

Electronic Signatures and Valid Prescriptions

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With the recent increase in physician practices using electronic office management and electronic record systems, we are getting an increased number of questions about “*what is a legitimate prescription*”.

North Dakota Administrative Code (NDAC) Chapter 61-04-06 – Prescription Requirements, subsections 02 and 03,

<http://www.legis.nd.gov/information/acdata/pdf/61-04-06.pdf> require that a hard copy prescription form contain the prescriber’s name, either printed or stamped **and** the signature of the prescriber. This signature should be the same signature as the prescriber would use when signing a check or other document. Thus, the rule requires that written, typed, or printed prescriptions given to the patient be signed by the prescriber. That means the prescriber takes pen in hand and physically signs the prescription. Rubber stamps, signature by a nurse or any other office personnel, for the prescriber and computer-generated or e-signatures are all examples of illegal signatures, when affixed to a hard copy prescription given to the patient. A hard copy prescription given to the patient that is “signed” in one of these ways is an illegal prescription and may not be filled as presented. If the prescription is for anything except a Schedule II Controlled Substance, the pharmacist may, of course, take a verbal order from the prescriber or the prescriber’s designated nurse. Under **no** circumstances should a prescription presented to a pharmacist by a patient that has one of the illegal signatures mentioned above be filled without contacting the prescriber or their nurse for a valid authorization. A Schedule II prescription with an illegal signature is not valid and must be re-written by the prescriber. This signature requirement applies to all paper prescriptions given to a patient or written and faxed by the prescriber, whether handwritten, typed, or computer generated. The prescriber must physically sign these prescriptions.

The DEA has issued a rule, effective June 1st, 2010, permitting electronic prescriptions for controlled substances in schedules II - V. A true electronic prescription is transmitted as an electronic data file to the pharmacy, whose application imports the data file into its database, where it is electronically stored. Prescribers will be required to obtain authorization credentials, which will be two-factor. Two-factor authentication requires two of the following: something you know (a password), something you have (a hard token), or something you are (biometric identification). Prescriber e-prescribing software and pharmacy dispensing software must be certified prior to being used.

Prescriptions generated by an electronic prescribing system and transmitted from the prescriber’s computer directly to the pharmacy fax machine will not have a manual signature. No paper prescription is generated by the prescriber, so there is nothing to sign. Depending on the system used by the prescriber, the electronically generated prescriptions may have a computer-generated signature or a printed name where the signature would be and a statement saying this is an electronic signature or “e-signature.” This is considered a valid prescription under North Dakota Law for non-

controlled substances. The exception here is for prescriptions for Schedule III, IV, and V Controlled Substances. The DEA considers these written prescriptions and requires the prescriber to manually sign the prescription for it to be valid. In this case, the pharmacy may take a verbal order from the prescriber or the prescriber's designated nurse, or the pharmacy may fax the prescription to the prescriber for the prescriber to manually sign and return by fax or mail. Of course, all prescriptions must contain all of the elements listed in NDAC Chapter 61-04-06-03 <http://www.legis.nd.gov/information/acdata/pdf/61-04-06.pdf>, if it is for a controlled prescription.

Additionally, keep in mind that if you write, type, or print out a prescription and fax it to the pharmacy and subsequently hand it to the patient, that patient now has two valid prescriptions which they can get filled. This could be a serious source of diversion of controlled substances and as a general rule should not be done.

Specific examples include:

Non-Controlled Substance

Patient presents hard copy of prescription

- Must be manually signed to be valid.
- If signed in another form (digital signature, rubber stamp, nurse's signature, e-signature, etc.), must contact the prescriber or their nurse for valid authorization

Prescription faxed from prescriber's office to the pharmacy

- Valid if signed with e-signature, digital signature, stamped signature, manual signature, etc.

LTC Prescription

- Valid if transmitted orally or via fax by a nurse and the name of the nurse, who is acting as the prescriber's agent, is included.

Schedules III, IV, and V

Patient presents hard copy of prescription

- Must be manually signed to be valid
- If signed in another form (digital signature, rubber stamp, nurse's signature, e-signature, etc.), must contact the prescriber or their nurse for valid authorization

Prescription faxed from prescriber's office to the pharmacy

- Must be manually signed to be valid under DEA law

LTC Prescription

- Must be manually signed to be valid under DEA law
- Valid if the nurse transmitting the prescription orally or via fax has been designated by the prescriber as their agent and that nurse's name is recorded.
- If signed in another form (digital signature, rubber stamp, nurse's signature, e-signature, etc.), must contact the prescriber or their nurse for valid authorization
- Once valid authorization is received, may consider order an oral prescription.

Schedule II

Prescription must be manually signed and pharmacy requires hard copy of prescription, except in those cases outlined in N.D.C.C. 19-03.1-22(1) and (2), such as when the patient is a hospice patient or resides in a licensed Long-term care facility and the prescription has been signed by the practitioner before faxing, the facsimile may serve as the original prescription without another signature.

Not valid if transmitted orally, except in a true emergency and then only by the prescriber directly, (no agent is allowed to phone in an emergency prescription).

Valid if transmitted electronically from a certified e-prescribing software to a certified pharmacy dispensing system.

Brand Medically Necessary Prescriptions NDCC 19-02.1-14.1 (3)

<http://www.legis.nd.gov/cencode/t19c02-1.pdf>

This is a special law intended to save money by being absolutely sure that the prescriber wants a particular manufacturer's product, because s/he has determined that others will not work well for the patient.

- Therefore: Oral prescriptions directly from the prescriber may be recorded by the pharmacist as "Brand Medically Necessary" and dispensed as such;
- Prescriptions transmitted through a true electronic process where the prescriber checks a box to specify substitution is not permitted and enters Brand Medically Necessary in a notes field, which is a field that cannot be changed by the pharmacy, may be dispensed as such.
- All other prescriptions must contain the hand written words, Brand Medically Necessary and be hand signed by the prescriber.

If you have any questions, contact the Board of Pharmacy – 701-328-9535 or email mhardy@ndboard.pharmacy

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