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**MINISTRY OF HEALTH**

**OFFICIAL Mexican Standard NOM-024-SSA3-2012, Electronic Health Record Information Systems. Health Information Exchange.**

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In the upper left corner, a seal with the National Coat of Arms, which reads: United Mexican States. – Ministry of Health.

GERMAN ENRIQUE FAJARDO DOLCI, Under-Secretary for Integration and Development of the Health Sector and President of the National Consultative Committee for the Standardization of Innovation, Development, Technologies and Information on Health, on the basis of the provisions set forth in Articles 39 of the Organic Law of Federal Public Administration; 4 of the Federal Law for Administrative Procedures; 3, parts II and XII, 5, 7, parts X, and 13, Section A, parts I, 45 and 47 of the General Health Law; 38, part II, 40, parts III and XI, 41, 43, 44, first paragraph, 47, part IV of the Federal Law on Metrology and Standardization; 28, 33 and 40 of the Regulation of the Federal Law on Metrology and Standardization and 8, parts V and XVI, 9, parts IV bis, XIV and 24, part IX of the Internal Regulation of the Ministry of Health, I hereby issue and order publication in the Official Journal of the Federation, of:

**OFFICIAL MEXICAN STANDARD NOM-024-SSA3-2012, ELECTRONIC HEALTH RECORD INFORMATION SYSTEMS. HEALTH INFORMATION EXCHANGE**

**WHEREAS**

On September 8, 2010 Official Mexican Standard NOM-024-SSA3-2010 was published in the Official Journal of the Federation; said NOM sets forth the functional objectives and functionalities that the products in the Electronic Medical Records Systems must comply with to ensure their interoperability, processing, interpretation, confidentiality, security, and use of the information standards and catalogues in the electronic health records, and which took effect 60 days following its publication.

Pursuant to the provisions set forth in Article 51 of the Federal Law on Metrology and Standardization, the respective National Consultative Committee for Standardization may request the office responsible for its issuance, carry out an analysis of its application, effects and compliance within a year of the aforementioned Official Mexican Standard taking effect; this, in order to determine any actions that might improve said application and whether or not any modification be warranted.

As a result of the analysis undertaken of the application, effects and compliance of Official Mexican Standard NOM-024-SSA3-2010, the Ministry of Health, through the Directorate General for Health Information, decided to modify the scope of its contents, as well as adding Article 109 bis to the General Health Law which was published on January 16, 2012 in the Official Journal of the Federation.

A detailed Conformity Assessment Procedure is required under Official Mexican Standard NOM-024-SSA3-2010 for total certification in Electronic Health Record Information Systems for Health Information Exchange.

On August 15, 2012 the Modification Project for Official Mexican Standard NOM-024-SSA3-2010 was published in the Official Journal of the Federation. Said project sets forth the functional objectives and functionalities that Electronic Medical Record System products must comply with in order to guarantee the interoperability, processing, interpretation, confidentiality and security of electronic health records, as well as their use of standards and information catalogues, and in this manner become Official Mexican Standard PROY-NOM-024-SSA3-2012, Electronic Health Record Information Systems, Health Information Exchange.

The Federal Regulatory Improvement Commission issued its Final Opinion in official correspondence COFEME 12/2497 on August 23, 2012; this opinion has the purpose of a Final Opinion with respect to the provisions of Article 69-L, paragraph two of the Federal Administrative Procedures Law concerning the draft bill titled Modification Project for Official Mexican Standard NOM-024-SSA3-2010, said NOM sets forth the functional objectives and functionalities that Electronic Medical Record System products must comply with in order to guarantee the interoperability, processing, interpretation, confidentiality and security of electronic health records, as well as their use of standards and information catalogues, and in this manner become Official Mexican Standard PROY-NOM-024-SSA3-2012, Electronic Health Record Information Systems, Health Information Exchange, in order to continue with the procedures for its publication in the Official Journal of the Federation pursuant to applicable legal provisions.

The responses to the comments received with regard to the aforementioned draft bill were previously published in the Official Journal of the Federation.

## **PREFACE**

The following entities participated in the preparation of this Official Mexican Standard:

