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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-364]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: DEA is announcing a new DEA-approved certification process for Electronic Prescriptions for Controlled Substances (EPCS). Certifying organizations with a certification process approved by DEA pursuant to 21 Code of Federal Regulations (CFR) 1311.300(e) are posted on DEA's website once approved.

FOR FURTHER INFORMATION, CONTACT: Alan G. Santos, Associate Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

The Drug Enforcement Administration (DEA) is a component of the Department of Justice and is the primary agency responsible for coordinating the drug law enforcement activities of the United States. DEA also assists in the implementation of the President's National Drug Control Strategy. The Diversion Control Program (DCP)

is a strategic component of the DEA's law enforcement mission. It is primarily the DCP within DEA that implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended (hereinafter, "CSA").[1] DEA drafts and publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. The CSA together with these regulations are designed to establish a closed system for controlled substances and to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

The CSA and DEA's implementing regulations establish the legal requirements for possession and dispensing of controlled substances, most notably pursuant to a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). A prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a

[1] The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

pharmacy have been dispensed legally. The maintenance by pharmacies of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress.

Electronic Prescriptions for Controlled Substances (EPCS)

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA recently amended its regulations to provide practitioners with the option of issuing electronic prescriptions for controlled substances (EPCS) in lieu of paper prescriptions. Efforts to develop EPCS have been underway for a number of years. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236-16319, and became effective on June 1, 2010. While these regulations have paved the way for controlled substance prescriptions to be issued electronically, not all states have authorized electronic prescriptions for controlled substances, particularly Schedule II controlled substances, which have a significant potential for abuse.

Update

All certifying organizations with a certification process approved by DEA pursuant to 21 CFR 1311.300(e) are posted on DEA's website once approved.

As noted above, the Interim Final Rule provides that, as an alternative to the audit requirements of 21 CFR 1311(b) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR Part 1311 by a certifying organization whose certification process has been approved by DEA.

The preamble to the Interim Final Rule further indicated that, once a qualified certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such information will be posted on DEA's website. 75 FR 16243, March 31, 2010. On May 22, 2012, DEA approved the certification processes developed by Drummond Group and by iBeta LLC. iBeta's approved certification process is limited to the certification of the biometrics subsystem, including its interfaces, to the requirements of the overall regulations and specifically to those in 1311.116. Relevant information has been posted on DEA's website at http://www.DEAdiversion.usdoj.gov.

Dated: July 25, 2012

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Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

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