIU. The HMIS/LMIS used by Health Facilities benefits from the Digital Health Registries i.e. ABHA ID, HPR and HFR.

b. Health Lockers (HIP)

The Health Locker service enables patients to keep a copy of their records in their own personal digital cloud storage. Patients shall have the ability to store all health records

throughout their lifetime in lockers of their own choice. Several Health Locker providers will give patients adequate choice & security for storing personal health records fetched from various HIP's and store user-generated health data. Health Lockers also allow users to upload their own health records.

c. Government Health Programs (HIP)

Various Health IT systems of the Central or State Government Schemes will be able to act as HIP in case they are the custodian of the patient's healthcare records. As an HIP, the records shall be fetched by the HIU after the consent is provided by the patient through HIE-CM.

d. Digital Repositories from PHR Apps (HIP & HIU)

The PHR apps shall act as either HIP or HIU, along with other PHR features. It is convenient for the patients to use PHR application for all purposes. For the PHR Apps to act as Digital Repositories (HIP & HIU), the integration with ABDM is required at M2 (HIP) and M3 (HIU) level, with FHIR data exchange framework.

Guidelines for Health Information Providers

All healthcare providers are expected to become Health Information Providers (HIPs) over time. They must share a digital copy of any health report they currently provide as a physical printout and/or handwritten records to the user via the ABDM architecture. Any Hospital, diagnostic center, clinic, public health program, etc. creating digital health records for patients can become a HIP by signing up with ABDM. The registry will issue them a digital key that needs to be configured in the application, being used by the facility, that is certified to be compliant with ABDM standards.

4.1 Obligations of a Health Information Provider

Healthcare providers must commit to the following when they agree to become HIPs:

- 1. **Issue ABHA to interested Patients** HIPs are expected to educate patients and help create ABHA for those who require assistance. Several sections of society, which include the elderly population, illiterate users etc., will require assistance in creation of ABHA. ABHA s can be created using Aadhar or any other KYC document as may be notified by NHA from time to time. It is recommended that a printed ABHA card is provided to these patients to ensure they can use this card across multiple health institutions. If a hospital is already issuing a patient registration card, it is encouraged to include the ABHA QR code on its existing cards. This integration can be achieved using the ABHA Open APIs. The process for issue of ABHA s is described in section 3.2.
- 2. Collect ABHA during registration As ABHA start to get widely adopted, HIPs must check with patients if they have an ABHA. If they do, then the HIPs must capture and validate ABHA at the point of patient registration. The process to be followed for correct capture and verification of ABHA Address is outlined in the documentation on the ABDM Sandbox website. HIPs to note that this process is voluntary, and they will not force any patient to provide an ABHA number/ABHA Address.
- 3. Link the ABHA Address to their health records and notify on new records Patients can share their ABHA address with the health provider either at the time of registration or at any time via a discovery request from their PHR app. HIPs must store the ABHA Address shared post verification in their system and link it with any health records they have already created or are creating for the same patient. HIPs are expected to continue to have their own provider issued patient ID and only link the ABHA Address in their systems from those users who voluntarily provide the ABHA Address.

If the HIP is participating in ABDM it must notify via APIs whenever a new health record is generated for any patient. For patients where the HIP already has the ABHA Address in their system, the HIP must link the record with the HIE-CM using the HIP initiated linking method. If the patient has not shared their ABHA address but provided a mobile number, the HIP must notify ABDM by calling the Send SMS API. The process in described in the documentation on the sandbox website.

4. Operate a HIP service – The HIP service is an online system that responds to data requests

from any HIE-CMs. The HIP service must be compliant to the ABDM Open APIs. The service is designed to ensure that sharing of any health records is only possible after validating the patient's consent. The HIP service also needs to meet the privacy and security guidelines specified by NHA. The service must offer high uptime and availability. The ABDM infrastructure uses a set of heartbeats to measure the uptime of the HIP service. All HIP services must first integrate with the ABDM Sandbox and undergo a certification to be enabled on the ABDM network. If a facility with on-premises software wants to play the role of both HIP / HRP – they must setup an infrastructure with a reliable connectivity, a static public IP and certified HIP service.

