Establishment and Utilization of Electronic Health Records in Iran: A Review of the Policy Documents of the Past Four Decades

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Abstract

Background: This study presents the legal obligations set for the main stakeholders in the establishment and implementation of electronic health (e-health) records in Iran and investigates the fulfillment of these obligations.

Methods: This qualitative study was conducted using document analysis. The research population comprised all the documents, laws, reports, and policies of the establishment and utilization of electronic health records in Iran. Sampling was purposive, and all the internal documents of Iran were included until the end of May 2022. A data extraction form was used to collect the data, and Scott's criterion was used to select the documents. Descriptive analysis was used to analyze the data.

Results: Based on the documents, 56% of the sentences were implemented, and 22% were not enforced according to the assigned tasks. The status of the execution of tasks by the main players was also extracted. The most important of these included the drafting of the electronic health security and privacy regulations, not providing the conditions for receiving electronic copies in the e-records, creating internal automation for the Ministry of Health and Medical Education instead of the e-health records system, instability of the integrated portal for exchanging health information and disconnection of the majority of service centers, eliminating the extension of the validity of paper booklets, operationalizing the online entitlement system, using the first phase of the electronic prescription project, not inserting nursing notes in the records, recording financial and administrative information instead of clinical ones, refusal of numerous doctors to write electronic prescriptions, using an alternative method of two-step verification instead of electronic signature, the progress of coding and drug authenticity, and the non-implementation of medical equipment coding.

Conclusions: Reviewing the status of the enforcement of approvals also revealed that the format of actions since 2018 has ended with a positive result. The main achievement so far has been electronic prescription, while it should be noted that prescription is only part of the electronic health record project.

Keywords: Electronic Health Records, Medical Records, Medical Electronics

1. Background

It is difficult to manage health systems based on traditional and paper-based processes. Due to the development of technology, electronic systems have come to the aid of health systems. Thus, many advantages have been created for service recipients, such as transparency, reduction of unnecessary services, reduced medical errors, and helping health research (1, 2).

According to the definition provided by Iran's Ministry of Health and Medical Education (MoHME), the electronic health record is the collection of information related to citizens' health events from before birth (from the fetal period and in vitro fertilization) to after death (autopsy, burial place, etc.), which is continuously stored electronically over time. This information is exclusively possessed by the owner of the file and will be given to authorized persons only with the owner's permission and in compliance with the rules of confidentiality and privacy. This file will also be a platform for providing various managed electronic health services (3).

According to the roadmap of the MoHME regarding electronic health, there are three key goals: (1) connecting all health service providers to the health information

exchange center; (2) launching the electronic health record for citizens to access their health records; and (3) deploying the electronic health service on the platform of electronic health records (3). For the realization of the first goal, it is necessary to have about 172,000 centers, including hospitals, clinics, laboratories, pharmacies, offices, emergency rooms, blood transfusion centers, and food and medicine centers in various governmental and nongovernmental sectors. Besides, health insurance organizations, health centers, health and treatment departments of the MoHME, and the medical system organization should be connected to each other. The second goal is to develop the electronic health record, whose components are the electronic record, information exchange portal, information systems of centers, the Sepas, SIAM, and Maxa systems, and an electronic file viewer. The third goal, which involves launching electronic health services for citizens based on the electronic health record, aims to use the files through the systems and provide services based on the files, process electronic documents, prescription and hard copies, eligibility assessment, and elimination of overlaps and referrals.

Over the past two decades, various laws regarding the establishment of electronic health records and the provision of health services via a platform have been approved in Iran. However, the extent of their enforcement is uncertain. Although Iranian health authorities have announced that the electronic health infrastructure is ready (3), our observation show that we are far from the complete and flawless enforcement of the provisions of the laws.

2. Objectives

We set out the current study to present a picture of the tasks set for the main institutions and stakeholders in the establishment and implementation of electronic health records in Iran and to examine the fulfillment of these tasks based on the documents.

3. Methods

The present qualitative study involved document analysis. All the documents, laws, policies of establishment, and uses of electronic health records in Iran were examined. The process and steps of the documentary research method include choosing the topic, determining the research goals and questions, performing exploratory investigations, collecting and selecting the documents, analyzing the documents, and presenting a report (4). Therefore, the research

population comprised all the reports made by the MoHME and other institutions and the approved high-level documents, including laws, policies, programs, and relevant national guidelines. We continued sampling of the documents related to the selected subject purposively with maximum variation until we did not find any other relevant document. All the documents were studied until the end of March 2022.

