F.No Z-18015/10/2013-eGov
Government of India
Ministry of Health & Family Welfare
(e-Governance Division)
***

New Delhi, dated the 16th March, 2015

NOTICE

Subject: **Placing the Concept Note on National e-Health Authority (NeHA) on public domain for comments/views-reg.**

Ministry of Health and Family Welfare proposes to set up a National e-Health Authority (NeHA) responsible for development of an Integrated Health Information System in India. It will also be responsible for enforcing the laws & regulations relating to the privacy and security of the patients health information & records. Accordingly, a Concept Note on establishment of NeHA has been placed in public domain with a view to elicit comments/views of the stakeholders including the general public.

The comments/views may be forwarded to Director (e-Governance Division), Ministry of Health and Family Welfare, Room No 307-D, Nirman Bhawan, New Delhi-110108 or emailed at jitendra.arora@gov.in **on or before 20th April, 2015**.

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National eHealth Authority (NeHA)

Executive Summary

This note brings out relevance and importance of the proposed National eHealth Authority (NeHA) as a promotional, regulatory and standards setting organization to guide and support India's journey in e-Health and consequent realization of benefits of ICT intervention in Health sector in an orderly way. It also spells out the proposed functions and governance mechanism of NeHA. These draw from earlier recommendations of high level bodies in India as also global experience.

It is also strongly recommended that NeHA be created at the earliest, as it will give a fillip to all the current and envisaged programs of the government in respect of IT in Health and accelerated adoption of EHR in an orderly manner. It will also help avoid problems arising out of uncoordinated induction of IT systems in hospitals and public health systems which will become inevitable with the passage of time in the absence of a suitable authority to guide and enforce orderly evolution.

1. Background

1.1 Indian Health Care System

The Indian health care system is one of India's largest and most complex sectors. It delivers services to a diverse population of approximately 1.24 billion across a wide range of geographic and socioeconomic settings. Services are provided by a complex network of public and private care providers, ranging from a single doctor rural PHCs (Primary Health Centres) to specialty and super-specialty health care institutions like the medical college hospitals in the public sector

and from a single doctor outpatient clinic to large trust or corporate hospitals and third party providers in the private sector.

India spends around 4.1% of GDP on health, of which only about 1.1% is the contribution of the government. Out of pocket expenses are high at over 60%, much higher than most of the countries in the world. Given that India today enjoys a demographic dividend which can contribute to the productivity and prosperity of the nation, the healthcare system is specially and fundamentally important to the country from both an economic and social perspective. A health population underpins strong economic growth, community well-being and prosperity.

India's disease burden

Due to the size of the population, high percentage of rural population (32% urban versus 68% rural) with rapidly growing urbanization, industrialization, environmental degradation and the persisting inequality in health status between and within States/UTs, India currently faces a "Triple burden of diseases", namely:

1. Unfinished agenda of Communicable Diseases
2. Emerging Non-Communicable Diseases related to lifestyles and
3. Emerging Infectious Diseases

Life expectancy at birth stands at 66 (both sexes), Infant mortality rate at 43.8, Under-5 mortality rate at 56 (both per 1000 live births), Maternal mortality ratio at 190 (per 100,000 live births), Total fertility rate at 2.5 and Adult Mortality rate (probability of dying between 15 and 60 years per 1000 population) at 242/160 (m/f). Prevalence of HIV has come down to 169, Incidence of Malaria to 1523 and Tuberculosis to 230 – all per 100,000 of population. In terms of mortality, (% of total deaths, all ages, both sexes), deaths due to communicable, maternal, perinatal and nutritional conditions account for 28%, Injuries 12% and Non-Communicable Deaths (NCDs) account for 60% (with a distribution of

Cardiovascular diseases 26%, Cancers 7%, Chronic respiratory diseases 13%, Diabetes 2% and other NCDs 12%).

WHO Disease and Injury Country estimates indicate that 22,750 to 29,500 life-years are lost in India out of 100,000 life-years due to any cause; of this NCDs account for 43% of the DALYs (Disability-Adjusted Life Year).

In terms of utilization of health services, Contraceptive prevalence was at 55%, Antenatal care (4+ visits) at 50%, Birth attended by skilled health personnel at 67%, Measles immunization (1-yr olds) at 74% and Smear-positive TB treatment-success at 88%.
However, adult risk factors remain high on account of Tobacco use (aged 15+) for males at 25% (2011), Raised blood pressure (aged 25+) at 23.1 (2008) and Raised blood glucose (aged 25+) at 11.1 (2008). Further, while percentage of population using improved water has risen to ~95%, the situation remains poor in respect of using improved sanitation at less than 40%.

