



April 6, 2011

Albert Linggi, Chair
Susan T. Boyer, Executive Director
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Washington State Board of Pharmacy

Dear Sirs and Madam:

We're writing in response to the following article in the April Board of Pharmacy Newsletter:

No. 1064 Requirements of a Faxed Prescription

A prescriber must sign all faxed (facsimile) prescriptions (legend drugs and controlled substances) before faxing it to the pharmacy. Failure to obtain the prescriber's signature often occurs when a pharmacy faxes a refill request to a prescriber and the agent of the prescriber faxes back an authorization without the prescriber's signature. This violation may also occur when someone at an extended care facility takes a verbal order from the prescriber, reduces it to writing, and faxes a copy of the order without the prescriber's signature to the pharmacy. Pharmacies can avoid these violations by having the prescriber or the prescriber's agent phone the prescriptions to the pharmacy. **Note:** Only the individual practitioner may phone in emergency Schedule II prescriptions (WAC 246-870-050 and 21CFR1306.11 & 21).

This article conflates concerns expressed by the DEA for controlled substances with procedures for issuing prescriptions, refill authorizations, or other clarifications for legend drugs. This article misstates the requirements of the relevant regulations, and overturns long-standing practices regarding legend drugs. This new interpretation could create significant problems for pharmacists who are subject to audits, and who have acted in good faith with repeated advice from Board staff to treat fax communications generally as if they were telephone calls. It also introduces restrictions on long-term care settings that are novel and not supported by statute or rule. A careful analysis of the Board's rules indicates that signatures of the prescriber are not required on faxes which communicate refills or other information relating to an already-prescribed drug, and that rules for "prescriptions" should not necessarily apply to "orders" in institutional settings.

I. Electronic transmission of prescription information requires a prescriber's signature on original prescriptions only

The Board is authorized by statute to promulgate rules regarding electronic transmissions of prescription information, and has exercised that authority. In doing so, it issued general requirements, but then explicitly issued a rule regarding faxes, which deals with the issue of signatures differently from the general rule. Neither the general rule nor the more specific fax rule requires a signature for communicating refill information.

RCW 69.41.010(10) defines electronic communication of prescription information as follows:

(10) "Electronic communication of prescription information" means the communication of prescription information by computer, or the transmission of an exact visual image of a prescription by facsimile, or other electronic means for original prescription information or prescription refill information for a legend drug between an authorized practitioner and a pharmacy or the transfer of prescription information for a legend drug from one pharmacy to another pharmacy.

The Board is authorized under RCW 69.41.055 to adopt rules regarding electronic communication of prescription information. The Board has done so under WAC 246-870. The rule allows for digital or electronic signatures. The Board specified that electronic transfer of prescription information "... includes the transfer of original and refill prescriptions and the transfer of prescription information from one pharmacy to another pharmacy." (WAC 246-870-030) The Board did specify that "Transmission of original prescriptions must include ... [the] electronic, digital, or manual signature of the prescriber." In WAC 246-870-030 the Board also specified information needed for transfers of information between pharmacies. However, the Board did not specify any particular elements, including prescriber's signature, for communication of other information about a prescription, including refills authorized following transmission of the original prescription.

In WAC 246-870-050, the Board dealt specifically with fax machines. It said that orders *may be* faxed directly from the prescriber using facsimile devices when: the order contains the date, time, and telephone number and location of the transmitting device; and, when, if the prescription is for Schedule II, the prescription is signed by the prescriber. The rule also specifies that "refill authorizations for prescriptions may be electronically transmitted." Under the rule for faxes, only Schedule II faxes require a signature; the rule is silent on all other transmission types with regards to a prescriber's signature.

In WAC 246-870-090, the Board dealt with electronic mail. In this rule, the Board also distinguished between "information concerning an original prescription or information concerning a prescription refill."

II. Physicians may direct agents to communicate information on their behalf

Under the FDCA and most state laws, the oral communication of prescription information to a pharmacist by an agent of the prescriber has been a standard of practice since the enactment of the Durham Humphrey Amendments. However, this must be communication of prescribing

decisions for individual patients. The recent DEA policy on physicians' use of agents to communicate verbal prescriptions for Schedule III-V drugs states this quite clearly (as summarized by FDA Law Blog):

The Policy provides a discrete summary of "acts that an agent may take in connection with controlled substance prescriptions." It enumerates that:

1. An agent may "prepare a written prescription for the signature of the practitioner," provided the practitioner has "in the usual course of professional practice" made the necessary determinations regarding the legitimate medical need, and has specified the "required elements" of the prescription to the agent. (Emphasis added).
2. An agent may telephone a pharmacy concerning a prescription for a controlled substance in schedules III through V and convey the practitioner's otherwise valid oral prescription provided the prescriber has specified all required prescription information.
3. Where otherwise permissible to fax a controlled substance prescription to a pharmacy, the agent may do the actual faxing.

III. Long-term care regulations suggest that nurses should be able to fax verbal orders to pharmacies

The Board regulates pharmacy services to nursing homes under WAC 246-865-060. The very first mandate listed in this rule is that "There shall be provision for timely delivery of drugs and biological from a pharmacy so a practitioner's *orders* for drug therapy can be implemented without undue delay." (*Emphasis added*) The Board also mandates that pharmaceutical services are provided under policies and procedures developed by a pharmaceutical services committee. Note that the rule discusses "orders" and not "prescriptions;" these are terms of art indicating two different formats for prescribing drug therapy. The Board's regulations regarding electronic transmission do not deal with elements for "orders," but only with those for "prescriptions." The extended care facility rule specifies that "Drug orders shall be received only by a licensed nurse and administered only on the written or verbal order of a practitioner. Verbal orders shall be signed by the prescribing practitioner in a timely manner." (WAC 246-865-060(7)(e))

Current practice by pharmacist consultants and pharmacies serving nursing homes has been to receive faxes of prescribers' orders directly from the nursing home. Those that are verbal orders are clearly marked as such by the nurse taking the order. The pharmacist consultant is in a position to verify the order at the site during routine reviews, and can verify orders by contacting the prescriber's office if needed. However, the nurse receiving the order is in a much better position to act as the prescriber's agent. The Board treats orders differently from prescriptions in its hospital rules, and insisting on treating orders as if they were outpatient prescriptions in LTC settings is contradictory to its mandate to provide prompt provision of therapy to nursing home residents.

IV. The Board's interpretation is not in the public interest

The article recommends turning clearly communicated written information into verbal communication as a way to avoid violating alleged requirements for electronic transmissions. It suggests that an agent of the physician can only communicate orders by phone, which certainly restricts the agent to only one avenue of carrying out his or her prescriber's directives. It forces the substitution of verbal exchanges (prone to miscommunication and sound-alike mix-ups) for information that is in writing. We don't believe the Board can show a public interest that is served thereby – at least when controlled substances are not involved.

We request the Board recall the article and distribute a revision that deals only with controlled substances, and does not conflate nursing home drug orders with ambulatory prescriptions.

Regards,

A handwritten signature in black ink, appearing to read 'W E Fassett'.

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A handwritten signature in black ink, appearing to read 'J J Rochon'.

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