We used a data extraction form to collect and extract the data to create a logical routine, unify the received information, and prevent the loss of relevant data. Moreover, we eliminated the possible shortcomings of the data extraction form based on experts' opinions and guidance. The form designed for data collection included the title, type, and general characteristics of the document, time and place of publication, related organizations, and items related to the content of the document. Since not all sources have the same scientific and content value, we selected high-quality sources according to the four criteria introduced by Scott (i.e., originality, credibility, visibility, and meaningfulness) (4). We ensured the authenticity of the author(s) of the documents by receiving the documents from reliable sources. By means of the visibility criterion, we determined that the document was representative of the data it introduced. The comprehensibility and transparency of the documents were checked with the criterion of significance. Based on the validity criteria, we checked the absence of errors and deviations in the documents (4). Meanwhile, we used descriptive analysis to analyze the data (5).

4. Results

The tasks related to the establishment of electronic health records have been approved over time and through different laws. Therefore, currently, some of the provisions contained in the fourth and fifth development plans or the notes approved in the annual budget laws of the past years have expired. Some of these tasks have been approved in the law of the sixth development plan. In addition, there are direct and indirect provisions in this regard within the high-level documents. Besides the emphasis on the use of advanced human sciences and techniques and efforts to advance them, the history of electronic health in the laws approved by the Islamic Council dates back to the law of the fourth development plan. Therefore, we think that this issue has been clearly included in Iranian laws since 2003. Of course, the use of technology in providing governmental services is generally mentioned in the laws of the previous development plans and other high-level documents. Table 1 lists the main provisions related to the

establishment of electronic health records contained in the high-level documents and laws.

The findings showed an increase of about 2.5 times in electronic health record approvals since 2016. Although the approvals in this area have a history of more than 4 decades, the electronic health project was selected as a high-priority project. Regarding the law enforcement status, despite the passage of a relatively long period (about 17 years) since the approval of the legal decrees related to electronic health (e-health), the enforcement has not been in accordance with the assigned tasks and has not been approved by the supervisors. Table 2 presents the law enforcement status based on the documents.

According to the documents, 56% of the laws have been enforced; on the other hand, the execution of 22% of the orders was not in accordance with the assigned tasks, and 22% of the orders were ambiguous in their implementation or were incompletely executed. Furthermore, the review of the enforcement status of the approvals showed that the status of tasks since 2018 has ended with a positive result. According to all the provisions contained in the high-level laws and documents, as well as the annual budget laws mentioned in the previous section, there are various players in the field of electronic health records. Table 3 shows the players and stakeholders mentioned above, along with the summary of each role and the status of law enforcement.

5. Discussion

Based on the results of this study, in 2004, the concept of a comprehensive health information system was introduced to the legal literature of Iran. Besides, the concept of an electronic health record was introduced for the first time in 2007. Until 2022, this concept (the creation of a comprehensive and integrated health information system) was still included in the legal provisions and other approvals.

Until 2007, the rules and tasks related to the establishment of electronic health records were limited to infrastructures only. However, as mentioned in the documents, the information platforms, including the integrated portal for the exchange of health information, have not had the necessary stability to determine the main path of receiving and exchanging information; for example, other insurance systems are slow during peak service times, as also mentioned by other studies (7-9).

Funds related to the establishment and operation of the electronic health record were not properly allocated and were often spent on the costs of unrelated systems. Studies also emphasize that, compared to other countries, the situation and mechanism for financing the electronic

health system in Iran is unclear, and the budget deficit is the most important factor (8, 10-12). Therefore, as the present study showed, financing of electronic health records has been specifically addressed by policymakers in annual budgets since 2016. Some of these issues are related to electronic health, and some are included in the annual budget laws to fulfill the provisions contained in the law of the sixth development plan, such as the enforcing the establishment of an online information database for the insured people, and the use of electronic tools instead of paper booklets that have been included in the budget laws since 2017. Some were approved to compensate for the backlogs of the assignments in the development plan laws, such as being obliged to establish the electronic health record in the sixth development plan due to its non-fulfillment in the fifth development plan, as well as the approval of the implementation of the electronic health record system in an integrated manner by the MoHME, which was not realized in previous years. Some notes have also been included in the budget laws to accelerate the actions and processes of e-health implementation; for example, the Supreme Council of Health Insurance was obliged to design an electronic prescription because, in 2019, basic treatment insurance organizations were required to accept only electronic prescriptions.

The results also revealed that since 2020, approvals related to the execution and operation of electronic health records were observed in the Iranian laws, but we still observed general and repeated approvals. Of course, actions in this regard have been accelerated in the last 2 years. Currently, additional measures have been taken (both by the legislature and the executive branch) to accelerate the work and compensate for the previous shortcomings and delays.