### **MINISTRY OF HEALTH**

#### **UNDER-SECRETARIAT FOR INTEGRATION AND DEVELOPMENT OF THE HEALTH SECTOR**

Directorate General for Health Quality and Education

Directorate General for Health Planning and Development

Directorate General for Health Information

Directorate General for Performance Assessment

National Center for Technological Excellence in Health

#### **UNDER-SECRETARIAT FOR ADMINISTRATION AND FINANCE**

Directorate General for Information Technology

#### **UNDER-SECRETARIAT FOR DISEASE PREVENTION AND HEALTH PROMOTION**

National Center for Preventive Programs and Disease Control

Directorate General for Epidemiology

#### **GENERAL HEALTH COUNCIL**

NATIONAL MEDICAL ARBITRATION COMMISSION  
NATIONAL COMMISSION FOR SOCIAL HEALTH PROTECTION  
NATIONAL BIOETHICS COMMISSION  
FEDERAL COMMISSION FOR PROTECTION AGAINST HEALTH RISKS  
COORDINATING COMMISSION FOR NATIONAL HEALTH INSTITUTES AND  
HIGHLY SPECIALIZED HOSPITALS  
Directorate General for the Coordination of Federal Reference Hospitals  
HOSPITAL JUAREZ DE MEXICO  
NATIONAL INSTITUTE FOR MEDICAL SCIENCES AND NUTRITION  
NATIONAL REHABILITATION INSTITUTE  
NATIONAL PSYCHIATRY INSTITUTE  
NATIONAL POLYTECHNIC INSTITUTE  
Postgraduate and Research Studies Section of the Mechanical and Electrical Engineering  
School, Culhuacán Unit  
NATIONAL AUTONOMOUS UNIVERSITY of MEXICO  
Faculty of Medicine  
Directorate General of Computer Sciences and Information and Communication  
Technologies  
INSTITUTE FOR DECENTRALIZED PUBLIC HEALTH SERVICES IN THE STATE  
OF CAMPECHE  
FEDERAL DISTRICT HEALTH MINISTRY  
STATE OF GUANAJUATO HEALTH MINISTRY  
STATE OF GUERRERO HEALTH MINISTRY  
STATE OF JALISCO HEALTH MINISTRY  
STATE OF MEXICO HEALTH INSTITUTE  
STATE OF MORELOS HEALTH SERVICES  
STATE OF NUEVO LEON HEALTH MINISTRY  
STATE OF QUERETARO HEALTH SERVICES  
STATE OF SAN LUIS POTOSI HEALTH SERVICES  
STATE OF TLAXCALA HEALTH MINISTRY  
INSTITUTE FOR SOCIAL SECURITY AND SERVICES FOR STATE WORKERS  
Medical Directorate  
Directorate for Technology and Institutional Development  
FEDERAL INSTITUTE FOR ACCESS TO PUBLIC INFORMATION AND DATA  
PROTECTION  
MEXICAN INSTITUTE OF SOCIAL SECURITY  
Medical Benefits Directorate  
Directorate for Technology and Institutional Development  
NATIONAL INSTITUTE OF STATISTICS AND GEOGRAPHY  
PETROLEOS MEXICANOS  
Corporate Medical Services Section  
MINISTRY OF COMMUNICATIONS AND TRANSPORTATION  
Coordination of the National System e-Mexico  
MINISTRY OF PUBLIC AFFAIRS  
MINISTRY OF THE INTERIOR  
Directorate General for Population Record and Personal Identification  
NATIONAL DEFENSE MINISTRY

Directorate General for Military Health  
Directorate General for Informatic  
NAVAL MINISTRY  
Directorate General for Naval Health  
TAX ADMINISTRATION SERVICE  
General Administration for Communications and Information Technology  
NATIONAL SYSTEM FOR FAMILY DEVELOPMENT  
MEXICAN ASSOCIATION FOR MEDICAL FACULTIES AND SCHOOLS  
MEXICAN HOSPITAL ASSOCIATION  
NATIONAL PRIVATE HOSPITAL ASSOCIATION  
NATIONAL CHAMBER OF COMMERCE, SERVICES AND TOURISM OF MEXICO  
CITY  
NATIONAL NURSES ASSOCIATION  
NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY  
NATIONAL POPULATION COUNCIL  
MEXICAN HEALTH FOUNDATION  
MEXICAN PUBLIC HEALTH SOCIETY

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### **0. Introduction**

The exchange of information among Health Care Providers in our country is an essential requirement for continuity in offering health care among providers. The technological advances in medical information make it possible for Electronic Health Record Information Systems, among which are to be found the Electronic Medical Records, to exchange useful information and also take advantage of public health information, which in turn facilitates decision making in the sector.

Official Mexican Standard NOM-024-SSA3-2010 sets forth the functional objectives and functionalities that Electronic Medical Record System products must comply with in order to guarantee the interoperability, processing, interpretation, confidentiality and security of electronic health records, as well as their use of standards and information catalogues; the

standard was published in the Official Journal of the Federation on September 8th, 2010 and took effect 60 days following its publication. However, as a result of the analysis of the application, objectives and compliance with Official Mexican Standard NOM-024-SSA3-2010, the Ministry of Health, through the Directorate General for Health information, has detected the need to fully specify the standards to which Official Mexican Standard NOM-024-SSA3-2010 refers to, such as Implementation Guidelines and Terminology Catalogues. Document drafting and structure are expected to improve for ease of comprehension, interpretation, application and assessment of this Official Mexican Standard.

The objective of the NOM-024-SSA3-2010 modification is to adjust the criteria under which the exchange of information must be generated, processed, conserved, interpreted and secured among the Electronic Health Record Information Systems; these include Electronic Medical Records, as well as mechanisms for issuing technical specifications for possible exchange scenarios and for the design of this type of system.

## **1. Objective and scope of application**

- 1.1 The purpose of this Standard is to regulate the Electronic Health Record Information Systems and also establish mechanisms so Health Care Providers within the National Health System may record, exchange and consolidate information.
- 1.2 This Standard is mandatory throughout the nation for all facilities that provide medical services under the National Health System and which adopt an Electronic Health Record Information System. It is also mandatory for those persons or companies within the country's borders that own property rights, use, copyright, distribution and/or sale of said systems; both cases are subject to the terms of this Standard and applicable legal provisions.
- 1.3 This Standard applies to the Electronic Health Records Information Systems that are used interchangeably within the Public, Private and Social Sectors of the National Health System.

## **2. References**

For the correct application of this Official Mexican Standard, the following current Official Mexican Standards (or those which may substitute them) should be consulted:

- 2.1 Official Mexican Standard NOM-035-SSA3-2012, on Health Information.
- 2.2 Official Mexican Standard NOM-004-SSA3-2012, on Medical Record.
- 2.3 Official Mexican Standard NOM-017-SSA2-1994, on Epidemiological Supervision.

### 3. Definitions

For the purposes of this Official Mexican Standard, the following definitions shall apply:

**3.1 Access.** – The possibility of entering into the information stored in the Electronic Health Records Systems. The access must be limited by security mechanisms, among which is that of authentication.

**3.2 Activity.** – An action carried out on an electronic system upon providing services or supplies that directly or indirectly impact on the health of an individual or population to which it is provided.

**3.3 Manage (data).** – Administer data through its capture, maintenance, interpretation, presentation, exchange, analysis, definition and visibility.

**3.4 Reference Architecture.** – General framework of technical specifications upon which the development of Guidelines and Information Interfaces are based with the aim of ensuring their standardization.

**3.5 Normative Appendix.** – An integral part of the text of this mandatory Official Mexican Standard which contains the description of concepts, data and their interrelationship.

**3.6 Health Care.** – A set of services offered to individuals with the aim of promoting, protecting and restoring their health.

**3.7 Authenticate.** – To control entry to a system by validating the identification of a user, system or other device prior to authorizing access.

**3.8 Authorize.** – A process consisting of permitting a user, organization or device to gain entry, manipulate or obtain something from the system; generally the system's administrator, based on the institution's policies and applicable standardization, is the person who defines access to the system and its usage privileges.

**3.9 Database.** – An organized set of data belonging to single context and systematically stored for later use.

**3.10 Certification.** – The procedure which ensures that a product, process, system or service complies with Official Mexican standards.