Against the above challenges, Indian healthcare system suffers from acute shortage of physicians and quality paramedics; per 10,000 population, doctors are at 7 and Nurses and midwives at 17.1, much below WHO recommended numbers. The situation is much worse in rural areas. Technology can play an enabling role in addressing the issue of absence of qualified service delivery personnel in remote areas, in improving the efficiency of the healthcare system and also in improving the quality of care.

This will require a fundamental shift in the way information is accessed and shared across the health system. We have to move away from a reliance on tools such as pen, paper and human memory to an environment where beneficiaries, providers and health care managers / administrators can reliably and securely access and share health

information in real time across geographic and health sector boundaries. The only way this can be achieved is through the implementation of world class ICT interventions and adoption of e-Health.

1.2 Use of ICT in the Indian Healthcare System

One of the major challenges faced by a patient in India today is that, whenever he visits any healthcare provider he is examined, typically undergoes a certain number of tests and the care provider initiates a treatment plan for his/her condition. If there is a subsequent need to visit another healthcare provider either within the same care setting or, as is more often than not, a different one, he/she is likely to undergo the same process of repeating examination, testing and treatment unless and until he carries around his medical records diligently irrespective of its size or form.

Over a period, many of the public and private hospitals have developed their own healthcare systems or hospital information systems that have served patients well, but without a focus on standards adoption, or the interoperability aspect and interconnection of systems across hospital settings that can lead to continuity of care – leading to ineffective results. Such non-interoperable discrete islands of information have created significant barriers to the effective sharing of information between healthcare participants, an issue compounded by India's multiple health service boundaries and geographic distances. It also poses real challenges when trying to understand and report what is really happening in the Indian healthcare system to support population health surveillance and guide policy, service planning, innovation and clinician and operational decision making.

With vendors incorporating different standards for similar or same systems, it is little wonder that inefficiency, waste and errors in healthcare information and delivery management are all too commonplace an occurrence. Consequently, a patient's health information often gets trapped in silos of legacy systems, unable to be shared with members of the healthcare community.

1.3 Complexities associated with the present eHealth system

Current eHealth IT systems in India are riddled with multiple complexities, largely arising out of compartmentalized approach to development of the ecosystem by various stakeholders, as opposed to a coordinated or integrated approach. The consequences of these include: Legacy systems, silos of data and multiple incompatible standards (arising partly out of lack of national standards until recently for IT and health informatics as well as those for reporting, identity and the like); poor or modest penetration of Hospital Information Systems; lack of demand and regulation for integration or exchange of EHRs across providers; challenges from vendors in terms of support to integration and easy to use interfaces; lack of focus on patient services and patient engagement; non-availability of Minimum Data Sets (MDS) and EHRs; and shortage of funding for sustainability – to name a few.

For building an interconnected e-Health system across public and private hospitals within a state or nationally, it is imperative that they should have consistent standards for identity management, data entry, messaging, data encryption, retrieval, reporting etc.

Doctors and other service providers will have to adjust their work flow in order to incorporate EHR use, and also to use the information gained for

continuous improvement of their health care delivery. They may not also be organized in a standardized / systematic way - either in the way they report / analyze the data but need to do so progressively.

To encourage standardization, integration and exchange of electronic information amongst the various healthcare providers and recognizing that the electronic collection, storage, processing and transmission of personal health data requires adherence to the highest standard of data protection, the “EMR/EHR Standards for India” were formulated after extensive discussion with all the stake holders and thereafter notified by the Government of India in September, 2013. India has also become a member of International Health Terminology Standards Development Organisation (IHTSDO) since April, 2014 to support affordable and consistent use of vocabularies through Systematized Nomenclature of Medicine Clinical terms (SNOMED-CT) by all care providers.

What is required at this stage is an institutional mechanism to guide early adoption of the EHR and SNOMED-CT standards by all care-providers as independent and continued deployment of a lot of non-conformant systems by public and private healthcare providers in states and centre can lead to an avoidable and costly situation from which putting together national e-Health system can be extremely cumbersome, time-consuming and expensive, as the experience of many countries has demonstrated.