In addition to the approval of detailed laws, a positive step in this field has been the acceleration of the enforcement and approval of binding laws regarding the establishment and operation of electronic health records in the last 4 years. These approvals include the following: Extension and issuance of the license of centers should be subjected to sending the files to the electronic health record system; monitoring and supervision of pharmaceutical items and consumables are done only through electronic prescription; controlling and monitoring of the identity and authenticity of doctors and their electronic signatures, prohibition of purchasing services outside the electronic health cycle, and a lack of binding laws in Iran for the faster development of e-health are quite noticeable compared to other countries (8, 13, 14).

However, we are far from the desired outcome. A

Table 3. Establishing the Electronic Health Record by the Main Players in Iran

Stakeholders	Assignments	Status of Implementation
MoHME	According to the rules of the development plan, this ministry has been designated as the trustee of the establishment of the electronic health record, and other relevant institutions are required to cooperate with it.	Compilation of the draft regulation of security and privacy in electronic health. The electronic health record system was unveiled by the MoHME but was not approved by the project supervisor (it was only an internal automation for the MoHME). The conditions for receiving the electronic prescriptions in the electronic health file have not been met. The integrated health information exchange portal has not had the necessary stability to determine the main path of receiving and exchanging information so far and has experienced occasional outages.
Executive Council of Information Technology	Electronic health project supervisor	Compilation of guidelines related to the establishment of electronic prescription; conducting field visits on the execution status of the electronic prescription and the establishment of the electronic health record and communicating it to executive bodies, universities of medical sciences, health service providers, and health insurance.
Supreme Council of Health Insurance	Basically, it is the regulator of basic medical insurance, and according to the budget law of 2019, it is assigned to design and issue the electronic version.	Announcing the rules of the electronic prescription
Medical insurance organizations and funds	Launching an online database of the country's medical insurance policyholders by the Iran Health Insurance Organization. Basic treatment insurance organizations, while updating the online database of insured persons, have made the strategic purchase of health services possible only through the electronic health record system of Iranians and are required to accept only electronic versions. The Iran Health Insurance Organization is the trustee of establishing a base on the country's medical insurance line. Medical insurance organizations and funds as buyers of health services	Removing the extension of validity of the paper booklet. Creating an electronic prescription portal (multiple insurance portals and their lack of integration is a challenge for this department). Implementation of the online eligibility system by Iran Health Insurance Organization. A part from the Social Security Organization, none of the basic insurance organizations and funds send their information to the entitlement assessment system. Insurance systems slow down during peak service times.
Health, diagnostic, therapeutic, and pharmaceutical centers	Providing services within the framework defined by the Iran Health Insurance Organization for assessing the eligibility of the insured based on the online treatment database of the insured and the standards announced by the MoHME to exchange information and send files to the electronic health record system so that the information on the services provided to the insured should be integrated and sent online.	Using the first phase of the electronic version project with an 80% progress (except for hospital information system (HIS) centers and governmental centers). Most of the service centers (about 140,000 out of 170,000 centers) are not connected to the health information exchange center. Nursing notes are included in the file only in a few hospitals and polyclinics. Regarding important cases such as clinical measures, they are included in less than 20% of offices and hospitals and in less than 40% of health centers and clinics. Apart from the patient's identity information and financial and administrative data, a large part of the information is not included in the system in many centers, and the nature of the files created in the centers is more financial than clinical. Despite numerous doctors joining the electronic prescription, a large number of them still refuse to do so.
IRI Medical Council	Electronic signature	Issuance of 60,000 electronic signatures for doctors practicing medicine in the country (40% of the population of 130,000 doctors). The signatures issued in the portals of the MoHME and the systems of insurance organizations cannot be accessed; currently, instead of an electronic signature, an alternative method of two-step verification is used.
FDA	Obliging the FDA to establish communication and exchange information between its own systems and alternative systems of the health insurance book and entitlement assessment system.	A 60% improvement in coding and drug authenticity; the coding of medical equipment has not been done yet and is in a limited and case-by-case preliminary test stage; managing the distribution and consumption cycle of medicine and medical equipment is challenging due to incomplete coding.

Abbreviations: MoHME, Ministry of Health and Medical Education; IRI, Islamic Republic of Iran; FDA, Food & Drug Administration; HIS, hospital information system.

mandatory rule is the inability to connect most of the service centers with the exchange center in Iran. In fact, less than 30,000 centers are connected to the health information exchange centers, which is mentioned in the present research and other studies (15).

