



Federal Regulations for the Electronic Prescribing of Controlled Substances

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[Certain content omitted from public version of this document]

Outline

- Overview of EPCS processes under the DEA regulations
- The relevant details
 - Requirements for the Provisioning of physicians who will prescribe controlled substances
 - Prove identity
 - Get two-factor authentication token
 - Verify authority to prescribe controlled substances
 - Set access privileges in EHR to prescribe controlled substances
 - Requirements for the Prescribing of controlled substances
 - Prepare prescriptions
 - Review/approve prescriptions
 - Electronically sign prescriptions
 - Monitor EPCS activity

Federal Regulations (“the source”)

- *Interim Final Rule on Electronic Prescriptions for Controlled Substances (“IFR”)*
 - www.gpo.gov/fdsys/pkg/FR-2010-03-31/pdf/2010-6687.pdf
- Clarifications to IFR
 - https://www.deadiversion.usdoj.gov/fed_regs/rules/2011/2011-26738-epcs-101411.pdf
- Other federal requirements included by reference
 - <http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-63-1.pdf> (Identity proofing)
 - <http://csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf> (Two-Factor Authentication Tokens)
- FAQ for prescribing practitioners
 - https://www.deadiversion.usdoj.gov/ecommm/e_rx/faq/practitioners.htm

Federal Regulations (“the source”)

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of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

§ 1311.105 Requirements for obtaining an authentication credential—Individual practitioners.

(a) An individual practitioner must obtain a two-factor authentication credential from one of the following:

(1) A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800-63-1 as incorporated by reference in § 1311.08.

(2) For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.

(b) The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority.

(c) The credential service provider or certification authority must issue the authentication credential using two

institutional practitioner (e.g., a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:

(1) Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.

(2) Ensure that the individual practitioner's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.

(3) Either ensure that the individual practitioner's DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under § 1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner's DEA registration number.

(4) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401-7408.

(5) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the

authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner's general obligation to maintain effective controls against diversion. Failure to meet this obligation may result in remedial action consistent with § 1301.36 of this chapter.

(e) An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing. An institutional practitioner that elects to issue the two-factor authentication credential must retain a record of the issuance of the credential.

§ 1311.115 Additional requirements for two-factor authentication.

(a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:

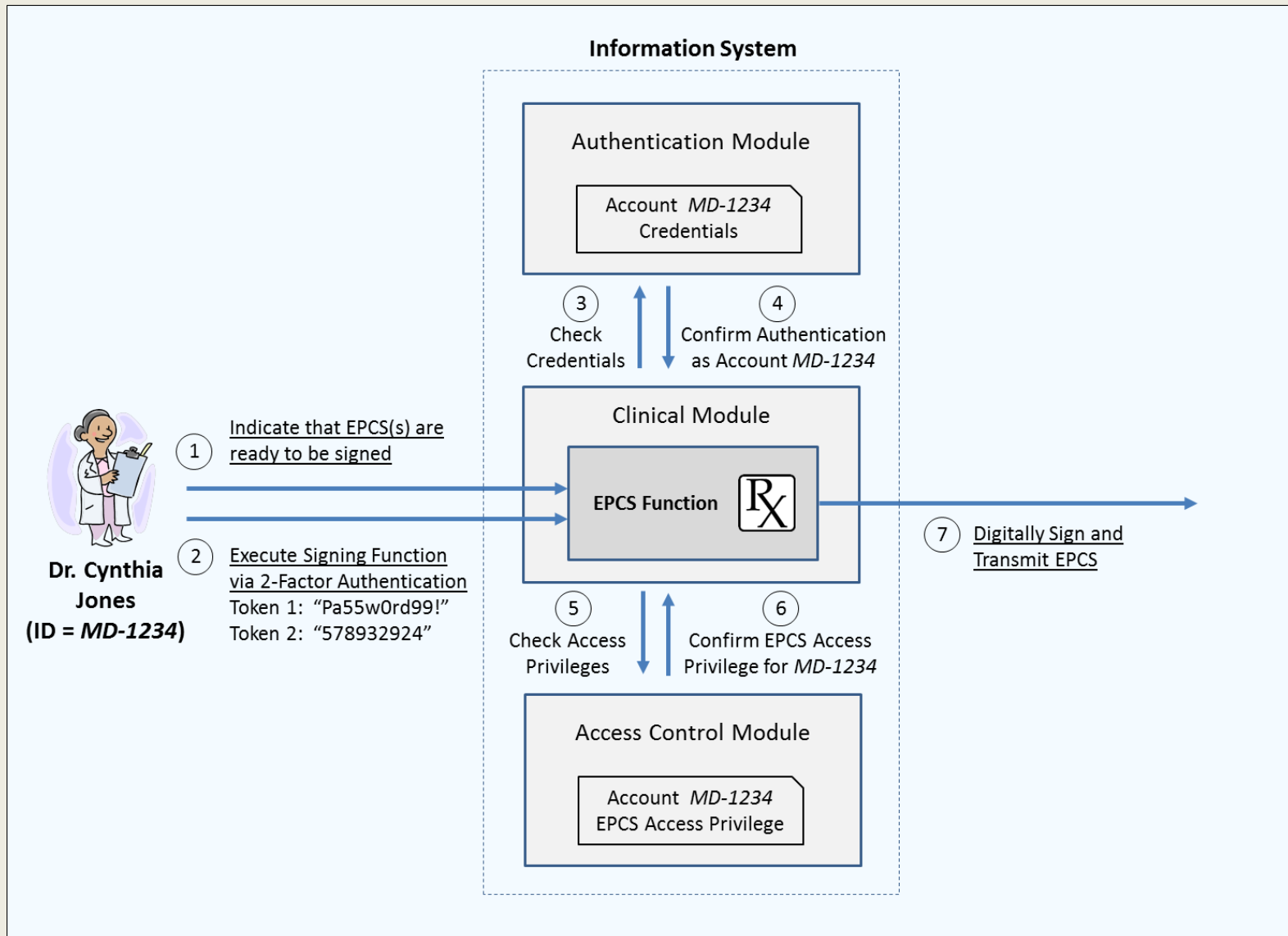
(1) Something only the practitioner knows, such as a password or response to a challenge question.

(2) Something the practitioner is, biometric data such as a fingerprint or iris scan.