- 5. **Provide structured health records** Any health record shared must meet the minimal health data interchange standards available at https://nrces.in/ndhm. These standards are designed to allow the HIP to start issuing records in existing formats (like PDF) and migrate to structured health data formats in Fast Healthcare Interoperability Resources (FHIR) over time. HIPs must start sharing fully structured data within one year of obtaining ABDM certification.
- 6. Maintain OPD and IPD records digitally for the long term All Electronic Medical Records (EMRs) must compulsorily be preserved and made available via the HIP service for the period specified in the forthcoming Health Data Retention (HDR) Policy/Guidelines. The HIP / HRP is expected to store digital formats of the health records as per these guidelines. Both In-patient and Out-patient records need to be stored. For diagnostic images like CT scans / MRIs which are very large in size and needs storage of the full resolution images, the policy will specify a reasonable period that would allow the patient to download such files and store a copy in their Health Locker. For these diagnostic reports, the HIP / HRP is expected to store the radiologist's opinion and diagnostic images that are normally part of the printed report provided to the patient. Any health records maintained by the HIP needs to be stored and managed securely in accordance with ABDM's Health Data Management Policy (HDM Policy) and Information Security Policy (ISP) for external ecosystem.
- 7. **Share aggregated data for public health** Every HIP service also generates a data feed with information that will be useful for public health purposes. This could include details like number of patients treated, List or details of treatments provided, number of tests conducted etc. Data from these services will be aggregated in a federated health analytics platform at the state & central levels and the platform is designed to be privacy preserving for both the HIP and the patient. Except wherever specifically authorized by law, any individual's HIP level data will not be available to any entity, including the Government, to maintain privacy and confidentiality of the patient and HIP's services.
- 8. **Migrate Health data on change of status -** Healthcare facilities could shut down their services, change locations, change their HRPs, etc. These scenarios can impact the HIP service and availability of Health data for their patients. HIPs shall commit to properly migrate data to an alternate provider in such scenarios. The HIP / HRP is expected to store and migrate health records in compliance with data migration guidelines to be issued by NHA.

4.2 Issuing ABHA to interested users

Any individual who wishes to obtain a digital copy of their health records must first obtain a ABHA. The process of generating a ABHA is completely voluntary. Creating a ABHA and sharing the same with the healthcare provider would be the patient's decision altogether. ABHA can be created by

either self-registration or in an assisted manner at a ABDM registered healthcare facility or through other authorized entities. HIPs are expected to educate patients on obtaining a ABHA to access their health records digitally. Various modes of creation of ABHA are described below:

- 1. **Self-Registration** -- ABHA Address can be created by providing a minimum set of information which includes the Full Name, Year of Birth, Gender and either a Mobile number or an email. Obtaining a ABHA number requires a user to provide a KYC document. Currently Aadhaar, driving license or pan card can be used as KYC documents. Most individuals with smartphones are expected to self-enroll for the creation of ABHA number and ABHA address by downloading Personal Health Records (PHR) mobile application or using the official ABHA portal (https://healthid.abdm.gov.in/).
- 2. Assisted Registration Healthcare providers can assist patients in creating ABHA using KYC documents such as Driving License, Passport, PAN or any other KYC document as notified by NHA from time to time. This is especially required in the case of an elderly, digitally illiterate etc. Every ABHA must be created only after educating the patient regarding the benefits of the same and obtaining a clear and informed consent of the patient. Healthcare facilities can either create the ABHA for patients from the official ABHA portal (https://healthid.abdm.gov.in/) or by integrating with the ABHA Open APIs from their own software. Details on setting up a ABHA desk is available in the ABDM Sandbox website. All patients obtaining ABHA via an assisted mode must also receive a printed physical card containing the ABHA number and the QR code. Users must be educated and encouraged to produce their ABHA card at every Healthcare facility.
- 3. **ABHA and existing healthcare provider cards** Many healthcare providers already issue patient identifier cards containing a provider specific patient ID. These providers are encouraged to update their processes to include the ABHA and the ABHA QR code on their existing cards. This can be achieved by integrating with the ABHA Open APIs in their software.
- 4. **ABHA and Children** Newborns and infants must also be issued ABHA. These ABHAs must be linked to a nominee usually a parent or a guardian. By creating ABHAs for newborns, HIPs can ensure that the vital health information right from their birth including immunization records become part of the child's longitudinal health record.
- 5. **Users who do not want to create ABHA** —One of the guiding principles of ABDM is to put the patient in control of their health data. There are many scenarios where a patient may not want to create a ABHA or provide a ABHA to a healthcare provider. HIPs are expected to follow their normal process of patient registration and care if a patient does not want to create a ABHA or provide existing ABHA.