**3.11 Certificate.** – The document whereby the Directorate General for Health Information or the Certification Body states that the Electronic Health Record Information System complies with the specifications set forth in this Official Mexican Standard and which validity is subject to its respective verification.

**3.12 Encryption.** – A process which uses an algorithm with a specific key to transform a message in such a way it is incomprehensible (or at least difficult to understand) to any person not holding the algorithm's secret access key used to be able to decrypt it.

**3.13 Unique Health Facility Code.** – A unique, sequential and non-transferable identification code that is mandatory in nature and which is assigned by the Ministry of Health, through the Directorate General for Health Information, to each public, private or social care setting (among which are medical units, laboratories, diagnostic centers, treatment centers, administrative offices, whether they be buildings or mobile units) located in the national territory, and with which everything reported by the facility is identified to each one of the National Health Information System's subsystems.

**3.14 Coded.** – A reference to vocabulary, a set of codes, databases, terminologies or catalogues.

**3.15 Component.** – An element of a system capable of operating independently but which is designed, built and operated as an integral part of the system.

**3.16 Confidentiality.** – A property through which information is not available and is not revealed to individuals, entities or processes without authorization.

**3.17 Conserve.** – To maintain systems in adequate operating conditions over time, to ensure the integrity, reliability and availability of the data and information contained in said systems.

**3.18 Access Control.** – Security mechanisms guaranteeing that the system's resources may be accessed only by authorized users, organizations and devices which meet requirements.

**3.19 Personal Data.** – Information concerning an identified or identifiable person and which may be expressed in alphanumeric, graphic, photographic, acoustic, or any other form.

**3.20 Standards.** – Documents containing the specifications and procedures for generating reliable products, services and systems. These practical documents establish a common language which defines the quality and security criteria, and set achievable goals that are subject to constant review to permit progress according to technological development. The standards can make reference to other international standards, codes, specifications or manuals, among others.

**3.21 Electronic Medical Record.** – A set of patient information stored in computer-processable form and which documents the health care provided by Health Care Professionals within a health care facility, as set forth in health care regulations. An Electronic Medical Record is managed through an Electronic Health Record Information System.

**3.22 Advanced Electronic Signature.** – A set of data and characters which have the same legal effects as the written signature, created electronically and exclusively under the control of by the signor for identification purposes, in such a way it is solely linked to the signor and the data, and which allows any ulterior modification to be detected.

**3.23 Strategic Working Group for Information Security.** – Personnel assigned by the Health Care Provider who are responsible for verifying that implementation and reviews of the Information Security Management System are carried out in order to verify compliance. Their activities must follow all legal provisions as they apply to the Health Care Provider.

**3.24 Guidelines and Forms.** – Technical health information exchange documents which are developed in the Specifications section.

**3.25 Health Level Seven International.** – An international organization which generates interoperability standards for medical information; it is more focused on the understanding and use of information than their means of transportation.

**3.26 Identify.** – A process for ensuring that a person, organization or device is who or what it says it is.

**3.27 Basic Health Information.** – Information which includes but is not limited to a) the affiliate and/or beneficiary and/or member and/or patient's full name, age, gender, address, as well as medical history, inpatient and information from the last emergency health care; and b) the infrastructure available for medical and hospital attention, as well as the installed capacity for providing medical services nation wide.

**3.28 Clinical Information.** – A patient's relevant health information or treatment that is recorded by or on behalf of a health professional. It can include patient information, as well as that of their families or environment.

**3.29 Health Information.** – Data, information, knowledge and evidence related to the generation, access, dissemination and use of personnel, services, resources, affiliates, members, beneficiaries, patients, treatments, and results within the health sector; it can include statistical, epidemiological and financial information interchangeably.

**3.30 Integrating the Healthcare Enterprise.** – An international organization of health and industry professionals focused on improving the way in which information systems share medical information. It promotes the coordinated use of proved standards for specific needs with the aim of delivering optimal patient care. As of this publication, their profiles are being used officially in several countries in Europe, Asia and America.

**3.31 Integrity.** – The property of the information referring to the fact that information contained in the systems for rendering electronic services are complete and unaltered and that they have been modified only by a trustworthy source.

**3.32 Information Exchange Interface.** – A set of protocols, standards and components that serve to exchange data among systems, regardless of the programming language or platform in which they were developed and operate.

**3.33 Interoperability.** – The capability of the systems in several organizations to interact among themselves with common and consensual objectives for mutual benefit and where the interaction implies that Health Care Providers may share information and knowledge



through the exchange of data between their respective information and communications systems technology.

**3.34 Semantic Interoperability.** – The capability to guarantee the precise meaning of information so it can be used by any system.

**3.35 Technical Interoperability.** – Technical specifications which guarantee that the technological components of the information systems are prepared for joint interaction.

**3.36 User Name.** – A set of alphanumeric characters based on the American Standard Code for Information Interchange – ASCII – with which a person would authenticate into a system.

**3.37 Certification Body.** – An accredited and approved agency, in accordance with current legal provisions which certifies that the products comply with the requirements set forth in this Official Mexican Standard.

**3.38 Patient.** – The direct beneficiary of health care.

**3.39 IHE Profile.** – A solution developed by IHE to a specific health information exchange problem based on integrating appropriate proven standards. It documents through guidelines, the actors, transactions, references to standards and design details which allow implementers to develop systems that resolve information communication problems.

**3.40 Health Care Provider.** – An individual or company from the public, private or social sector who provides health services under the terms of applicable legal health care provisions and who make up part of the National Health System.

**3.41 Health Care Professional.** – A person who practices a profession, technical activity, auxiliary or specialty in health, and who is subject to current legal provisions for the practice of said activity.

**3.42 Auditing Log.** – A chronological record of user activities on an information system which allows previous states to be faithfully reconstructed.

**3.43 Electronic Health Record.** – Structured and electronically stored data of clinical, imaging, demographic, social, financial, infrastructure and any other type of information which documents the medical care offered to an individual and/or the installed capacity in health facilities, stored in computer-processable form.

**3.44 Structured Record.** – A set of basic data organized as differentiated values with the aim of making their handling possible by both automatized and manual means within information systems.