Refusal of doctors to register electronic prescriptions and nonfulfillment of doctors' digital signatures are other legal requirements that are still far from the desired level and need more legal requirements. However, the final implementation of this plan was given more serious attention due to the legal requirement from the beginning of December 2020; despite the request to stop it, even with the approval of the president, governmental hospitals and clinics also joined this project. Studies also confirm that the resistance of healthcare workers and their lack of understanding and awareness of the advantages of e-health, especially among doctors, are still the most serious obstacles to the widespread implementation

of health information systems, especially electronic healthcare records (3, 16-18). In this regard, the findings of another research indicated that professional and social norms influence the acceptance of electronic health records by doctors (16, 19, 20). In addition, proper training and direct or indirect incentives can improve the participation of doctors (14, 18).

Based on the results of the present study, like other studies, the monitoring and supervision of pharmaceutical items and consumable equipment has been done only through electronic prescriptions since 2020, which clarifies and creates a suitable platform for gathering information for decision-making, supply chain monitoring, and management of drug and medical equipment shortages; meanwhile, the most important result is the elimination of corruption paths (21, 22).

One of the results of the review of the enforcement status was the electronic prescription coding problems. For example, each of the main basic insurance companies has set up its own systems to carry out their tasks separately; if it were to be extended to all 19 basic medical insurance funds in the country, it would create many problems. Besides the problems related to data collection and the lack of communication between systems, the approaches are also different; for instance, prescriptions for people in the Social Security Organization are based on the national code, but in the Iran Health Insurance Organization, a tracking code is assigned separately to each service (15).

The lack of optimal security of the electronic prescription systems is another result of the present study and other studies, which has been emphasized even in the current approvals under the general policies of social security organizations (22, 23). In fact, ethical-legal barriers are very important in electronic health, and the most important of them are security and privacy issues caused by the vast accessibility of electronic data (24-26).

Another finding of the current study in relation to enforcement status is the lack of reliable reports, poor quality of electronic health record systems, and the wide discrepancies in the statistics of patients' hospitalization records. Moreover, the laws related to the use of electronic health records from the sixth development plan in 2016 were introduced into the legal literature of Iran, with the legal provision of establishing a database on the line of medical insurance. Studies show that in countries such as Canada, England, and Australia, the private sector has participated along with the public sector in the design and creation of electronic health records and making appropriate investments in this field. In fact, to advance the related measures faster, various duties have been approved for some of the main players in recent

years; moreover, various measures have been taken to execute the aforementioned legal duties that have not been fully implemented yet. In addition, studies indicate that multiple players and the lack of a comprehensive plan are among the problems of the establishment of electronic health records in Iran. The division of tasks and project execution stages are also crucial and can appear as obstacles or facilitators (18). In this regard, the experience of other countries indicates the gradual and phased implementation of electronic health (8). In other words, the lack of a plan and macro-architecture agreed upon by the players is one of the main reasons for the scattered, parallel, and isolated actions of the electronic health record project. Studies also highlight that the information technology infrastructure in Iran is vague and complex; as a result, the custodians, policymakers, implementers, and users of the country's information technology are not exactly known, and different institutions claim to be in charge of the country's information technology and approve the related documents separately (3, 8).

5.1. Limitations

This study was limited by the lack of similar studies on the establishment and utilization of electronic health records in Iran.

5.2. Conclusions

One of the findings of the current study was an increase of about 2.5 times in electronic health record approvals since 2016. Besides, although the approvals in this area have a history of more than 4 decades, the electronic health project was selected as a high-priority project only in 2017. Similar results were obtained regarding the enforcement status of the approvals. As the results showed, the actions since 2018 have ended with a positive outcome.

The findings revealed that although many efforts have been made to implement electronic health in Iran, the electronic health strategy is rather general and has not been fully implemented due to the lack of stability and the existing obstacles. Seriousness and follow-ups in the coming months will lead to full implementation, which in many ways is considered a success for the promotion of Iran's health system in the region and the world. The timely emphasis of the 2020 budget law and the President's emphasis on law enforcement have also been effective in the progress of this plan.

Note that electronic prescription writing and filing are only parts of the electronic health project, and by implementing them only, one cannot claim that the electronic health record project has been executed.