4.3 Notifications and Linking of Health Records

Every ABHA Address in the ABDM ecosystem is linked to a Health Information Exchange and Consent Manager (HIE-CM). ABDM users choose this HIE-CM and obtain a ABHA Address if they wish to have access to their health records digitally. They share these ABHA Addresses with the Healthcare facilities. ABHA Addresses are represented like username@abdm where @abdm represents the HIE-CM which holds the links and consents for the ABHA Address username@abdm. There shall exist multiple HIE-CM in the ABDM ecosystem over time. The HIE-CM maintains information on which HIPs have health records for each ABHA Address. HIPs link a 'care context' for each health encounter of the patient. Each 'care context' can contain multiple health records such as diagnostic reports,

discharge summaries and prescriptions.

The following guidelines should be followed while issuing notifications and linking of health records:

- 1. HIPs are encouraged to share a **digital** copy of any report that they share as a **printed and/or written** report with patients. This includes diagnostic reports, discharge summaries, OPD notes, prescriptions, etc.
- 2. If the HIP has collected and verified a ABHA Address from the patient, the HIP must use the HIP initiated linking method to link the 'care context' with the associated HIE-CM. The HIE-CM will notify the patient that a new health record is available and allow the patients to access the same on their mobile using PHR Application.
- 3. If the HIP does not have a verified ABHA Address of the patient but has captured their mobile number during the registration, the HIP must notify ABDM that a new record is now available. ABDM will send a SMS to the patient containing a link for generating the same to the patient. The content of the SMS will educate the patient that they can access their health records from the healthcare provider. The patient will be able to select and download any PHR application of their choice from the marketplace.

4.4 Format of health records to be shared

ABDM's approach is to ensure that the health data can be shared in both human readable and machine-readable formats while it works with the ecosystem for stronger adoption of eHealth standards. The general approach is to create a solution which operates on a set of standards, be it the data construct, interoperability standards and the standard medical terminologies. The set of clinical documents (as available on NRCeS website https://nrces.in/ndhm) will be used as minimum standards. HIPs are expected to visit NRCeS resources and Implementation Guide for ABDM and to build their solution accordingly as per the health data and exchange standards as available on NRCeS website. NRCeS is a single point of contact for assistance in developing, implementing, and using health data standards in India.

As mentioned in the Implementation Guide, the health data interchange standards support sharing of information in one of the following ways:

- Simple text- based format
- Simple structure with attachments like PDF, JPEG, MPEG etc.
- Fully structured format with use of standard terminology code sets like SNOMED-CT, LOINC, ICD-11 etc.

The following guidelines have been adopted for the design of the health data interchange specifications:

- 1. All health records will use FHIR R4 resource bundles that have been profiled for the Indian context in collaboration with National Resource Centre for EHR Standards (NRCeS) (available at https://www.nrces.in/ndhm).
- 2. The health data interchange standards cover the following document types:
 - a) **Diagnostic reports** Formats are available for both pathology and radiology reports. While the format allows for existing PDFs / images to be attached, we encourage HIPs to move to a strongly

coded format over time. Full DICOM images (Imaging studies) are not yet supported and standards for the same will be released in the later versions.

- b) **Discharge summary** For recording of the final discharge summary for all inpatients.
- c) **Prescriptions** The OPD prescription or Discharge Prescription can be shared in a semi-structured format with adoption of SNOMED-CT to capture the medication names. There is an option to attach a PDF version of the prescription as well.
- d) **OPD Consultation Note** The consultation notes given to a patient at the end of the OPD encounter. The health data interchange standard provides a semi-structured, free text version and attachment options for sharing this document.
- e) **Immunization Records -** Immunization Record covers one or more Immunization doses taken in a visit by a patient. The details of the next immunization to be taken will also be covered based on the Immunization Recommendation issued by NHA.
- f) **Health Document Records** This format is recommended only for user uploaded records where the specific type of document may not be known. Users uploading historical records can use this type when they add scanned documents to their PHR App.
- g) **Wellness Records** These are used to record details of daily observations such as vital signs, body measurements, physical activities, etc. collected via various healthcare devices by a patient or a healthcare provider.