**3.45 Security.** – The preservation of the confidentiality, integrity and availability of information; includes also other concepts such as authenticity, responsibility, non-repudiation and reliability.

**3.46 Security Information Management System.** – Part of a global management system which is based on risk analysis, establishes, implements, operates, monitors, reviews, maintains and improves information security. The management system includes an organization structure, policies, activity planning, responsibilities, procedures, processes and resources.

**3.47 Electronic Medical Record System.** – A type of Electronic Health Record Information System wherein health personnel record, annotate and certify their intervention as it relates to the patient in accordance with current legal health provisions.

**3.48 Information System.** – A set of elements which allows for process and store of information with the support of computer equipment.

**3.49 Electronic Health Record Information System.** – An information system which captures, manages and exchanges the structured and integrated information of a medical record as well as geographical, social, financial, infrastructure and information of any other type and which documents the medical care offered to an individual and/or the installed capacity within health facilities. The information generated by these latter, together with the information contained in the National Health Information System are integrated into the National Basic Health Information System.

**3.50 Health Information System.** – A set of elements, resources and people who interact under defined criteria and procedures, to systematically carry out activities related to the organization and administration of health information.

**3.51 National Health System.** – A system consisting of federal and local offices and entities of the Public Administration, companies and persons from the social and private sectors who provide health services; it includes mechanisms established for the coordination of actions and has as objective to comply with the right to health protection.

**3.52 National Health Information System.** – A system which integrates the information for elaborating national health statistics and which comprises, a) births, deaths, morbidity and disability; b) demographic, economic, social and environmental factors related to health; c) physical, human and financial resources available for health protection of the population and their use, which is administered by the Ministry of Health through the Directorate General for Health Information, under the terms of Articles 104 and 105 of the General Health Law, as well as NOM-035-SSA3-2012, on Health Information.

**3.53 National Basic Health Information System.** – A system which guarantees the exchange and analysis of health information at a national level and which structurally and systematically integrates basic health information through procedures, protocols and technological platforms. Electronic Health Record Information Systems, which include Electronic Medical Records, form part of the National Basic Health Information System. The latter is administered by the Ministry of Health, through the Directorate General for Health Information, in its capacity as coordinator for the National Health System under the terms set forth in Articles 5, 6 and 7 Part X of the current General Health Law, in addition

to the agreement for which the National System for Basic Health Information was established by the Ministry of Health in its capacity as coordinator of the National Health System and published in the Official Journal of the Federation on September 5, 2012.

**3.54 Tracking.** – A quality which allows all actions concerning information or an information treatment system be associated unequivocally to an individual or entity.

**3.55 Verification Unit.** – A Person or company which carries out verification activities in accordance with the provisions of the Federal Law on Metrology and Standardization and its Regulations which are duly accredited and approved to verify compliance with the Official Mexican Standard.

**3.56 User.** – A person authorized to access to the resources and services offered by a system.

**3.57 Verification.** – Visual evidence or proof through sampling, measuring, laboratory testing or document examination which is carried out to evaluate compliance at any given time.

**3.58 Epidemiological Supervision.** – A permanent and dynamic study of the state of health as well as its conditioners on the population.

#### **4. Abbreviations**

**4.1 ASCII.** – American Standard Code for Information Interchange.

**4.2 CEMECE.** – Mexican Center for the Classification of Diseases.

**4.3 ICD.** – International Classification of Diseases and Health-Related Problems, of the World Health Organization.

**4.4 CLUES.** – Unique Health Facility Code.

**4.5 CURP.** – Unique Population Registry Code.

**4.6 DGIS.** – Directorate General for Health Information.

**4.7 HL7.** – Health Level Seven.

**4.8 IHE.** – Integrating the Healthcare Enterprise.

**4.9 INEGI.** – National Statistics and Geography Institute.

**4.10 LFMN.** – Federal Law on Metrology and Standardization.

**4.11 LFPA.** – Federal Law for Administrative Procedures.

**4.12 LFPDPPP.** – Federal Law for the Protection of Personal Data Held by Private Parties.

**4.13 LFTAIPG.** – Federal Law for Transparency and Access to Public Government Information.

**4.14 NOM.** – Official Mexican Standard.

**4.15 RENAPO.** – National Population Registry.

**4.16 Ministry.** – Ministry of Health.

**4.17 SHCP.** – Ministry of Finance and Public Credit.

**4.18 SINAIS.** – National Health Information System.

**4.19 SNIBMS.** – National System for Basic Health Information.

**4.20 EHR-S.** – Electronic Health Record Information System.

**4.21 SNS.** – National Health System.

## **5. General Provisions**

**5.1** It is the Ministry's responsibility to establish, in accordance with applicable legal provisions, the regulations to which the EHR-S used by Health Care Providers is subject to, in order to guarantee the exchange, processing, interpretation and security of the information contained in said systems.

**5.2** The Health Care Providers who use EHR-S must do so using a system that complies with the terms provided for in this standard, in the Official Mexican Standards mentioned in parts 2.1, 2.2 and 2.3 of this standard, and in the applicable legal provisions; Health Care Providers are jointly and severally responsible, with respect to compliance with this obligation for the actions of the people who render services for them, independently of the terms of their labor contract.

**5.3** Through EHR-S, Health Care Providers must guarantee the confidentiality of patients' identity, as well as the integrity and reliability of the clinical information and establish the pertinent and proper security measures in order to avoid illicit or illegal use which may affect the legal situation of the owner of the information, in accordance with applicable legal provisions.

**5.4** The information contained in the EHR-S must be managed with discretion and confidentiality at all medical facilities, in accordance with applicable legal provisions and the scientific and ethical principles that guide medical practice; said information may be communicated to the patient, family members, the legal representative or third parties, in accordance with the terms set forth in part 2.1 of this Official Mexican Standard.

**5.5** The Health Care Providers may exchange information through the EHR in accordance with the LFTAIPG and other applicable legal provisions.

Any unauthorized revelation of information contained in the EHR-S, without the express consent of the Health Care Providers, the owner of the information or whoever has the legal standing to decide for the owner, will be sanctioned in accordance with applicable legal provisions.

