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Health Law Diagnosis

E-PRESCRIBING

In March of 2010, the Drug Enforcement Administration ("DEA") published an Interim Final Rule that set forth rules for electronic prescriptions ("eRX") of all controlled substances. Previously, only written prescriptions, and in certain circumstances, oral and facsimiles, could be issued for controlled substances. Although the Interim Final Rule does not replace the existing provisions of the Controlled Substances Act, 21 C.F.R. § 1306, or accompanying rules, it gives practitioners the option of writing eRX for controlled substances in addition to written, oral or facsimiles of written prescriptions. State laws and regulations governing written and electronic prescriptions of controlled substances will also still apply.[1] Effective June 1, 2010, provided all of the applicable requirements have been met, controlled substances generally may be prescribed and dispensed as follows:

- **Schedule II** through written and electronic prescription; by oral prescription in an emergency only, followed by written or electronic prescription; or by facsimile of a written prescription in an emergency only, followed by written prescription (exceptions apply, such as long-term care facilities);

- **Schedule III through V** through written, electronic, oral and facsimile prescriptions.

Software used for eRX must be appropriately **certified or audited** as compliant with the Interim Final Rule requirements before it can be used for controlled substances. Hospitals must therefore request and obtain certificates or reports from their application vendor prior to implementing and using the eRX solution. Additionally, the following are also key mandates for eRX of controlled substances:

- Requirements for **creation, review, signing** and **transmission of** eRX (Note, an agent of a practitioner may prepare an eRX as they would a written prescription prior to the practitioner's reviewing and digitally signing the eRX);

- **Two-step identity proofing** through the hospital or a certification authority (CA) or credential service provider (CSP) that provides a digital certificate or credential with the two-factor authentication required to digitally sign eRX (A hospital can in the alternative

[1] Note that New Jersey permits an eRX to serve as the "original signed prescription" where federal law would permit an eRX to serve as the original signed prescription. N.J.A.C. 13:35-7.4A(g); 13:39-7.11(h).

require a practitioner to obtain identity proofing and authentication credentials on his or her own before granting access to the hospital eRX system);

- **Two-factor authentication** requiring two out of three authentication factors: biometric (e.g., fingerprint, iris scan), knowledge (e.g. password, response to question) or hard token (e.g., smart card, USB token) for digitally signing eRX;

- **Logical access controls** restricting who and what type of access to the eRX system is permitted;

- **Auditing** of specific events and maintenance of audit trails and audit logs.

Additionally, multiple eRX for a single patient (but not multiple patients) may be signed by one digital signature and a delay is permitted after the digital signing of the eRX before actual transmission. A copy of an eRX may also subsequently be printed out (for example, for a patient), provided that it clearly indicates that it is a copy, for informational purposes only, and not for dispensing. Practitioners may also use a non-compliant eRX application or EHR to prepare a prescription for a controlled substance and print it out for written signature. There are also specific requirements regarding archiving and recordkeeping, notifications for loss or theft of hard tokens or security incidents, and security, as well as requirements for application vendors and pharmacies.

Final Rule is still awaited from the DEA. For additional information, the Interim Final Rule for E-Prescribing is available in HTM and PDF format on the DEA's website at http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.htm.

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Attorneys at Oscislawski LLC is a health law firm with its main office located in Princeton, New Jersey but a nationwide reputation for experience with and understanding of federal and state privacy and security laws, as well as electronic health information exchange, health information technology, and managing health data breaches. Our attorneys also advise clients on wide-range of other legal issues. For more information about our firm visit www.oscislaw.com. ***For excellent compliance information, tools and solutions, please also visit our affiliated blog & resource website*** *www.legalhie.com.*