NRCES and ABDM will evaluate need for additional document types and resources on a regular basis. If there are specific types of documents that are currently not covered or areas that require more attention, please write to the ABDM team. Contact details are available at https://sandbox.abdm.gov.in/

Health Repository Provider Guidelines Aurora service providers who offer

Health Repository Providers (HRPs) are software service providers who offer ABDM compliant software and long-term storage of health records to HIPs. HRPs are required to fully comply with all the guidelines issued for HIPs by NHA. Their primary role is to enable HIPs to meet their obligations of sharing and securely maintaining health records of patients digitally. For example, a hosted Lab Information Management System (LIMS) provider may update their software to become an ABDM compatible HRP. Any lab using this LIMS software can rapidly become a HIP by adopting the software.

The following guidelines are applicable to such HRPs:

- a) The HDM Policy issued by NHA, outlines data fiduciary as an entity who determines the purpose and means of processing personal data. These would include HIPs and HIUs. The HRPs will assist the healthcare providers to meet their obligations under the HDM Policy.
- b) The HRPs must integrate themselves with ABDM. An access key is issued once they make their software compliant with ABDM specifications.
- c) HRPs must provide long term storage of health records in compliance with the applicable Health Data Retention Policy/Guidelines and also offer high availability (uptime) of the HIP service.
- d) Large healthcare providers and public health programs can play both the role of an HIP and HRP. For example, the e-Hospital software from NIC would enable one or more district hospitals and also maintain all the health records created at the hospital for several years. Similarly, the RCH program would maintain the immunization records of children as a HIP / HRP for several years.
- e) HIPs / HRPs are expected to store digital records of healthcare interventions including inpatient and out-patient treatments in a long-term storage and make them accessible to the health information provider service. HRPs are expected to use storage optimization techniques that provide high efficiency. Large format files like CT scans / MRIs are expected to be available for a reasonable period allowing individuals to download and store the records. Users are expected to download and save their data in their personal PHR App. For these diagnostic reports, the HIP / HRP is expected to store the radiologist opinion and relevant diagnostic images that constitute the usual printed radiology report provided to the patient, for long duration
- f) There will be several scenarios when a HIP / HRP may not be able to continue to retain the health data of the patients anymore, for example, when an HIP or HRP decides to stop providing the health services. Such HRPs will need to ensure that they comply with the data migration guidelines to be issued by NHA to avoid any adverse impact on the patient's data.

6 Health Information User Guidelines

Any entity that would like to access health records of a patient is called a Health Information User (HIU). This would include hospitals / doctors who would like to access medical history of patients, mobile applications or portals that want to display health data to patients including Personal Health Record (PHR) applications etc. The following guidelines are applicable to such HIUs:

- 1. Any entity that wants to become an HIU will need to register with ABDM and obtain the access key.
- 2. No records will be accessible to HIUs without the consent of the patient. Consent in ABDM is based on the MeITY consent framework (http://dla.gov.in/sites/default/files/pdf/MeitY-Consent-Tech-Framework%20v1.1.pdf). A digital consent artefact defining the purpose of using the data, the duration for which data will be available and document to the HIU is created each time the health records are shared. Users can provide and manage consents from their PHR App (e.g. ABHA App).
- 3. Consents can be revoked. Patient can revoke their consent or refuse access to information at any given point they desire. HIUs implementation will require certification to ensure that they adhere to the rules of the consent artefact.
- 4. Consents granted / revoked are stored on the HIE-CM. PHR Apps can provide front ends for HIE-CMs and enable their users to manage consents from their smartphone PHR app.
- 5. Any health data that is held by an HIU is bound by the data rules set in the consent artefact provided along with the data. The consent artefact provides for copyrights included and the period for which the data can be retained by the HIU. Patients have the right to revoke their consent any time.
- 6. NHA may publish guidelines from time to time on the purposes for which consent can be sought by various stakeholders. All HIUs must ensure that the consent requests for the individuals generated by them adhere to policies/guidelines issued by NHA.
- 7. HIUs need to correctly handle variations of the health record formats as per the ABDM Health Data interchange specifications. The specifications allow Simple text- based format, Simple structure with attachments such as PDF, JPEG & MPEG and Fully structured format with use of standard terminology code sets such as SNOMED-CT, LOINC and ICD-11 for sharing of information. The specifications are published at https://www.nrces.in/ndhm
- 8. Any health records obtained by the HIU needs to be stored and managed securely in accordance with Health Data Retention Policy/guidelines, Health Data Management (HDM) policy and Information Security Policy (ISP) for external ecosystem.