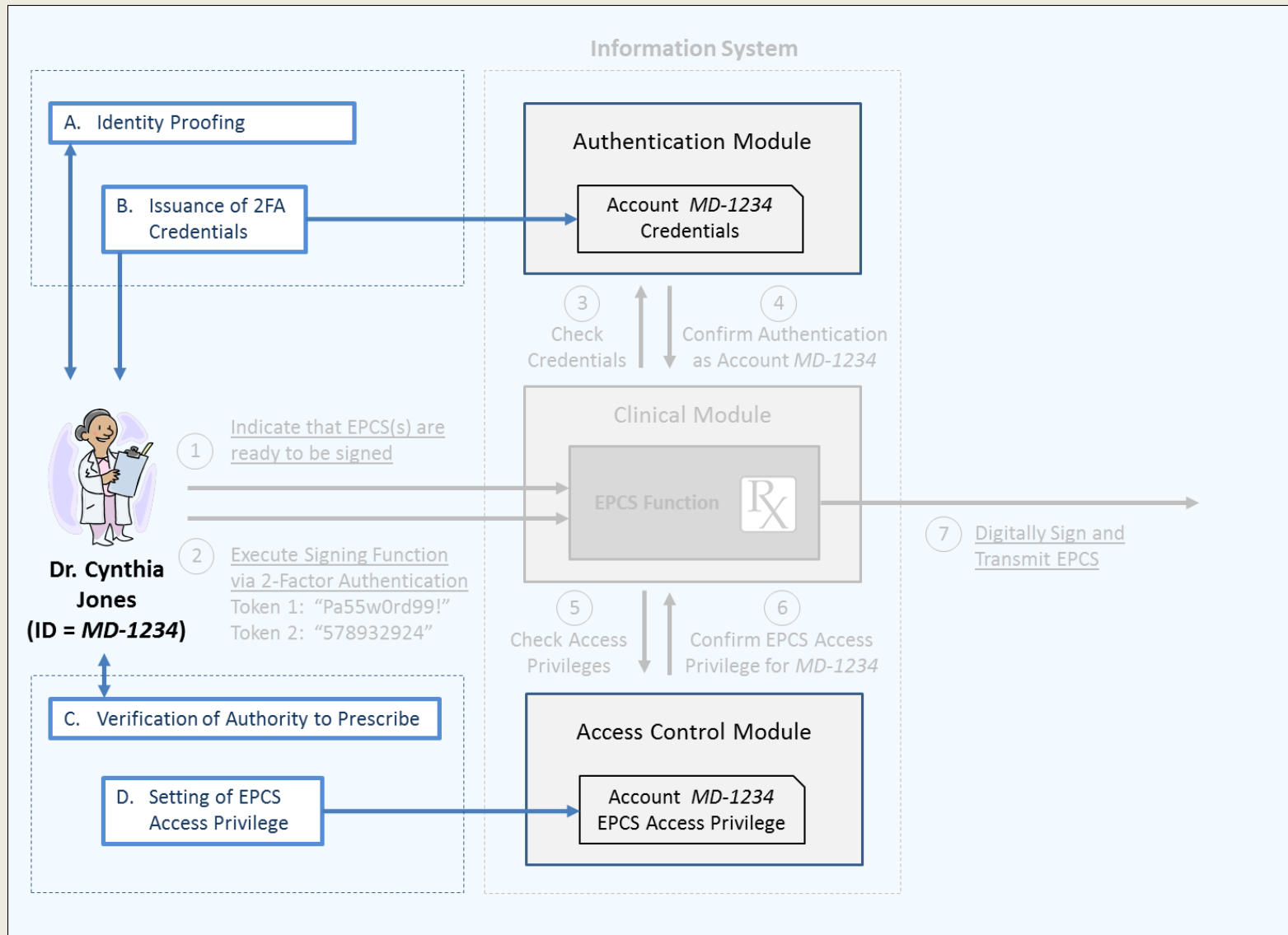
(3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

(b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140-2 Security Level 1, as incorporated by

Federal Requirements for EPCS – Prescribing



Federal Requirements for EPCS – Provisioning



IFR Specifies Two Alternative Paths to Provision Providers for EPCS

“Institutional Practitioner”

- Provider must work at a clinic/practice that is a DEA registrant
- Staff at clinic identity-proof the provider and issue 2FA credentials
- Staff at clinic verify provider’s EPCS authority
- Staff at clinic configure provider’s access controls for EPCS

“Individual Practitioner”

- Provider is a DEA registrant (may or may not work at a clinic that is also a DEA registrant)
- An authorized 3rd party identity-proofs the provider
- An authorized 3rd party issues 2FA credentials
- Staff at clinic verify provider’s EPCS authority
- Staff + DEA registrant at clinic configure EPCS access

Two-Factor Authentication

- Authentication by providing two separate forms of “proof” that the user owns the account.
 1. “Something you know” (password)
 2. “Something you have “ (2FA token or biometric pattern)