1.4 Benefits of Electronic Health Record (EHR)

EHR and the ability to exchange health information electronically can help the providers to extend higher quality and safer care for patients while creating tangible enhancements in the efficiency of operations of

their organization. EHRs helps providers to: better manage care for patients by providing accurate, up-to-date, and complete information about patients at the point of care; access patient records quickly for more coordinated, efficient care; share electronic information securely with patients and other clinicians; diagnose patients more effectively, reduce medical errors and provide safer care; prescribe more reliably and safer; promote legible, complete documentation and accurate, streamlined coding and billing; improve productivity and work-life balance; and reduce costs through decreased paperwork, improved safety, reduced duplication of testing, and improved health.

Critical issues in implementing EHR include: the need to streamline the processes and workflows relating to administrative and clinical functions; the need to build capacities of providers and management in introduction, operation, management and use of Hospital Information Systems meaningfully by support to various administrative and clinical functions through standards compliant EMR/EHR; the need to handle change management issues arising out of the above; and the need to ensure compliance to security, privacy and confidentiality as prescribed in standards and guidelines so that legal, audit guidelines are met and citizen and provider interests are protected.

Given constraints of resources, there are compelling benefits, outcomes and impacts of e-Health that India can ill-afford to forego in improving healthcare delivery to citizens. Notable among them include:

a. Improved timeliness (better quality of healthcare delivery)
b. Effectiveness (right intervention / audit trails for adverse events)
c. Efficiency (less resources in terms of manpower, time and cost)
d. Informed patients and their caregivers
e. Better access

Additional and specific benefits of e-Health include: diagnostic accuracy, reduced waiting times, better referral management and greater satisfaction with services.

Given the growing penetration of mobile phones and Internet, including smartphones and tablets, other services that can be delivered on a large scale include: SMS-based services, live and asynchronous telemedicine, and interactive voice response service (IVRS).

1.5 International Experience

Roll-out of national e-Health systems, interconnecting EHR with unique identifiers for citizens and providers has been progressively undertaken by various countries.

Canada was one of the earliest to start in 2002, setting up Canada Health Infoway as a federally funded, independent, not-for-profit organization to lead the development and implementation of electronic health projects across Canada. It has been working with provinces and territories to invest in electronic health projects to support safer, more efficient healthcare delivery. It targets to respect patient confidentiality fully and provide private and secure systems to healthcare professionals with immediate access to complete and accurate patient information, enabling better decisions about diagnosis and treatment. Government of Canada provides supporting funding and sets national priorities through Canada Health Infoway. In many ways, it has been a pioneer in nationwide EHR system and standards.

U.K., Australia and Singapore have been other prominent countries who have taken initiatives for setting up nationwide e-Health since then.

In U.K., NHS is the provider of healthcare services for all and is funded through general taxation. Department of Health is responsible for national plans. National Program for IT (NPfIT) has been put in place to provide the information infrastructure. After some early hiccups, U.K. has progressed in terms of creating NHS Care Records Service (NHS CRS) to improve the sharing of records of consenting patients across the NHS, providing patients access to their own records, providing a system for electronic transmission of prescriptions, creating a Picture Archiving and Communication System, ensuring a secure broadband network infrastructure to connect all NHS bodies in England, making it easier and faster for GPs and other primary care staff to book hospital appointments for patients and the like. NHS Information Centre is an independent NHS Special Health Authority that collects analyses and distributes national statistics on health and social care. It therefore has a key role in defining NHS data standards.

In Australia, National e-Health Transition Authority (NEHTA) is a not-for-profit company set up by Federal, State and Territory governments to develop better ways of electronically collecting and securely exchanging health information. NEHTA is in a unique position to influence key e-Health policy and regulation. It supports Australian healthcare system by improving the quality of healthcare services, by enabling authorized clinicians to access a patient's integrated healthcare information and history, directly sourced from clinical notes, test results and prescriptions using standardized clinical data formats and terminologies; streamlining multi-disciplinary care management, enabling seamless handovers of care by ensuring efficient electronic referrals; improving clinical and administrative efficiency, by standardizing certain types of healthcare information to be recorded in e-Health systems; maintaining high standards of patient privacy and information security and the like.