Personal Health Record App Guidelines

PHR Apps are software service providers which offer front ends to Individuals and enable them to create a ABHA address, discover & link health records from various HIPs, allow users to view their records, offer long term storage of records, upload users health records and share records on the ABDM network. Every PHR App works closely with one HIE-CM. PHR Apps provide a front end for HIE-CM actions like viewing and granting consents. The specifications are published at the ABDM Sandbox website, available at https://sandbox.abdm.gov.in/docs/build_PHR_App.

PHR Apps are treated as separate entities as they behave like HIUs (for viewing/storing the records), HRP (storing records) and HIPs (sharing of records). PHR Apps need to implement the following additional guidelines:

- 1. Any entity that wants to become a PHR App will need to register with ABDM and obtain the access key.
- 2. PHR Apps need to obtain the following permissions from the user-
 - A consent artefact from the user that allows the PHR App to obtain a copy of the health record of the user from any HIP. PHR Apps can setup an auto approval policy for such consents with the HIE-CM.
 - Subscribe for notifications for new care contexts, new data or new consent / subscription requests.
 - Obtain an authorization to upload any user provided data.
- 3. All health records in the PHR App needs to be stored and managed securely in accordance with ABDM Health Data Management policy and Information Security Policy for external ecosystem.
- 4. PHR Apps need to implement the HIP service to allow sharing of records on the ABDM network with appropriate user consent. The guidelines related to the HIP service including support for standards and uptime of services must be followed.

8 ABDM Sandbox

The ABDM sandbox is the starting point for software developers who wish to ensure their healthcare software is compliant to the HIP, HRP, HIU and PHR App guidelines.

- 1. Access to the Sandbox and its APIs is open to everyone under the ABDM Sandbox policy. Just sign up at Error! Hyperlink reference not valid to obtain access.
- 2. The Sandbox hosts the following digital building blocks:
 - a) ABHA number Service and APIs Create a sandbox ABHA number, ABHA Address, integrate your software with the ABHA number APIs.
 - b) HIE-CM Register your software as a HIP, HRP, HIU or PHR App and ensure you are able to correctly link records, process consent requests.
 - c) Sandbox ABHA Mobile Application for Android Use the application to manage your ABHA, view health records and manage consents.
 - d) Sandbox HIU application to create consent requests for a ABHA Address.
 - e) Sandbox EMR Application to register a ABHA Address and issue health records
 - f) Sandbox HPR and APIs to register and verify doctors.
 - g) Sandbox HFR and APIs to register and verify facilities.
- 3. Documentation will be available on all the open APIs hosted in the Sandbox.
- 4. Discussion forum is accessible to developers where the ABDM team will answer technical queries and support implementers in the process.
- 5. ABDM test harnesses that will allow developers to check their implementation against the Open APIs and then apply for certification.
- 6. Once a software system has been integrated and tested in the Sandbox, it can apply for ABDM compliance certification. ABDM will notify the agencies who are empaneled to certify the software as compliant to ABDM requirements. This is required to ensure correct capture and linking of ABHA Address, secure storage of health data, use of standards in data exchange etc.
- 7. Access keys to ABDM production systems will be issued only post verification of the entity in the ABDM Registry and software being certified. This ensures only valid healthcare facilities and compliant software can participate in the ABDM ecosystem.