Additional BNDD Guidance on Controlled Substance Electronic Prescribing

Electronic prescribing may be performed in accordance with the DEA rules in Title 21 Code of Federal Regulations §1306.08 and §1311.100 through §1311.305.

The BNDD is including the following information in the next Missouri Board of Pharmacy Newsletter, coming out later this week:

1. The previous forms of transmission (writing, telephoning, and faxing) are still permitted where applicable.
2. The option of electronic prescribing is a new voluntary option and is not mandatory or required.
3. The new federal rules were effective June 1, 2010. Missouri registrants may begin when they have met all the federal guidelines. Missouri will not be implementing additional requirements.
4. Prescriptions may be transmitted electronically in Schedules II, III, IV, and V.
5. There are certain requirements for practitioners, pharmacies, and hospitals. Practitioners will be focusing on security and manner of transmitting. Pharmacies will be focusing on security and archiving.
6. Not all providers may be ready at the same time. A doctor may be ready to transmit, but a local pharmacy may not be ready yet to receive. It will take some time for all parties to become authorized.
7. There are medical software companies that may have an approved system in place. These companies are called “application providers.” They will have their new systems audited and reviewed by a third-party independent company. Once they have received clearance from the auditing company, these application providers will receive authorization and a certificate to begin implementing their software and hardware systems. There are similar software companies for pharmacies. These software providers and application providers cannot implement their systems until receiving approval.
8. Once the application provider has received a certificate and is authorized to begin, these providers may begin providing their systems to individual practitioners and pharmacies. The practitioners should receive a certificate from the software provider that shows they are an approved provider. These software providers may also provide the practitioners with a certificate that shows that the practitioners are authorized to electronically prescribe using their system.
9. What starts electronic must stay electronic. If a practitioner transmits an electronic prescription, it shall arrive at a pharmacy and then be stored and archived electronically. The practitioner cannot transmit a prescription and then have it printed to a pharmacy fax machine. A faxed prescription arrives on paper, and those require a physical and manual signature before the document is faxed.
10. Participating prescribers must undergo “identity proofing” before hitting the send/transmit button each time. Verification is required in order to ensure that the transmission of the prescription is from the proper registrant. There are three ways to verify identity, and prescribers will be required to provide any two of them:
   A. Something you know, e.g., a user ID or password;
   B. Something you are, e.g., a fingerprint scan or retina eye scan; and
C. Something you have, e.g., a USB device to be inserted or smartcard to swipe.
11. A prescription gets filled out with all of the information required. The prescriber must undergo two of the identity checks above before transmitting. An assistant or employee may hold an electronic device and prepare it; however, only the registered practitioner with proper identity may transmit it. The completion of the two-factor identity code is considered part of the signature.
12. A digitally scanned in signature or a follow-up is not considered an acceptable method of identity proofing.
13. Prescriptions can only be transmitted for one patient at a time.
14. Prescriptions must be transmitted as soon as possible after identity proofing/signature.
15. If any prescription data/record is printed after transmission, the document must be labeled “COPY ONLY – NOT VALID FOR DISPENSING.”
16. If the transmission fails, the prescriber must be notified that the transmission failed. Then, the prescription may be printed out for manual signature. The prescription must document that the initial prescription was electronic, the name of pharmacy, date, and time.
17. Controlled drug records must be maintained for two years.
18. Pharmacies have controls on who is allowed to access and retrieve data. Any changes or annotations must also be electronic. Receipt of a prescription is documented electronically.
19. Pharmacy records must be backed up daily and retained electronically.