In Singapore, the National e-Policy to promote the use of ICT across all sectors has been extremely effective, as has been the public funding for ICT support of programs addressing national health priorities. Regulations to protect the privacy and security of individual patient data where e-Health is used are rated as very effective. Four Singapore public hospitals had been awarded the Stage 6 benchmark of U.S. Healthcare Information and Management Systems Society (HIMSS) for adopting EHR systems among the very first implementations in Asia. Singapore has progressed from hospital department systems to integrated electronic orders processing, on-line radiology imaging, closed loop medication management, timely laboratory receivables and analysis results and ultimately facilitating good clinical decision support and data integration.

In United States of America, Office of National Coordinator for Health Information Technology (ONC) was created in 2004 but with the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, it has been charged with building an interoperable, private and secure nationwide health information system and supporting the widespread and meaningful use of health information technology. ONC is a staff division of the Office of the Secretary within the U.S. Department of Health and Human Services. ONC leads national health IT efforts, charged as the principal federal entity to coordinate nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information.

HITECH act seeks to improve American healthcare through an unprecedented investment in health information technology. They are specifically designed to work together to provide the necessary assistance and technical support to providers, enable coordination and alignment within and among states, establish connectivity to the public health community in case of emergencies and ensure that the workforce

is properly trained and equipped to be meaningful users of EHRs. The Act sets meaningful use of interoperable EHR adoption in the healthcare system as a critical national goal and incentivize EHR adoption. ONC works to improve Adoption, Standards, Incentive, Privacy and security and Governance. The Federal Health IT Strategic Plan 2011-'15 has set the goals for use of health IT as: adoption and information exchange through meaningful use; improving care, improve public health and reduce healthcare costs; inspire confidence and trust in use of health IT; empower individuals to improve their health and healthcare system; and achieve rapid learning and technological advancement.

There are over thirty other countries who are building up valuable experiences in nationwide e-Health adoption, though none has truly completed the full scale adoption. ITU included adoption of e-Health as a strategic priority from 2008 onwards.

1.6 Background for setting up NeHA

The National Knowledge Commission (NKC) had recommended in 2008 formation of National Health Information Authority (NHIA) to support implementation on e-Health. High Level Expert Group (HLEG) set up by Planning Commission in the context of XII Plan had recommended EHR adoption and setting up of a nationwide network to support the same. They had done so as part of recommending Universal Health Coverage.

'Digital India' Program has been announced by Government of India in August 2014 and a set of on-line Healthcare services are scheduled to be offered as part of the same in a definite time-frame in the next 4-5 years.

2. National eHealth Authority (NeHA)

2.1 Mission

NeHA will be the nodal authority that will be responsible for development of an Integrated Health Information System (including Telemedicine and mHealth) in India, while collaborating with all the stakeholders, *viz*., healthcare providers, consumers, healthcare technology industries, and policymakers. It will also be responsible for enforcing the laws & regulations relating to the privacy and security of the patients health information & records.

2.2 Vision / Goals

a) To guide the adoption of e-Health solutions at various levels and areas in the country in a manner that meaningful aggregation of health and governance data and storage/exchange of electronic health records happens at various levels in a cost-effective manner

b) To facilitate integration of multiple health IT systems through health information exchanges

c) To oversee orderly evolution of state-wide and nationwide Electronic Health Record Store/Exchange System that ensures that security, confidentiality and privacy of patient data is maintained and continuity of care is ensured.

2.3 In the light of the above, National e-Health Authority (NeHA) has been envisaged to support:

a) Formulation of policies, strategies and implementation plan blue-print (National eHealth Policy / Strategy) for coordinated eHealth

adoption in the country by all players; regulation and accelerated adoption of e-health in the country by public and private care providers and other players in the ecosystem; to establish a network of different institutions to promote eHealth and Tele-medicine/remote healthcare/virtual healthcare and such other measures;

b) Formulation and management of all health informatics standards for India; Laying down data management, privacy & security policies, standards and guidelines in accordance with statutory provisions; and

c) To promote setting up of state health records repositories and health information exchanges (HIEs);

d) To deal with privacy and confidentiality aspects of Electronic Health Records (EHR).