**5.6** The Health Care Providers are responsible for conserving and maintaining their EHR-S under proper operating conditions, in order to ensure over time the integrity, reliability and availability of the data and information contained therein.

**5.7** The Health Care Providers will share information and knowledge for the purposes of rendering comprehensive health services, as well as for proper decision-making within an agreement framework among themselves and the health authority.

**5.8** The Health Care Providers must put together the mechanisms to make information, functionalities and technological solutions available for sharing among those who may require them; said exchange must include record tracking for identifying and analyzing situations, general or specific about the electronic services.

**5.9** The Health Care Providers are responsible for ensuring that the data and information contained in their EHR-S for providing health care services remain complete and unaltered.

## **6. Specifications**

### **6.1 Guidelines and Forms for the Exchange of Health Information**

**6.1.1** The Ministry, through the DGIS, in accordance with applicable legal provisions and medical criteria, exchange of information provisions and proven technical standards, coordinates the preparation of Guidelines and Forms which lead Health Care Providers towards achieving Semantic and Technical Interoperability in specific scenarios for the exchange of information among EHR-S.

**6.1.2** The Guidelines and Forms are technical documents focused on achieving Semantic and Technical Interoperability and are set up as text format, diagrams and accompanying files, and include at least a) the scope of the types of systems, types of Health Care Providers and the types of exchange they apply to; b) the dictionary of variables, distinguishing those of a confidential nature, catalogues and validation rules; c) the conformation of the electronic document, data message or service; d) the standards based interconnection mechanism; and e) examples, references and bibliography.

**6.1.3** The Guidelines and Forms are based on the Reference Architecture and procedures issued by the Ministry through the DGIS. This Reference Architecture may consider the standards and guidelines published internationally by IHE or HL7 or those that the Ministry

itself, through the DGIS determines in accordance with the technological advances and situation of the National Health System.

**6.1.3.1** The following standards may be considered in accordance with the scope of the information exchange: HL7 CDA, HL7 V3, XML and/or the proven standard determined by the Ministry through the DGIS, in accordance with technological advances and the situation of the National Health System. Health Care Providers may choose the standards that best resolve their needs to supply said services for the exchange of information within their organizations, and are subject to the provisions of this standard.

**6.1.3.2** The standards configurations defined in the IHE profiles may be considered in accordance with the scope of the information exchange, as well as proven configuration standards determined by the Ministry through the DGIS, in accordance with technological advances and the situation of the National Health System. Health Care Providers may choose the standards that best resolve their needs to supply said services for the exchange of information within their organizations, and are subject to the provisions of this standard.

**6.1.4** The Guidelines and Forms specify the detail of the information exchange among Health Care Providers independently of the providers' internal processes.

**6.1.5** The procedure for the preparation and updating of the Guidelines and Forms is coordinated by the Ministry through the DGIS, in its capacity as coordinator of the National Health System. The Guidelines and Forms must comply with the characteristics described in this standard and be submitted to the Ministry through the DGIS for approval and publication on its website: [www.dgis.salud.gob.mx](http://www.dgis.salud.gob.mx).

## **6.2 The Ministry's Administrative Units' Health Information Systems**

**6.2.1** The Ministry's information systems for compilation and consultation of information must implement information exchange interfaces in accordance with the standards defined in this standard, and its design must also comply with the Reference Architecture issued by the Ministry through the DGIS.

## **6.3 EHR-S**

**6.3.1** The EHR-S must implement information exchange interfaces in accordance with the specifications of the Ministry in the corresponding Guidelines and Forms for each scenario as applied to the Health Care Provider that operates it. It is the obligation for those Health Care Providers using EHR-S to keep this implementation updated in accordance with the published Guidelines and Forms.

**6.3.2** In the event that Guidelines or Forms do not exist for a type of information exchange among EHR-S, Health Care Providers involved must develop the corresponding Guidelines and Forms in compliance with the provisions of section 6.1.

**6.3.3** The EHR-S must, at the least record the information required for the specific variables in the applicable Guidelines and Forms, in accordance with the scope and applicable health legal provisions.

**6.3.4** The EHR-S must record in structured and unalterable electronic documents the information derived from providing health care services.

#### **6.4 The Use of Standards and Catalogues**

**6.4.1** With the aim of achieving semantic interoperability among Health Care Providers and the alignment of systems in national and international environments, EHR-S must use the format standards for the messaging, transport and terminology defined in the applicable Guidelines for each EHR-S in accordance with their scope.

**6.4.2** The EHR-S must use the basic catalogues set forth in the Normative Appendix A of this standard “Fundamental Catalogues Matrix”, in its current valid version in accordance with the terms published by the Ministry through the DGIS, and must follow the usage guidelines that set forth by the guiding body in Normative Appendix A. It is mandatory for Health Care Providers who use EHR-S to maintain updated the catalogues and to comply with its guidelines in accordance with the terms published on the DGIS’s website [www.dgis.salud.gob.mx](http://www.dgis.salud.gob.mx)

#### **6.5 Identification of Patient and Health Professionals**

**6.5.1** For health information exchange purposes, and in accordance with the guidelines issued by the Ministry of the Interior, the validated CURP must be the sole personal identification attribute. EHR-S must not self-generate the CURP.

**6.5.2** Each EHR-S can support the handling of other identifiers in addition to the CURP in accordance with the requirements of the Health Care Provider.

**6.5.3** Each Health Care Provider must be capable of reporting the minimum data for the identification of persons as specified in Table 1 “MINIMUM DATA FOR PERSONAL IDENTIFICATION” to the Ministry, through the DGIS, from the information contained in the EHR-S, in accordance with the Guidelines and Forms which are issued for said goal.

