



Electronic signatures on low risk clinical communications Guide to requirements

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Introduction

This document outlines methods of electronic signature considered appropriate for use with low risk clinical communications including referrals and requests for Medicare-funded services.

Disclaimer

The content of this guide is general information only and does not constitute legal advice, is not intended to be a substitute for legal advice and should not be relied upon as such. If you require legal advice or other professional advice about anything contained in or related to this guide, you should seek your own independent legal or other professional advice.

Scope

This Guide is intended for use with low risk clinical communications where the Australian Government is not the receiver of the communication.

Note that:

- Specific requirements apply to signatures on prescriptions and dispense records and these are not within the scope of this Guide.
- Referrals and requests relating to Medicare-funded services require a signature. Where the Commonwealth is not the receiver of the communication, this Guide may be used.

Guidance

Services Australia has guidance for electronic referrals and requests for Medicare-funded services:

<https://www.servicesaustralia.gov.au/organisations/health-professionals/subjects/referring-and-requesting-medicare-services>

This guidance states:

You must comply with the [Electronic Transactions Act 1999](#) when sending referrals and requests electronically between third parties. Section 10 has more information about electronic signatures.

Where an electronic communication is required by a law of the Commonwealth to be signed, the [Electronic Transactions Act 1999 \(Cth\)](#) will generally apply unless the law includes specific signature requirements.

The Agency's [Electronic Signatures Final Recommendations](#) (*Recommendations*) contains recommendations for signature methods for clinical communications, including referrals and requests for Medicare-funded services.

Guidance on how to apply these recommendations to low risk clinical communications follows below. Refer to the *Recommendations* for examples of low risk communications.

General

For low risk clinical communications, including referrals and requests for Medicare-funded services, the general approach described in the *Recommendations* is:

- The system ascertains the identity of the person signing the communication (the *Approver*) using a suitable authentication method chosen by the organisation that operates the system.
- The *Approver* must indicate their approval of the communication
- The *Approver's* name must be recorded in the communication
- The system must apply an *Organisational Seal* to the communication

An *Organisation Seal* is a digital signature generated with a credential that is trusted by the receiver of the communication and which identifies the organisation that applied the seal. A *NASH PKI certificate for healthcare provider organisations* is a widely trusted credential suitable for this purpose, but other credentials may be used by agreement with the receiver of the communication.

CDA Clinical Documents

The Agency's [CDA Package v1.0](#) specification gives technical requirements in Section 2.4 for including an *Organisation Seal* in the *eSignature* element of a package that contains a CDA clinical document.

The [Agency's Common Conformance Profile v1.7](#) has specific requirements in Section 2.4.8 for recording the approver of a clinical document in the *eSignature*. Whilst this section makes the recording of the name and identifier of the approver optional, to be a valid signature of an individual person, the name and identifier of the person are required. The identifier can be any identifier that the sender uses to identify the person.

HL7 V2 messages

There is no nationally agreed method for packaging a HL7 V2 message with an *Organisational Seal*. It is common for a clinical system to create an HL7 V2 message that includes the name of the *Approver* of the communication and for a secure messaging system to then apply an *Organisational Seal* to the HL7 V2 message.

Clinical systems must include the name of the *Approver* as specified in [Australian Diagnostics and Referral Messaging - Localisation of HL7 Version 2.4](#):

- As described in section 5.4.1.12 for observation orders
- As described in section 4.4.1.32 for observation reports
- As described in section 2.2.2.8 for referrals

Secure messaging systems apply the *Organisational Seal* to the HL7 V2 message using a *NASH PKI certificate for healthcare provider organisations* or another suitable credential. When different secure messaging systems interoperate, they must apply the seal in accordance with [ATS 5822-2010 E-health secure message delivery](#).

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Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000 digitalhealth.gov.au
Telephone 1300 901 001 or email help@digitalhealth.gov.au

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