The measures related to electronic prescriptions are also conducted in an isolated manner. Although the measures seem to respond to insurance processes despite the challenges, they need to be integrated with other electronic health components to serve the electronic health system. Given the role of different stakeholders in the execution of e-health and various considerations (e.g., training of role-players, culture-building in society, defense considerations, issues related to confidentiality and security of systems and information, and legal considerations), it is necessary to establish e-health based on a macro-architecture (trusted by the main players), including project execution stages and accurate distribution of the roles of each stakeholder to address the above-mentioned considerations.

Footnotes

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Table 1. The Main Provisions Related to the Establishment of Electronic Health Records Contained in the High-level Documents and Laws

The Title of the Document	Reporting/Ordering Department	Classification	Implementation Period	Related Provisions	Important Assignments	Target Organization
Constitution	The Assembly of Experts of the Leadership	High-level documents	Since 1980	The second principle	Using advanced human science, techniques, and experiences and trying to advance them	Government
Law of the first development plan	Parliament	Laws of Development Plans	1989 - 1993	Paragraph 3 of note 22	Using advanced technology to provide high-quality service at an optimal speed	Government
Electronic commerce law	Parliament	Permanent laws of the parliament	2003	Article 60	Preparing and approving regulations for storing, processing, or distributing messages related to health medical records	Government
Law of the fourth development plan	Parliament	Laws of Development Plans	2005 - 2009	Clause E of article 88	Designing and establishing a comprehensive health information system for Iranian citizens	MoHME
Determining the strategic document for the security of the country's production space and information exchange	Presidential Legal Assistant	Resolution of the Council of Ministers	2008	Vision	Determining a 10-year timeframe for the provision of infrastructure and information platforms	Government
Regulations of the Supreme Council of Health and Food Safety	Presidential Legal Assistant	Government approvals	2008	Resolution of the sixth meeting	Compilation of an operational plan and executive regulations for the creation and development of electronic health records within one year; creating appropriate information platforms to provide new services to citizens within a 10-year period	MoHME
Comprehensive scientific map of the country	Supreme Council for Cultural Revolution	High-level documents	2010	Health priorities	Emphasis on health information and knowledge management	National actions
				Grand strategy 11	Development of information and communication technology in health to create an electronic health system	National actions
General health policies	Supreme leader	High-level documents	2014	Clause 1-10	Clarification of expenses, income, and activities	Government
				Clause 5	Efficient policy-making and monitoring of production, consumption, and import	Government
Law of the fifth development plan	Parliament	Laws of development plans	2011 - 2015	Clause A of Article 35	Establishing the electronic health record system of Iranians and the information systems of health centers	MoHME
				Clause A of Article 35	Obliging health centers (governmental and nongovernmental) to cooperate	Health centers (government and nongovernment)
				Clause B of Article 35	Organizing health insurance services in an integrated and information technology-based manner in interaction with the "electronic health file of the Iranians" system	Ministry of Welfare and Social Security
				Clause B of Article 35	Obliging all relevant units, both governmental and nongovernmental, to cooperate	All related governmental and nongovernmental units

Table 1. The Main Provisions Related to the Establishment of Electronic Health Records Contained in the High-level Documents and Laws (Continued)

Document	Approving body	Type of document	Year	Article/Clause	Provision	Responsible organization
Law of the sixth development plan	Parliament	Laws of development plans	2017 - 2021	Part 2, Clause A, Article 67	Investing in the infrastructure of electronic services in deprived and rural areas (so that at least 4 main electronic services of the government are provided in 80% of villages with more than 20 households in the country)	Ministry of Information and Communications Technology
				Clause H of Article 68	Establishment and operation of electronic health systems covering all stakeholders until the end of the enforcement of the program law	Government
				Clause C of article 70	Forming an online database of medical insurance policyholders in the 1st year of law enforcement and designing and implementing the reception of services for insured persons as a unit from the beginning of the 2nd year of law enforcement	Iran Health Insurance Organization
				Clause A of article 74	Establishing the electronic health file system and organizing health insurance services in an integrated manner in interaction with the Electronic Health File of Iranians within 2 years	MoHME
				Clause C of article 74	Recognizing the electronic health record of Iranians as an axis of implementing the system of comprehensive and universal health services	MoHME
				Clause C of article 74	Obligation of organizations and basic insurance funds to make strategic purchases only through the electronic health record system of Iranians	Basic insurance organizations and funds
				Clause C of article 74	Forming an online database of the insured	Health Insurance Organization
Annual budget of 2017	Parliament	One-year financial document of the government	2017	Paragraph C 2-note 18	Through development organizations and subsidiary companies, internal and external private-public partnerships to carry out electronic government projects and develop electronic services	Ministry of Information and Communication Technology
Approval No. 105816/T54607H	Presidential Legal Assistant	Resolution of the Council of Ministers	2017	Resolution 1	The relevant trustee, as the case comes up, should be provided to realize the operational plan regarding the provision of information on integrated portals.	All executive bodies
Annual budget of 2018	Parliament	One-year financial document of the government	2018	Paragraph D of note 17	Sending the information of insured persons online to the online information database of the insured persons of the country and using the aforementioned database by substituting electronic tools for booklets; provision of all services through entitlement assessment from the online database	Basic and supplementary treatment insurance companies and funds, executive bodies
Resolution No. 12176 of the Council of Ministers	Presidential Legal Assistant	Resolution of the Council of Ministers	2018	Paragraph 1	- Selection of the electronic health project as a high-priority project among the 23 priority technological projects of e-government; the selection of the Secretariat of the Information Technology Executive Council of the country as the supervisor of the electronic health project	Secretariat of the Information Technology Executive Council of Iran
Resolution of the 12th session of the Information Technology Executive Council	Ministry of Information and Communication Technology	Government regulations	2018	Article 1	Compilation and submission of the architectural plan until the operation of 4 key projects: Electronic health file, eligibility assessment and elimination of insurance overlaps, electronic referral and prescription, and electronic receipt within 1 month to the Council Secretariat	Electronic health task force

