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I.S. ENV 13607:2000

Health informatics - Messages for the exchange of information on medicine prescriptions

I.S. ENV 13607:2000

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EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

ENV 13607

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English version

Health informatics - Messages for the exchange of information on medicine prescriptions

This European Prestandard (ENV) was approved by CEN on 29 July 1999 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European Prestandard complies with the third edition of ISO/IEC Directives, part 3, 1997.

All annexes of this European Prestandard are informative.

Introduction

The use of data processing and telecommunications capabilities have made possible the interchange of information in machine-readable and machine processable formats. As automated interchange of information in healthcare increases, it is essential to provide appropriate information interchange standards.

Computer systems are now used by many healthcare persons for the storage and processing of information. Physicians, dentists, and veterinarians request, via a prescription message, that pharmacists dispense medicines and appliances for the treatment of patients/animals by a process commonly called ”prescribing”.

Standards are required to facilitate electronic transfer of prescription messages and reports between the many systems currently used. Information transferred in the prescription message and any reports passing between healthcare parties form part of the information system of each of the communicating parties. Electronic transfer of these prescription messages and reports reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

This standard requires medicinal products to be defined in a way that significantly reduces the risk of misinterpretation of issued prescription messages. The following should be particularly noted:

— Official names or titles of medicines should be used as they may otherwise be misinterpreted;
— The strength and quantity to be contained in capsules, lozenges, tablets, etc. should be stated;
— Instructions for use should describe precisely how and in which cases the medicinal product is used.

Health informatics - Messages for the exchange of information on medicine prescriptions

1 Scope

This European Prestandard specifies general messages for electronic information exchange between computer systems used by healthcare parties prescribing, dispensing or administering medicinal products/medicinal appliances[a)]. The content and structure of the messages specified in this European prestandard have been developed with the aim of optimising the safety of prescribing and dispensing and to facilitate compliance monitoring and secure audit trails.

Whenever medicinal products are mentioned within this European prestandard, medicinal appliances may be substituted if they serve similar purposes and can be represented in similar ways in a message as medicinal products.

This European prestandard is applicable to messages for electronic information exchange of prescription sets issued (i.e. prescribed) by healthcare persons (and possibly other persons who on this occasion act as healthcare persons) authorised by national regulations.

This European prestandard is applicable to messages for electronic information exchange of prescription sets sent by a prescriber to a dispensing healthcare party (dispensing agent) and to healthcare persons/organisations or official authorities as permitted by national regulation. This European prestandard is also applicable to messages for electronic information exchange of prescription sets sent by the prescriber to a relaying agent and from a relaying agent to a dispensing agent.

NOTE A relaying agent is a special Electronic Message Handling Service from where one and only one dispensing agent may retrieve any single prescription set; once only, upon the request of the party for whom the prescription message is issued or their agent.

This European prestandard is applicable to messages for electronic information exchange of prescription sets issued for single human patients, single animals, a group of animals, for personal use by the prescriber or for use at the prescriber's premises without specified end user. The categories for which any authorised prescriber may prescribe are regulated nationally.

This European prestandard specifies a message, **new prescription message,** for electronic prescribing of medicinal products/medicinal appliances sent from the prescriber to a dispensing agent, possibly via a relaying agent.

This European prestandard specifies messages for retrieval of a new prescription message temporarily stored by a relaying agent. This European prestandard specifies:

— **Prescription query message** querying if any or specified prescription set(s) exist for a single subject of care at a relaying agent matching a set of selection criteria**.** This message is sent from a dispensing agent to a relaying agent.
— **Prescription set list message** listing the prescription set(s) (and the contained prescription items) stored at a relaying agent in reply to a prescription query message. This message is sent from a relaying agent to a dispensing agent.
— **Prescription set selection message** for requesting a relaying agent to transmit new prescription message(s) referenced by one or more prescription set identifier(s). Identifiers are either obtained by a previous prescription query message/prescription set list message or supplied by the subject of care or animal carer without a previous query. The message is sent from a dispensing agent to a relaying agent who will respond by sending the new prescription messages identified by the prescription set selection message.

NOTE The above three messages always handle prescription sets as a whole, a single prescription item in a prescription set cannot be handled individually. Locally it may be agreed to allow only one prescription item per prescription set, thus permitting individual handling of prescription items.

[a)] Not all medicinal appliances can be prescribed, this will depend on local traditions, regulations, rules and coding schemes. Examples of suitable medicinal appliances are syringes, bandages, diagnostic kits, colostomy bags, diapers for incontinent persons.

This European prestandard specifies a message, **prescription dispensing report message,** containing information about prescription items in a prescription set as they have actually been dispensed (or not dispensed), normally in response to a new prescription message**.** This message may be sent from a dispensing agent to the original prescriber and/or to any other party that is legally permitted to receive such message

This European prestandard specifies two messages for cancelling a previously sent new prescription message or prescription dispensing report message:

— **prescription cancellation message** and
— p**rescription dispensing report cancellation message.**

For a number of reasons the end user may decide not to take delivery of some of the originally prescribed items. The handling of these non-delivered prescription items may require solutions best dealt with locally.

NOTE Depending on national legislation and available printing facilities the non-delivered part of a retrieved prescription set may be handed over (in paper form) to the subject of care or his/her representative or may be kept by agreement with the subject of care by the dispensing agent for later dispensing or (by local agreement) the dispensing agent may issue a new prescription message containing the non-delivered part of the prescription set (maintaining information about the original prescriber).

This European prestandard is applicable to repeat prescription messages. If permitted locally, new prescription messages containing repeat prescribing of prescription items, whether sent directly to a dispensing agent or via a relaying agent, may only, according to this European prestandard, be transferred to a dispensing agent in their entirety.

NOTE Non-delivered repeat prescribing of prescription items may be dealt with as non-delivered prescription items in general.

This European prestandard is applicable to the issue of new prescription messages carrying a first date for dispensing. Such messages may be used according to national regulations e.g. in countries where repeat prescribing is not allowed. The mechanisms and rules for checking and releasing these new prescription messages are outside the scope of this European prestandard.

When implementing information exchange based upon this European prestandard, data protection and confidentiality principles have to be guaranteed according to the laws actually in force in the different CEN member countries. The mechanisms needed to secure data integrity, data protection and confidentiality, authentication of communicating parties and patients are outside the scope of this European prestandard.

While the messages specified in this European prestandard may convey clinical and administrative information concerning patients, the way in which this information is treated in this European prestandard does not constrain the development of future standards for the electronic healthcare record or for other clinical and administrative messages.

The provisions of this European prestandard have been validated for the purposes described above. However, since the messages described in this European prestandard are designed for general application in prescribing, the users are required to decide for themselves whether or not these messages meet their particular requirements. A requirement for using other messages, e.g. generic messages for cancellation or acknowledgement, in addition to or instead of messages specified in this European prestandard, does not invalidate the use of this European prestandard.

This European prestandard is not applicable to messages related to medicinal product orders exchanged between pharmacies and medicinal product suppliers.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this European Prestandard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this European Prestandard are encouraged to investigate the possibility of applying the most recent editions of the normative documents below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.