



Standard Practice for Healthcare Certificate Policy¹

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1. Scope

1.1 This practice covers a policy (“the policy”) for digital certificates that support the authentication, authorization, confidentiality, integrity, and nonrepudiation requirements of persons and organizations that electronically create, disclose, receive, or otherwise transact health information.

1.2 This practice defines a policy for three classes of certificates: (1) entity certificates issued to computing components such as servers, devices, applications, processes, or accounts reflecting role assignment; (2) basic individual certificates issued to natural persons involved in the exchange of health information used for healthcare provisioning; and (3) clinical individual certificates issued to natural persons and used for authentication of prescriptive orders relating to the clinical treatment of patients.

1.3 The policy defined by this practice covers: (1) definition of healthcare certificates, healthcare certification authorities, healthcare subscribers, and healthcare relying parties; (2) appropriate use of healthcare certificates; (3) general conditions for the issuance of healthcare certificates; (4) healthcare certificate formats and profile; and (5) requirements for the protection of key material.

1.4 The policy establishes minimum responsibilities for healthcare certification authorities, relying parties, and certificate subscribers.

2. Referenced Documents

2.1 ASTM Standards:²

E2084 Specification for Authentication of Healthcare Information Using Digital Signatures (Withdrawn 2009)³

E2086 Guide for Internet and Intranet Healthcare Security (Withdrawn 2009)³

¹ This practice is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics, and is the direct responsibility of Subcommittee E31.25 on Healthcare Data Management, Security, Confidentiality, and Privacy.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.

2.2 Other Documents:

Public Law 104-191, Aug. 21, 1996, Health Insurance Portability and Accountability Act of 1996⁴

RFC 2527—Internet X.509 Public Key Infrastructure Certificate Policy and Certification Practices Framework, PKIX Working Group Internet Draft, January 3, 2002⁵

RFC 2560—Internet X.509 Public Key Infrastructure Online Certificate Status Protocol, OCSP, June 1999⁶

3. Terminology

3.1 *Certificate and Related Terms*—A certificate, also referred to as a digital certificate or public key certificate, binds a public key value to information identifying the entity associated with the use of a corresponding private key. An entity may be an individual, organization, account, role, computer process, or device. The entity identified within the certificate is referred to as the certificate subject. The certificate is typically used to verify the digital signature of the certificate subject or to encrypt information for that subject. The reliability of the binding of a public key to a certificate subject is asserted by the certification authority (CA) that creates, issues, and distributes certificates. Certification authority is synonymous with certificate authority. Parties that depend on the accuracy of information in the certificate are referred to as relying parties. Certificate users are the collective relying parties and subscribers.

3.2 Certificate Policy:

3.2.1 The X.509 standard defines a certificate policy (CP) as “a named set of rules that indicates the applicability of a certificate to a particular community and/or class of application with common security requirements.” For example, a particular certificate policy might indicate the type of certificate applicable for authenticating electronic data interchange transactions for the trading of goods within a specified price range. In contrast, Practice E2212 addresses rules for certificates that support the authentication, authorization, confidentiality, integrity, and nonrepudiation requirements of persons and organizations that electronically create, disclose, receive, or otherwise transact health information.

⁴ Available at <http://aspe.hhs.gov/admsimp/pl104191.htm>.

⁵ Available at www.ietf.org/html.charters/pkix-charter.html.

⁶ Available at <http://www.ietf.org/rfc/rfc2560.txt>.