

## Questions & Answers

### Electronic Prescriptions for Controlled Substances (EPCS)

**Question:** During the COVID-19 public health emergency, may DEA-registered hospitals/clinics conduct remote identity proofing of individual practitioners eligible to use the hospital/clinic's electronic prescription application to sign prescriptions for controlled substances?

**Answer:** Yes, DEA regulations generally authorize the use of remote identity proofing when issuing authentication credentials for use in the electronic prescribing of controlled substances (EPCS), even in the absence of a public health emergency. If a hospital/clinic wishes to conduct remote identity proofing, DEA suggests using a device that allows for real-time, two-way, audio-visual interactive communication.

DEA regulations require individual practitioners engaged in EPCS, including individual practitioners working under the DEA registration of a hospital or clinic pursuant to 21 CFR 1301.22(c), to obtain an authentication credential and use that credential to electronically sign prescriptions for controlled substances. See, e.g., 21 CFR 1311.120, 1311.140. A hospital, clinic, or other institutional practitioner may obtain the necessary authentication credentials for individual practitioners eligible to use the institution's EPCS application in either of two basic ways.

First, the hospital/clinic may elect to conduct its own in-house identity proofing as part of its credentialing process of these individual practitioners and itself authorize the issuance of the authentication credentials. If an institutional practitioner chooses to conduct its own internal identity proofing, DEA regulations require that process to meet a number of specific requirements. See 21 CFR 1311.110. DEA regulations, however, do not require that this process occur in-person. Thus, if the hospital/clinic is able to remotely conduct identity proofing in a manner that satisfies these DEA regulatory requirements, it may do so.

Second, rather than conducting its own identity proofing, a hospital/clinic may require practitioners to obtain identity proofing and authentication credentials in the same manner as practitioners not operating under an institution's DEA registration, *i.e.*, through a credential service provider (CSP) or certificate authority (CA). See 21 CFR 1311.105. DEA regulations require CSPs and CAs to conduct identity proofing at Assurance Level 3 or above of the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-63-1, "Electronic Authentication Guideline," which allows either in-person or remote identity proofing. (Since those regulations were published,

changes in technology have led to the creation of new, updated NIST guidelines, NIST SP 800-63-3, "Digital Identity Guidelines." Under NIST SP 800-63-3, the relevant identity proofing assurance level is Identity Assurance Level 2. Identity Assurance Level 2 of NIST SP 800-63-3, like Assurance Level 3 of NIST SP 800-63-1, allows either in-person or remote identity proofing).

Thus, DEA regulations generally allow hospitals and clinics (as well as CSPs and CAs) to remotely conduct the identity proofing necessary to issue EPCS authentication credentials to individual practitioners. A DEA registered hospital/clinic may also want to check with their state regulatory boards to maintain compliance with any state rules or regulations regarding this matter.

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