**TABLE 1**

**MINIMUM DATA FOR PERSONAL IDENTIFICATION**

ATTRIBUTE	DESCRIPTION	TYPE AND LENGTH	REQUIRED	VALIDATION
CURP	Unique Population Registry Code, assigned by the National Population Registry (RENAPO).	Alphanumeric (18)	YES	As per RENAPO guidelines.
FIRST SURNAME	First surname noted in the substantiating document	Alphanumeric (50)	YES	Avoid use of abbreviations in

	presented to the Health Care Provider.			surnames or compound names.
SECOND SURNAME	Second surname noted in the substantiating document presented to the Health Care Provider.	Alphanumeric (50)	NO	For exchange purposes, this information must be in capital letters.
NAME	Name(s) noted in the substantiating document presented to the Health Care Provider.	Alphanumeric (50)	YES	The only special characters to be used on capital letter vowels are the accent, diaeresis and apostrophes.
D.O.B.	Date of birth noted in the substantiating document presented to the Health Care Provider.	Numeric (8)	YES	<p>The date of birth must consist of 8 digits, assigned in the following order [yyyymmdd].</p> <p>Four digits for the year.</p> <p>Two digits for the month (from 01 to 12).</p> <p>Two digits for the day (from 01 to 31).</p> <p>Example for somebody born on August 15, 1994: 19940815</p>
BIRTH STATE	Code of the federal entity where the beneficiary was born presented to the Health Care Provider.	Alphanumeric (2)	YES	<p>The value must exist in the INEGI's federal entity, municipality and small town key catalogue.</p> <p>In the event the person was born abroad, capture the "NE" key (Born abroad).</p> <p>In the event the person is Mexican but his/her birth state is unknown, capture code "00" (Not available).</p>
GENDER	Gender of the beneficiary noted in the substantiating document presented to the Health Care Provider.	Alphabetic (1)	YES	<p>According to the RENAPO catalogue the only possible values are:</p> <p>"M" for Female</p> <p>"H" for Male</p>
NATIONALITY	Nationality of the beneficiary noted in the	Alphanumeric (3)	YES	The value must exist in the RENAPO



	substantiating document presented to the Health Care Provider.			Nationalities Catalogue  In the event nationality is unknown, capture NND (Nationality Not Available).
FOLIO	Folio or number with which each institution internally identifies a person.	Alphanumeric (18)	YES	Each Health Care Provider defines the structure of this folio.
STATE (RESIDENCE )	The federal entity residence code.	Alphanumeric (2)	YES	The value must exist in the INEGI's federal entity, municipality and small town code catalogue.  In the event the information does not exist, capture "00".
MUN (Municipality)	The municipality residence code.	Alphanumeric (3)	YES	The value must exist in the INEGI's federal entity, municipality and small town code catalogue.  In the event the information does not exist, capture "000".
LOC (Small town)	The small town residence code.	Alphanumeric (4)	YES	The value must exist in the INEGI's federal entity, municipality and small town code catalogue.  In the event the information does not exist, capture "0000".
<b>EXCLUSIVE FOR FEDERAL HEALTH CARE PROVIDERS</b>				
TYPE OF BENEFICIARY	Identifying code for beneficiary type.	Alphanumeric (2)	YES	01 = Worker/Insured. 02 = Seguro Popular Beneficiary. 03 = Family Member. 04 = Pensioner.
AGENCY KEY	Code of the Agency in charge of the program.	Alphanumeric (3)	YES	The agency must notify of this code the Ministry of Health through the DGIS.
PROGRAM KEY	Code of the program in which the beneficiary is registered.	Alphanumeric (20)	YES	The agency must notify of this code the Ministry of Health through the DGIS.  In the event the information does not exist, capture "ND" (Not available).

**6.5.5** For the purposes of information exchange, the minimum mandatory data are: CURP, name, first surname and second surname (if available), as set forth in Table 1 (see 6.5.3).

## **6.6 Universal Considerations for Handling Information and its Security**

**6.6.1** The Health Care Providers who use EHR-S must implement an Information Security Management System in accordance with the applicable legal provisions concerning transparency, protection of personal information and standards for information security and which ensure confidentiality, integrity, availability, tracking and non-repudiation of the health information.

**6.6.2** The EHR-S must record and protect the information derived from the health care services provision in the form of structured and unalterable electronic documents, in accordance with applicable legal provisions. The EHR-S must allow the health professional's advanced electronic signature to be used as the Health Care Provider sets forth in its information security management system, in accordance with applicable legal provisions.

**6.6.3** At a minimum, all users, organizations and devices must be authenticated in the EHR-S with a user name and password which definition must be approved by the organization's strategic information security working group. The use of additional authentication factors is recommended.

**6.6.4** The EHR-S must implement role-based authorization mechanisms. The user profiles must be defined by each Health Care Provider, in accordance with applicable legal provisions for each organization.

**6.6.5** For information exchange purposes among Health Care Providers, the EHR-S must implement authentication, encryption and advanced electronic signature mechanisms, in accordance with applicable legal provisions, Guidelines and Forms.

**6.6.6** The EHR-S must allow the export of patient information, in accordance with applicable legal provisions governing transparency and protection of personal information, using the Guidelines and Forms which are defined for this purpose. Likewise, the EHR-S must implement controls regarding the information owners' consent, or whoever has the legal capacity to decide for said person, in accordance with applicable legal provisions regarding transparency and personal information protection.

## **7. Conformity Assessment Procedure**

### **7.1 Objective**

This objective of this procedure is to establish the requirements for the Conformity Assessment for EHR-S certification compliance by the persons indicated under the terms of part 1 of this standard.

## **7.2 References**

For the correct application of this Conformity Assessment Procedure, the relevant sections of the following valid ordinances need to be consulted and complied with:

**7.2.1** Federal Law for Administrative Procedures (LFPA).

**7.2.2** Federal Law on Metrology and Standardization (LFMN).

**7.2.3** Regulations Governing the Federal Law on Metrology and Standardization (RLFMN).

## **7.3 General Provisions**

**7.3.1** The Certificates could be obtained from the Ministry through the DGIS, and from accredited and approved Certification Bodies under the terms set forth in the LFMN. Once accredited and approved third party agencies have been identified as Certifying Bodies for this standard's Conformity Assessment, the Ministry through the DGIS, will cease offering Certification services and will solely limit itself to supervision and oversight tasks which are conferred by the applicable legal provisions for this standard.

**7.3.2** A Verification Opinion showing compliance with the standard's requirements is necessary for obtaining the Certification. For the purposes of the verification, this must be carried out by the Ministry through the DGIS, or by Verification Units which are accredited and approved under the terms of the provisions set forth in the LFMN and its Regulations.