2.4 Functions of National eHealth Authority

2.4.1 Core Functions

a. Policy and Promotion

i. Working out vision, strategy and adoption plans, with timeframes, priorities and road-map in respect of eHealth adoption by all stake-holders, both Public and Private providers, formulate policies for eHealth adoption that are best suited to Indian context and enable accelerated health outcomes in terms of access, affordability, quality and reduction in disease mortality & morbidity

ii. To engage with stakeholders through various means so that eHealth plans are adopted and other policy, regulatory and legal provisions are implemented by both the public & private sector stakeholders.

iii. It shall provide thought leadership, in the areas of eHealth and mHealth.

b. Standards Development

i. Government of India, MoHFW has published EMR/EHR standards for India in 2013. Similarly, MoHFW has become a member of IHTSDO with a view of widespread adoption of SNOMED-CT in India; MoHFW has also nominated C-DAC (Pune) as interim NRC (iNRC). As such, initial focus of NeHA would be on addressing implementation issues and promoting mechanisms in support of the same.

ii. Concurrently, NeHA will be nurtured to undertake the role of a standards development, maintenance and support agency in the area of Health Informatics

c. Legal Aspects including Regulation

i. NeHA will be setup through an appropriate legislation (Act of Parliament).It is also proposed to address the issues relating to privacy & confidentiality of Patients' EHR in the legislation. NeHA may act as an enforcement agency with suitable mandate and powers.

ii. NeHA will be responsible for enforcement of standards & ensuring security, confidentiality and privacy of patient's health information & records.

d. Setting up and Maintaining Health Repositories, Electronic Health Exchanges and National Health Information Network

NeHA, while avoiding the implementation role by itself, will prepare documents relating to architecture, standards, policies and guidelines for e-Health stores, HIEs and NHIN; it may also initiate or encourage PoCs, in close consultation with government – centre and states, industry,

implementers and users. Later, it would lay down operational guidelines and protocols, policies for sharing and exchange of data, audit guidelines and the like; these shall be guided by experience in operation and use of PoC, global best practices and consultations with stake-holders (MoHFW, State governments and other public and private providers, academia, R&D labs, and others).

e. Capacity Building

Spreading awareness on Health Informatics / eHealth to healthcare delivery professionals through various educational initiatives and flexible courses according to the background of the learners will form a component of NeHA activities, as it is seen as critical to acceleration of adoption of eHealth.

f. Other functions may be assigned to NeHA as the situation warrants.

2.5 Governance

The Authority will have a Chairman and four full time members. The tentative composition of NeHA may be as follows:

a) Chairman: An eminent person in the field of Medicine, Public Health or Judiciary

b) Three full time Members: They shall be from the following fields:- Medicine, Public Health, IT Standards, Health Economics/Management, Administration/ Finance, Legal

c) Member Secretary: Same as above but shall also discharge the role of co-ordination and effective functioning of the Authority.

Standing Consultative Committee: The Committee shall be chaired by Chairman of NeHA and, besides its four members, shall have members who represent experts and stake-holder community.

Indicative membership positions of Standing Consultative Committee are:

Ministry of Health & Family Welfare (4) {AS&DG(CGHS), AS&MD(NHM), DGHS, Mission Leader of Health MMP}, Principal Secretaries (Health)/ Mission Leaders from States(3), Expert Doctors by rotation (2), Private Healthcare providers by rotation (2), IT industry reps by rotation (2), Standards org rep (2), DeitY rep (1), DOT rep. (1), Independent Medical Practitioners by rotation (1), MCI Chairman or nominee (1), NASSCOM & NATHEALTH Presidents (2), FICCI President, ICMR DG or nominee (1), IRDA Chairman (1), Consumer Rights Activists (2 by rotation), WHO rep (1).

It shall meet once in six months or more often when considered necessary. It shall function as a two-way consultation forum between NeHA and diverse stake-holders to enable evolution of sound eHealth policies and road-map and solicit participation of all stake-holders in adoption of nationwide eHealth and Standards at various levels, in a manner that ensures benefits are realized in a phased and orderly manner that protects the interests of citizens/patients and providers.

The Authority will have powers to co-opt additional members to contribute to specialist needs and points of view. They shall be part-time members and will not have voting powers. Otherwise, they will have full authority to participate in all proceedings of the Authority. These members shall be co-opted on a one-year at a time basis to enable rotation of members and thus diversity of views to be heard.

Conclusion

Health being a state subject in India and much depends on the ability / regulatory framework enacted by the State governments, NeHA shall be created through legislation (Act of Parliament) that empowers it to take leadership and strategic role for setting directions for public and private eHealth initiatives, including electronic health records storage and health information exchange capabilities and other related health information technology efforts & regulation of the same.

NeHA shall ensure ongoing interagency cooperation – while engaging with various stakeholders through the Standing Consultative Committee and also through other means, in a structured, open and transparent manner to support successful evolution of national integrated health information system.

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