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Table 1. The Main Provisions Related to the Establishment of Electronic Health Records Contained in the High-level Documents and Laws (Continued)

Document	Issuer	Type	Year	Article/Clause	Provision	Responsible body
Statutes of the Information Technology Executive Council	The Council of Ministers	Government regulations	2019	Article 1	Determining executive policies in the field of information technology for the development and establishment of electronic government and laying the ground for the expansion of information and communication technology applications in the country	Information Technology Executive Council
				Article 2	Development of the industry and use of information technology; development of electronic government and maximum use of nongovernmental capacities; continuous monitoring of the progress of e-government development programs	Information Technology Executive Council
Resolution of the 13th session of the Information Technology Executive Council	Ministry of Information and Communications Technology	Government regulations	2019	Clause 6	e-Government field evaluation as appropriate	Secretariat of the Information Technology Executive Council
					Creating the necessary accesses and cooperation with the Secretariat of the Council	Executive units
					Presenting the investigation report to the heads of the executive bodies and the president	Secretary of the Council
Annual budget of 2019	Parliament	One-year financial document of the government	2019	Paragraph C of note 17	Updating the online database of the country's medical insureds for free and continuously and using the aforementioned database by substituting electronic tools for booklets to provide all insurance and medical services	All basic and supplementary insurance companies and funds and executive bodies
				Paragraph C of note 17	Eligibility assessment of the insured, including the possibility of insurance validation and review of their overlapping using the country's online information database of the insured and electronically	Iran Health Insurance Organization
The annual budget of 2020	Parliament	One-year financial document of the government	2020	Paragraph C-1, note 17	Sending the information of insured persons online and updating the said database free of charge and continuously from the said database by substituting electronic tools for booklets and using the entitlement assessment system of the Iran Health Insurance Organization	All basic and supplementary insurance companies and funds and executive bodies
				Paragraph C-2 of note 17	Providing and preparing the necessary electronic platforms when the insured are referred and performing all insurance validation services; investigating insurance coverage and monitoring service insurance rules electronically and through the entitlement system	Iran Health Insurance Organization through affiliated companies
				Paragraph G of note 17	Acceptance through electronic versions only	Basic treatment insurance organizations
				Paragraph G of note 17	Designing and communicating the electronic version based on the criteria in this paragraph and implementing it to all the people and institutions mentioned in paragraph c. (Supreme Insurance Council in the 1st quarter of 2019 and otherwise, basic treatment insurance organizations within a maximum period of 1 month)	Supreme Insurance Council

Table 1. The Main Provisions Related to the Establishment of Electronic Health Records Contained in the High-level Documents and Laws (Continued)