**7.3.3** The following procedure applies for obtaining the Certificate issued by the Ministry through the DGIS:

**7.3.3.1** The interested party must request an information package containing the Certificate Request Form for this standard, the list of topics to be verified, the auditing process and other documentation and information deemed relevant for the purposes of the Certification from the DGIS, as well as the list of existing accredited and approved Certification Bodies for this standard.

**7.3.3.2** The interested party will deliver a duly signed and completed original request form together with a copy to the DGIS, as well as any documentation necessary for certification.

**7.3.3.3** Once the step described in the previous sub section has been accomplished, the DGIS must review the documentation presented and in the event any defect is detected, it will return the request form and its attachments to the interested party, together with an explanation clearly indicating the deficiency in question which must be corrected by the interested party, as set forth in the LFPA.

**7.3.3.4** The response to the Certification request will be issued in a term not exceeding 60 business days after the request form was delivered. If in said period the DGIS does not issue a response, this will indicate that the request was denied.

**7.3.4** The following procedure applies for obtaining the Certificate issued by a Certification Body:

**7.3.4.1** The interested party must request an information package containing the Certificate Request Form for this standard, the list of topics to be verified, the auditing process and other documentation and information deemed relevant for the purposes of the Certification from the Certification Body, as well as the list of existing accredited and approved Verification Units for this standard.

**7.3.4.2** The interested party will deliver a duly signed and completed original request form together with a copy duly to the Certification Body, the certification service provision contract duly signed with said Certification Body, as well as any documentation necessary for certification.

**7.3.4.3** Once the step described in the previous sub section has been accomplished, the Certification Body must review the documentation presented and in the event any defect is detected, it will return to the interested party the request form and its attachments together with an explanation clearly indicating the deficiency in question, which must be corrected by the interested party as set forth in the LFPA.

**7.3.4.4** The response to the Certification request will be issued in a term not exceeding 60 business days as of the full and complete delivery of the request form.

If in said term the Certification Body does not issue a response, this will indicate that the request was denied.

**7.3.5** The accredited and approved Certification Bodies and Verification Units will keep the DGIS informed on a permanent basis, of the Certificates and Verification Opinions they issue, as well as the verifications they undertake in accordance with the applicable legal provisions.

## **7.4 Verification Procedure**

**7.4.1** The DGIS or Certification Body that carries out the Certification, must do so based on the results of the corresponding EHR-S verification which was carried out by the DGIS or the accredited and approved Verification Unit.

**7.4.2** The DGIS or accredited and approved Verification Unit must establish the terms and conditions of the verifications. The interested party must deliver to the DGIS or accredited and approved Verification Unit the information needed to undertake this Procedure, independently of any agreements, under the terms and conditions of the verifications.

Based on the above, the DGIS or the accredited and approved Verification Unit must verify the following points in the EHR-S:

**7.4.2.1** That they demonstrate the capacity to exchange information in accordance with each Guideline and Form they apply, in accordance with their scope and the specifications indicated in Part 6.3. The “Verification Opinion” and “Certificate” need to clearly indicate which Guidelines and Forms were evaluated.

**7.4.2.2** That they use the basic catalogues described in Normative Appendix A, in accordance with the specifications noted in Part 6.4.

**7.4.2.3** That they record the minimum data for identification, in accordance with the specifications noted in Part 6.5 and Table 1.

**7.4.2.4** That they implement security functionality in accordance with the description noted in Part 6.6.

**7.4.3** In the same manner, the DGIS or accredited and approved Verification Unit must verify that the Health Care Providers:

**7.4.3.1** Use a “Certified” EHR-S, in accordance with the scope required by the Health Care Provider.

**7.4.3.2** Demonstrate the capacity to exchange information as set forth in each applied Guideline and Form, in accordance with their scope and the specifications indicated in Part 6.3. The “Verification Opinion” and “Certificate” will need to clearly indicate which Guidelines and Forms were evaluated.

**7.4.3.3** Establish an Information Security Management System in accordance with section 6.6, and in accordance with the legal provisions as they apply to the Health Care Provider.

**7.4.4** If the system complies with the conditions set forth in this standard, the DGIS, or accredited and approved Verification Unit must deliver to the user an original and copy of the Verification Opinion.

**7.4.5** If the system does not comply with the conditions set forth in this standard, the DGIS, or accredited and approved Verification Unit must notify the interested party in a period not exceeding 60 business days and make note of the findings (observations and nonconformities) encountered in the system’s verification compliance in the technical report and verification list, and give a copy of said documents to the applicant.

**7.4.6** Within the period considered in the previous section, the user must carry out the pertinent modifications and notify the DGIS or accredited and approved Verification Unit so they may once more verify the system. In the event the non-compliance is repeated, the interested party must present a new request form.

**7.4.7** The verifications conclude upon delivery of the “Verification Opinion” to the applicant. When the Verification Procedure has been carried out by an accredited or approved Verification Unit, the latter must deliver a copy of the respective Verification Opinion to the DGIS.

## **7.5 The Certification Procedure**

**7.5.1** Once the applicant has the Verification Opinion, he/she must deliver it to the DGIS or the accredited and approved Certification Body for the purpose of carrying out the Certification process, in accordance with the provisions of this Conformity Assessment Procedure.

**7.5.2,** A satisfactory Verification Opinion must be achieved in order to obtain the Certificate; additionally, the necessary technical information documentation is required, in accordance with the provisions of this standard and applicable legal provisions.

**7.5.3** The Certificates are valid for two years and are subject to corresponding verifications by the DGIS and /or accredited and approved Certification Bodies, as well as the system evaluation in the event modifications are made. In this latter case, the Certificate titleholder must swear before the DGIS or Certification Body as the case may be, that there are no significant changes in the function, design or process, under advisement that if the truth is not told, the validity of the Certificate will be suspended or cancelled; this is independent of any and/or all sanctions that the titleholder may be liable for.