- SecureID device



- Smartphone

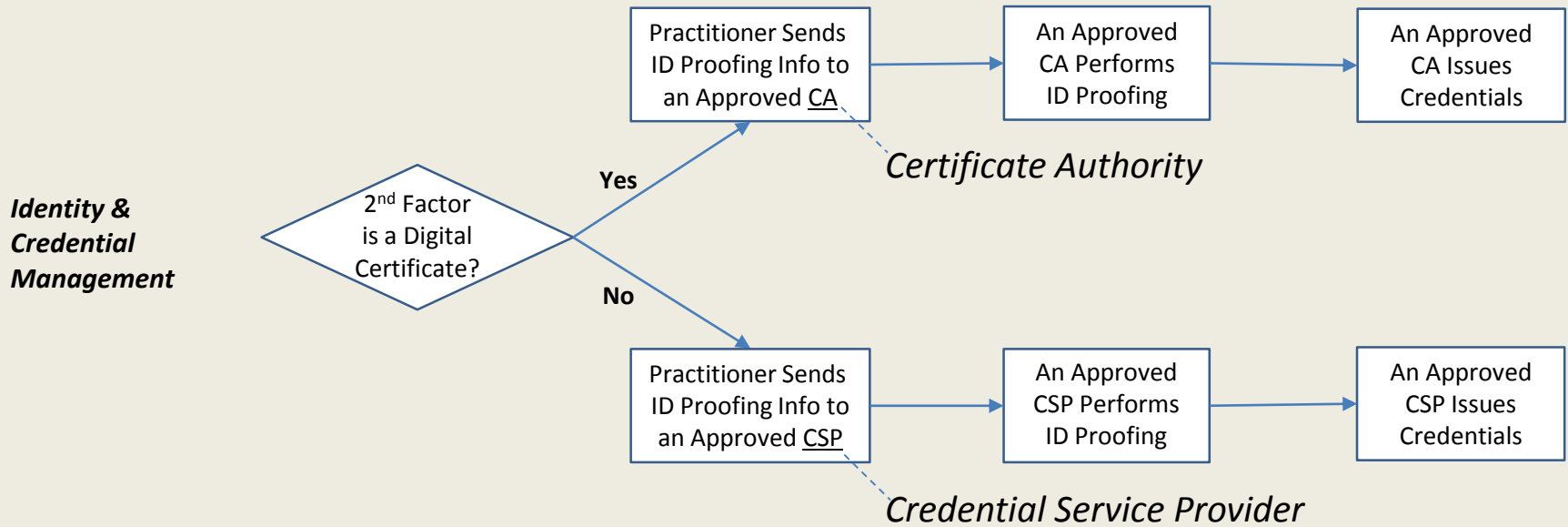


- USB Token



Identity Proofing and Issuance of 2FA Credentials

Again Two Possible Paths!



Comments

Any CA or CSP used for ID proofing and/or issuance of credentials must be approved or certified with respect to certain criteria specified in the IFR

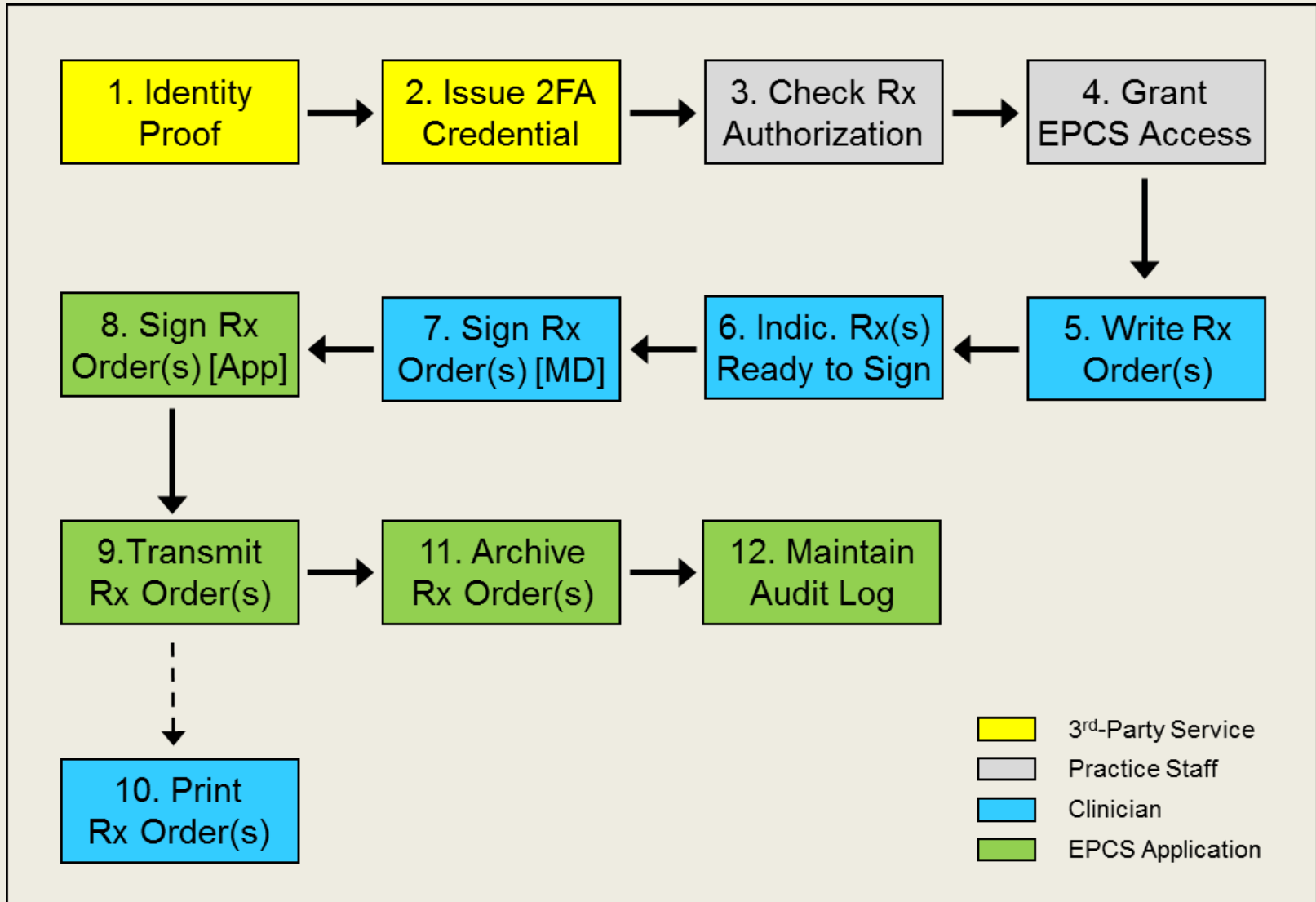
The CA or CSP must conduct ID proofing at NIST SP 800-63-1 assurance level 3 or above