Document	Issuer	Type	Year	Section	Provision	Responsible body
Annual budget of 2021	Parliament	One-year financial document of the government	2021	Paragraph C of note 17	Updating the online database of the country's medical insureds for free, substituting electronic tools for booklets, and using the entitlement assessment system of the Iran Health Insurance Organization	All basic and supplementary insurance funds and executive bodies
				Paragraph G1 of note 17	Prohibition of offering and insurance coverage of any medicine and medical equipment by pharmacies and medical centers without inquiry and verification of authenticity	MoHME
				Paragraph G2 of note 17	Operationalization of the electronic health record system of Iranians in an integrated manner	MoHME
				Clause K 3 note 17	Implementation of the eligibility process for the purchase of services	All basic and supplementary insurance funds and executive bodies
				Clause K 4 note 17	Using the authorized systems of the Iran Health Insurance Organization to assess the eligibility of insured persons based on the online treatment database to exchange information and send files to the electronic health record system.	All natural and legal persons, health centers, and institutions
				Clause K 4 note 17	Considering the enforcement of this paragraph in renewing the license or issuing a license to establish centers	MoHME
				Clause K 6 note 17	The ability to monitor the authenticity of all medicinal items and medical consumables through electronic prescription using the authenticity monitoring and drug tracking system	IRI Medical Council
				Clause K 6 note 17	Controlling and monitoring the identity and authenticity of doctors and their electronic signature	The IRI Medical Council
				Clause K 7 note 17	Prohibition of any purchase of health services and payment outside the electronic health cycle	Insurance organizations and institutions
General social security policies	Supreme leader	High-level documents	2022	Under paragraph 2	Forming the information base, respecting the security considerations related to the armed forces and the country's security apparatus	Government
Comprehensive scientific map of health	Supreme Council for Cultural Revolution	High-level documents	Since 2019	General orientations	Prioritizing science and technology that meet the health needs of society	National actions

Abbreviations: MoHME, Ministry of Health and Medical Education; IRI, Islamic Republic of Iran.

Table 2. Law Enforcement Status

Year	Important Events	Realization Status and Evidence
2010	Preparation related to the implementation of the electronic file project by the MoHME	Completed (3) [a]
2016	Announcement of the complete execution of the electronic file project by the MoHME	Not clear (3) [a]
2019	Announcement of the launch of 4 electronic health record projects by the MoHME	Completed (3) [a]
2019	Announcement of the launch of the electronic health file by the MoHME	Failure of implementation during the project supervisor's visit [a]: Only health centers can provide defined services; some hospital doctors were not in the process of implementing the plan; the representative of the administrative organization failed to see his/her records by referring to medical centers; it was not possible to refer the medicine prescribed in the hospital to the pharmacy of the same hospital; the 13 Aban Pharmacy was not in the process of setting up the plan and did not have access to the designed system (3).
October 2019	Changing the title of the project to "Beginning of the establishment of the electronic health record" with the announcement of the secretariat of the project supervisor	Completed (3) [a]
2019	Investigating the possibility of preparing reliable and high-quality reports from electronic records systems, as well as reviewing centralized information in other information systems related to electronic health records in a centralized manner in the MoHME	Wide discrepancies, according to the reports of the State Accounts Court: It is possible to change the previously issued invoices and remove the service in the patients' files without the supervision and coordination of the central headquarters and other beneficiaries of the electronic file. Currently, due to the lack of complete and correct registration of service performance in the systems of the MoHME by hospitals, it is not possible to prepare reliable and high-quality reports from electronic file systems, including the HIS. The review of centralized information in other information systems related to the electronic health records in a centralized manner in the MoHME shows that there are wide discrepancies in the statistics of the hospitalization records of inpatients at the national level. Of course, the manual entry of information into the aforementioned systems, as well as the transfer of information related to outpatients instead of hospitalization by medical universities, are also among the reasons for these discrepancies (3) [b]
2019	Examining the allocation of the predicted credits in recent years according to the report of the State Court of Accounts	Improper budget allocation, according to the report of the State Accounts Court. The budgets foreseen in recent years for the e-government development plan and expansion of information and communication technology in healthcare have not been properly allocated and were often spent on costs unrelated to electronic health records, such as office automation (3) [b]
Since the beginning of 2020	Realization of the online eligibility assessment service by the appointed board and insurance organizations, especially the Iran Health Insurance Organization	Completed (3) [a]
April 2020	Removing the validity extension of the paper insurance service booklets and replacing them with the online eligibility assessment	Completed (3) [a]
June 20, 2020	Announcing the rules of electronic prescription	Completed (3) [c]
December 2020	Notification of implementation instructions to universities of medical sciences by the MoHME	Completed (3) [a]
2020	Checking the status of the electronic signature of doctors	Non-fulfillment. Refusal of some doctors to write electronic prescriptions despite the presence of free panels through correspondence from the IRI Medical Council. According to the officials of the IRI Medical Council, electronic signatures have been issued for about 60,000 doctors, which includes 40% of the population of about 130,000 doctors practicing medicine in the country. Moreover, in case of issuing an electronic signature, this tool should be available on the portals of the MoHME and insurance organizations, which has not been achieved so far (3, 6) [a]
2020	Examining the performance of the medical system organization regarding the issuance of the electronic signature of doctors	Improper performance: Currently, the alternative method of two-step verification text message is used for this part (3, 6)
February 13, 2020	The beginning of the trial phase of removing paper insurance service booklets in the Iran Health Insurance Organization	Completed. Due to the effectiveness of the measures and re-evaluations of numerous hospital centers, pharmacies, and paraclinical centers, the preparation of the first phase of this project was practically confirmed by the Secretariat of the Council at the end of 2019 (3) [a]

