

Consultation Paper on Health Data Retention Policy

Synopsis:

The National Health Authority (NHA), on 23rd November 2021 published a consultation paper to invite comments on the various aspects of Health Data Retention Policy (HDRP) of medical records. HDRP is proposed to be a critical link facilitating the entire Health Data Management policy, with respect to health data storage. It is envisioned to retain, protect, and safeguard the medical health records of participating individuals in ABDM environment. Details of ABDM are available on <https://abdm.gov.in>

The complete text of the consultation paper can be downloaded from:

https://abdm.gov.in/assets/uploads/consultation_papersDocs/Consultation_Paper_on_Health_Data_Retention_Policy_21.pdf

This document is primarily intended to provide an overview and summary of the key concepts and issues raised in the consultation paper.

1. Objective:

The key objective of the consultation paper is to elicit feedback from the public and concerned stakeholders on the functional, legal, and technical aspects of data retention of medical health records, to ensure that the medical health records are retained in a safe and secure manner thus ensuring data privacy and safety of participating individuals and related healthcare ecosystem players in ABDM environment

2. Scope:

This consultation paper is restricted to the proposed Health Data Retention Guidelines/Policy of the Ayushman Bharat Digital Mission (ABDM). It describes NHA's current approach related to data retention, and how a health data retention policy for ABDM stakeholders will help the healthcare ecosystem, importantly, the Health Data Retention Policy is prospective, not retrospective.

3. Importance of Health Data Retention:

Healthcare organizations establish appropriate retention, archival and destruction schedules, to ensure timely availability of relevant data related to patient care, supported by robust life cycle of records management, which begins when information is created and ends when information is archived/destroyed. This ensures that patient diagnosis, prognosis, and health profiles are available for longer period, throughout patient lifetime or at least until completion of ongoing care delivery. These organizations, hence, need a directive via necessary policies governing their practice of data retention. In pursuance to the aforesaid, the consultation paper describes the requirement and specifications for data retention guideline.

4. Existing Guidelines for Health Data Retention in India:

Patient health information is defined as 'Sensitive Data' under the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, but no guideline on retention schedule exists. In the absence of any superseding legislations or policies defined

on health data retention in the country, many healthcare providers currently comply with self-prescribed standards applicable to their organization for storing, retaining, and maintaining applicable health records, which may cover compliance requirements per state, central or accreditation guidelines. The MoHFW (Ministry of Health and Family Welfare) had notified the EHR Standards 2013 (revised in 2016), which are applicable for all Healthcare Providers, such that all electronic records must compulsorily be preserved and never destroyed during the lifetime of the person. With regards to ABDM, these standards could be adopted as a foundation for a policy on data retention, while considering a broader framework for the entire healthcare ecosystem. With reference to the Indian HealthCare regulations, the consultation paper hence describes a few other guidelines/policies that exist in this regard.

5. Relevance With ABDM:

As per the National Digital Health Blueprint, 2019 (“Blueprint”) a federated architecture shall be adopted, for the management of digital health data to ensure interoperability across the National Digital Health Ecosystem.

- **Generation and Exchange of Health Records:**
 - Patient health data relating to an encounter or a set of encounters, is generated and maintained at the facility level (at the Point of Care) and would not be stored centrally. The current ABDM building blocks have been built with the primary goal of ensuring seamless interoperability of health-related data. Stakeholders in the ecosystem may use the ABDM APIs to access, share, and verify health records, healthcare professionals, and healthcare facilities
- **HIP/HIU Guidelines:**
 - The HIP/HIU guidelines suggest that a healthcare provider who is creating health data (diagnostic reports, discharge summaries, prescriptions, etc.) digitally should be able to share these records with the patients, fetch records issued by other providers with patient’s consent. To enable this, the hospital or the lab information management system need to be ABDM compliant and will be required to modify and integrate their systems with ABDM building blocks and maintain health records of patients digitally to offer long term storage of health records on behalf of an HIP
- **Health Data Management Policy:**
 - ABDM has published the Health Data Management Policy (HDMP), and as per clause 6, it is required that a data retention policy is to be notified with adequate representation from all stakeholders involved in implementation of the ABDM. Clauses 14, 16.2, 19.2, 22.2 of Health Data Management Policy necessitates notification of a data retention policy. As per clause 26.6 any personal data collected will not be retained beyond the period necessary to satisfy the purpose for which it is collected, and the data fiduciary will delete such personal data at the end of such processing in accordance with Clause 14 of HDMP as well as any guidelines relating to data retention and archival that may be notified from time to time.

6. Stakeholders:

Option 1: Entire Healthcare Ecosystem in India

In this option, the policy scope shall include all healthcare facilities and associated entities in India who will adopt the data retention guidelines as defined, irrespective of their decision to opt-in or opt-out of NDHE. Several entities who may not be covered, or those who may decide to opt out of the NDHE, including insurance providers, third-party administrators (TPA) offering individual and group insurance schemes, providers of open API systems, private PHR apps, teleconsultation platforms, data processors etc., will also be required to ensure that data retention guidelines are followed.

Option 2: Healthcare entities opting-in for ABDM.

In this option, the policy shall be applicable to only the health facilities and other entities opting in for ABDM. Any hospital, diagnostic center, clinic, public health program, etc. creating digital health records for patients can become an HIP or an HIU by signing up with the ABDM registries. 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 and the policy will be applicable for all types of health records generated via associated IDs pertaining to an individual. The entities operating as part of ABDM, shall be responsible for ensuring that records are retained as per the predefined period under this policy.

For either options, the policy would be applicable for all health records generated by the entities. However, to ensure that the policy is adopted, regulatory and legal considerations shall be required. The details for both the options have been discussed in the consultation paper.

7. Key Elements of Health Data Retention:

The consultation paper will consider two critical elements of data retention, i.e. ***duration of retention and data classification***, to understand if different duration periods should be defined for different types of health records.

As retention schedules for very complex classification can be time consuming and resource intensive, it is important to evaluate the ideal minimum duration for each type of health data. Thus, the consultation paper is focused on the benefits of short-term vs long-term duration, types of health data collected and international comparison of data type as applicable to evaluate and arrive at a proposed policy with retention schedules for each type of health data.

8. Anonymization and Pseudonymisation:

The consultation paper also describes about alternatives like anonymisation and pseudonymisation which can be used instead of data deletion. For anonymised data, possibility of re-identification is comparatively less whereas pseudonymized data still allows re-identification. Hence considering this aspect, the data retention period for anonymised /pseudonymized data can be longer than the original data.

9. Country Comparison on Data Retention:

The consultation paper also describes, how the data retention policies of countries like Canada, United States, United Kingdom etc. vary. A single or a standardized retention schedule does not exist, and healthcare entities or health service providers in these countries must follow both federal- and state-specific retention requirements, as well as rules applicable to them from other laws or acts.

10. Use cases as per requirement of the health record in India.

As observed across facilities in India, the predominant purpose of longer-term data retention is to facilitate the below specific use cases:

- Insurance requirements as specified by IRDA
- Clinical trials
- Medico-legal cases where records maybe kept for up to 10 years or until the case has been closed

11. Key Issues for Consultation

The consultation paper describes, in detail, all aspects of the proposed Health Data Retention Policy. Consultation is sought in on all proposed concepts including, but not limited to scope and feasibility of applicability of the guideline or policy, granularity of classification, duration of retention, mode of retention and governance approach Please note that this paper is only a summary paper. All stakeholders are requested to please read the full text of the consultation paper here_____ for further clarity.

[Disclaimer](#)

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