

Submission to the Public Consultation on NHA Data Sharing Guidelines for PM-JAY

IT for Change

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We welcome the National Health Authority's (NHA's) attempt to evolve [data sharing guidelines](#) for beneficiary data under the Prime Minister Jan Arogya Yojana (PM-JAY) in consultation with civil society and members of the wider public. In the current paradigm, with the increasing datafication of health services, an effective health data governance framework is essential to maximize the public value of health data by enabling the secondary use of aggregate health data for social interest innovation without compromising individual and collective privacy.

From this standpoint, we make the following inputs to the consultation on the draft shared on July 20th by the NHA:

1. For the PM - JAY, the personal data collected by the NHA includes socio-demographic personal identifiers of beneficiaries, proof of address information, health information, and bank account details. The data sharing guidelines attempt to provide some safeguards for privacy rights of beneficiaries.

Section 7 specifies that health data exchange of such beneficiary data in the NHA ecosystem must adhere to 'privacy by design' principles. Section 9.5 lays down a range of data rights of beneficiaries that the NHA must protect in data sharing arrangements. Section 9.8.2 states that "any health data under these Guidelines, whether identifiable or anonymized, shall not be accessed, used or disclosed to any person for any commercial purpose and in no circumstances be accessed, used or disclosed to insurance companies, employers, human resource consultants and pharmaceutical companies, or any other entity as may be specified by the Central Government." However, in the absence of a personal data protection legislation at the national level, the enforceability of these privacy and personal data protection safeguards will be a major challenge. This concern assumes gravity as the draft National Health Data Management Policy shared by the NHA in the public domain does not have sufficiently robust guardrails to protect citizens from discriminatory profiling and data breaches in downstream processing, as civil society organizations including IT for Change have [highlighted](#) in earlier public consultations.

2. The focus of the draft data sharing guidelines is on making anonymized data collected by the NHA and its ecosystem partners in the course of PM-JAY implementation available for the following purposes: improving public health activities and emergency response; facilitating health and

clinical research, chronic disease management, public health research, public health policy formulation, and undertaking academic research and other public purposes (Section 9.6.5). While a wide array of primary and secondary uses of health data are recognized, our contention is that the granular checks and balances for addressing the twin concerns of privacy and health equity essential for expanding the secondary uses of health data in public interest are not sufficiently spelled out.

A leaf needs to be taken out of the proposed European health data space regulation in this regard, with respect to the following:

- (a) Comprehensive listing of the categories of health data to be made available for secondary use, drawing upon Article 33(1) of the draft European health data space regulation.
- (b) Ensuring that "*cooperation rules for data altruism in health and complementarity on access to private data for secondary use*" are not impeded because of intellectual property and trade secrets of private enterprises. This is a costly omission as it could potentially mean that private healthcare providers empaneled under the PM-JAY can refuse to share health information of PM-JAY beneficiaries for non-commercial secondary use by claiming IP rights in health records they hold. Article 33 (4) of the draft European legislation attempts this balancing act by making it clear that "*Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken*" through mediation by a public sector body set up for this purpose — a 'Health Data Access Body' governing secondary use of electronic health data.
- (c) For balancing privacy and protection from harm of data subjects with the public interest imperative to expand secondary uses of aggregate health data for public interest research and innovation, a dedicated legislative instrument is essential. A mere policy guideline cannot succeed in providing the necessary rights guarantees and institutional safeguards. We would recommend that the NHA consider the development of a pan-Indian common health data space legislation, backed by a legislation modelled on the [EU's draft health data space regulation](#) that will govern health data exchange across the National Digital Health Ecosystem of the Ayushman Bharat Digital Mission.