Table 2. Law Enforcement Status (Continued)

March 15, 2020	Complete elimination of issuing new paper booklets in the Iran Health Insurance Organization	Completed. Non-issuance of new insurance booklets in offices (3) [a]
March 23, 2021	By-laws for the use of the first phase of the electronic prescription with progress of nearly 80% (except for the HIS centers and governmental centers)	Completed (3) [a]
April 2021	Checking people's and centers' satisfaction with the execution of the electronic prescription project by the Council's Secretariat	Satisfaction: According to the investigations of the Secretariat of the Council, some medical centers advertised their connection and the provision of electronic services as an achievement and tried to use these facilities (3). Great reduction of in-person visits to the offices and agencies of the Social Security Organization and the offices of the Iran Health Insurance Organization (3). [a]
June 2021	Examining the nature of the files that are formed in the centers in terms of covering clinical information	Recording more financial information than clinical information. Many services are not included yet. Clinical measures are included in less than 20% of medical offices and hospitals, as well as in less than 40% of health centers and clinics. Regarding other cases, apart from the patient's identity information and financial and administrative data, a large part of the information is not included in the system in many centers (3) [d]
December 2021	Examining the necessary measures to obtain the AFTA security assessment certificate (security of production space and information exchange) on electronic prescription systems	Not completed: According to the director of the Statistics and Information Technology Management Center of the MoHME, the AFTA Strategic Center has explicitly declared the mentioned systems as lacking the necessary security. It takes between 6 and 12 months to achieve the desired security status, perform the necessary tests, and obtain the EFTA security certificate (3) [e]
2021	Examining the connection of centers to the health information exchange center	About one-sixth of the centers: This means that less than 30,000 centers (out of about 170,000 centers) are connected to the health information exchange center (3) [d]
March 2021	The efforts of the Food and Drug Administration to clarify and create a suitable platform for gathering information, monitoring the supply chain, managing the shortage of drugs and medical equipment, and eliminating the paths of corruption	Not clear (3) [a]
2021	Examining the problems of providers regarding the coding of electronic prescriptions	Insurance coding is not the same. In the current prescription, the codes used by the two insurance companies do not match each other, and there are overlaps with the health codings announced by the MoHME. Therefore, service providers are forced to send information for each insurance according to its data model and coding (3) [d]
2021	Due to their legal obligations, basic insurance organizations have implemented programs for reimbursement for electronic prescriptions.	Completed (3) [a]
2021	Execution of 400 operations and 90 services on the platform of the integrated health information exchange portal	Completed (3) [f]
2021	Compiling and communicating the coding of the electronic prescription to the beneficiaries	Completed (3) [f]
2021	Establishment of prescription writing in national first-class governmental hospitals and health centers	Completed (3) [f]
2021	Drafting of the privacy and data sharing regulations	Completed (3) [f]
2021	Compilation of the draft regulation of digital health systems	Completed (3) [f]

Abbreviations: MoHME, Ministry of Health and Medical Education; HIS, hospital information system; IRI, Islamic Republic of Iran.

[a] The report of the Information Technology Implementation Council Secretariat regarding the enforcement status of the Council's approvals regarding electronic health; The second meeting of the rules and regulations task force of the Electronic Health Committee of the Islamic Council [December 4, 2021].

[b] Pathology report of the electronic health record, The confidential report of the Court of Accounts. 2018.

[c] Publication of the rules of the electronic version of letter No. 670/100. [June 20, 2020].

[d] Baitaraf, Ehsan. "Digital Health," Iran's Electronic Health Record Symposium; Academy of Medical Sciences. July 2021.

[e] Correspondence of the Head of the Statistics and Information Technology Management Center of the MoHME with the Minister of Health, letter No. 670/100. [June 20, 2020].

[f] Report of the Statistics and Information Technology Management Center of the MoHME regarding the enforcement of electronic health (e-health) laws and regulations. The third session of the Task Force on Rules and Regulations of the Electronic Health Committee of the Islamic Council [February 12, 2022].