The CA or CSP must issue the 2-factor authentication credentials via a combination of two separate communication channels

Identity Proofing at NIST Level of Assurance 3

Level 3		In Person	Remote
Basis for issuing credentials		Possession of verified current primary Government Picture ID that contains Applicant's picture and either address of record or nationality of record (e.g., driver's license or passport)	Possession of a valid Government ID (e.g., a driver's license or Passport) number and a financial or utility account number (e.g., checking account, savings account, utility account, loan or credit card) confirmed via records of both numbers. Note that confirmation of the financial or utility account may require supplemental information from the applicant.
RA and CSP actions		<p>RA inspects photo-ID and verifies via the issuing government agency or through credit bureaus or similar databases. Confirms that: name, DoB, address and other personal information in record are consistent with the application. Compares picture to Applicant and records ID number.</p> <p>If ID is valid and photo matches Applicant, then:</p> <ol style="list-style-type: none"> a) If personal information in records includes a telephone number, the CSP issues credentials in a manner that confirms the ability of the Applicant to receive telephone communications at a number associated with the Applicant in records, while recording the Applicant's voice or using alternative means that establish an equivalent level of non-repudiation; or b) If ID confirms address of record, RA authorizes or CSP issues credentials. Notice is sent to address of record, or; c) If ID does not confirm address of record, CSP issues credentials in a manner that confirms the claimed address. 	<ul style="list-style-type: none"> • RA verifies information provided by Applicant including ID number AND account number through record checks either with the applicable agency or institution or through credit bureaus or similar databases, and confirms that: name, DoB, address and other personal information in records are consistent with the application and sufficient to identify a unique individual. For utility account numbers, confirmation shall be performed by verifying knowledge of recent account activity. (This technique may also be applied to some financial accounts.) • Address confirmation: <ol style="list-style-type: none"> a) CSP issues credentials in a manner that confirms the ability of the applicant to receive mail at a physical address associated with the Applicant in records; or¹⁴ b) If personal information in records includes a telephone number, the CSP issues credentials in a manner that confirms the ability of the Applicant to receive telephone communications at a number associated with the Applicant in records. CSP records the Applicant's voice or using alternative means that establish an equivalent level of non-repudiation.

Verification of Prescribing Authority and Setting of EPCS Access Privileges





Thank you

Questions? Email inquire@sujansky.com