## **7.6 Documentation**

**7.6.1** In accordance with the provisions of Articles 73, 84, 85, 86, 87 and 88 of the LFMN and 80 of the RLFMN, the accredited and approved Certification Bodies and Verification Units must both deliver to the address of the DGIS in writing, a report of Certificates and/or Verification Opinions issued during the respective period, and attach the support documents (among which are Verification Acts and Opinions, Certificates and Contracts) within the first twenty business days following the expiration of each quarter of the calendar year; non-compliance will be cause for revocation of the accreditation and approval of the Certification Body and/or corresponding Verification Unit.

The DGIS can establish an alternative system for sending and receiving the above mentioned Verification Opinion reports and Certificates, needing only to notify the accredited and approved Verification Units and Certification Bodies, for their compliance and application.

**7.6.2** The accredited and approved Certification Bodies and Verification Units must both keep Record of the service requests received and of the certification service contracts and/or verifications carried out.

**7.6.3** The accredited and approved Certification Bodies and Verification Units must both keep record of the following documents for clarification or audits; these will serve as objective evidence for administrative and legal purposes:

- a. Verification or certification services application form.
- b. Verification or certification services contract.
- c. Technical reports.
- d. Verification Acts.
- e. Copy of issued Verification Opinions.
- f. Copy of issued Certificates.

**7.6.4** The documents and information must be maintained in the available active archive at the address of the Certification Body and/or Verification Unit for a minimum of five years as of their date of issuance.

## **8. Concordance between International and Mexican Standards**

There was no equivalent international or Mexican standard at the time this standard was prepared.

## **9. Bibliography**

**9.1** General Health Law.

**9.2** Federal Law on Metrology and Standardization.

**9.3** Federal Law for Transparency and Access to Public Government Information.

**9.4** Federal Law for the Protection of Personal Data Held by Private Parties.

**9.5** National Institute of Statistics and Geography.

**9.6** Advanced Electronic Signature Law.

**9.7** Regulations Governing the General Health Law on the Provision of Medical Care Services.

**9.8** Regulations Governing the General Health Law on the Provision of Social Services.

**9.9** Regulations Governing the Federal Law on Metrology and Standardization.

**9.10** Regulations Governing the Federal Law for Transparency and Access to Public Government Information.

**9.11** Regulations Governing the Federal Law for the Protection of Personal Data Held by Private Parties.

**9.12** Manual on the use of Personal Identifiers.

**9.13** Agreement which Establishes the National Basic Health Information System.

**9.14** Agreement for the Adoption and Use of the Unique Population Registry Code by the Federal Public Administration.

**9.15** Health Level Seven V. 3.0.

**9.16** NOM-Z13-1977, Guidelines for the Drafting, Structuring and Presentation of Official Mexican Standards.

**9.17** Guidelines for the Protection of Personal Information.

**9.18** Guidelines for the Classification and Declassification of Information in the Offices and Entities Comprising the Federal Public Administration.

## **10. Oversight**

The Ministry and the federal states are responsible for overseeing the application of this standard within their respective jurisdictions.

## **11. Validity**

This standard shall take effect 60 calendar days as of its publication date in the Official Journal of the Federation.

**TRANSITORY PROVISION:** Upon taking effect, this Standard invalidates Official Mexican Standard NOM-024-SSA3-2010 which established the functional objectives and functionalities that must be observed the products of the Electronic Medical Record Systems to guarantee the interoperability, processing, interpretation, confidentiality, security and use of information standards and catalogues of electronic health records, published in the Official Journal of the Federation on September 8th, 2010.

Effective suffrage, no re-election.

Mexico City, Federal District, November 9, 2012. – The Under-Secretary for Integration and Development of the Health Sector and President of the National Consultative Committee for the Standardization of Innovation, Development, Technologies and Information on Health, **Germán Enrique Fajardo Dolci**. – Rubric.



## 12. Normative Appendix A

### “Matrix of Basic Catalogues”

IDENTIFIER	CATALOGUE NAME	GOVERNING BODY	PURPOSE OF THE CATALOGUE IN THE EHR-S
CAT_CLUES	Unique Health Facility-Code	DGIS	To identify health facilities. To determine the institution to which the facility belongs (from 3 to 5 characters in the CLUES key). To determine the address and type of facility (from the catalogue's contents).
CAT_SMALL TOWNS	Small Town Codes Catalogue	INEGI	To locate any geographical reference in the systems.
CAT_MUNICIPALITIES	Municipality Codes Catalogue	INEGI	To locate any geographical reference in the systems.
CAT_ENTITIES	Federal Entity Codes Catalogue	INEGI	To locate any geographical reference in the systems.
CAT_DIAGNOSTICS	International Classification of Diseases and Related Health Problems, current official version	DGIS/CEMECE	To record diagnostics, causes of death, consultation motives, and conditions.
CAT_PROCEDURES	International Classification of Clinical Procedure Coding, current official version	DGIS/CEMECE	To record diagnostics and therapeutic procedures carried out.
CAT_HEALING MATERIAL	Basic schedule and catalogue of healing material	General Health Council	To classify healing material.
CAT_MEDICAL INSTRUMENTATION AND EQUIPMENT	Basic schedule and catalogue of medical instrumentation and equipment	General Health Council	To classify medical instrumentation and equipment, as well as their information reports.
CAT_MEDICINES	Basic schedule and catalogue of medicines	General Health Council	To record prescription medicines and the medicine supply for administrative purposes.  To show indications and verify interactions with other medicines and allergies, as well as adequate doses and routes of administration.
CAT_FORMATION	Mexican Classification of Study Programs by Field of Academic Formation	INEGI	To identify the human resources in the health field according to the

			type of formation and area of specialization.
<b>CAT_INDIGENOUS_LANGUAGES</b>	Classification of Indigenous Languages	INEGI	To record the indigenous language.
<b>CAT_RELIGION</b>	Classification of Religions	INEGI	To record the patient's religion, only if the institution requires it.
<b>CAT_ADMINISTRATION_MODE</b>	Administration Route	General Health Council	To record the administration route through which a medicine is administered.
<b>ZIP CODE</b>	Zip Code	Mexican Postal Service	To locate addresses in the systems.
<b>CAT_CIF</b>	International Classification of Functioning, Disability and Health (ICF), current official version	DGIS/CEMECE	To record information regarding functioning levels and states of health.
<b>CAT_NATIONALITY</b>	Nationality	RENAPO	To record information regarding the individual's nationality.

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