

JOINT REGULATORY STATEMENT

The State Medical Board of Ohio, the Ohio Board of Pharmacy and the Ohio Board of Nursing jointly issue the following statement:

Regarding the Use of Protocols to Initiate or Adjust Medications
February, 2003

This statement should not be construed as new policy, but rather, as an attempt to clarify existing law. Such clarification is intended for the benefit of practitioners and the public as a way to promote better understanding of the laws governing the practice of medicine and nursing.

It has been brought to our collective attention that protocols are being used often, and in a variety of settings, as a means to have unauthorized individuals initiate or adjust medications. **Only an authorized prescriber (a physician, a certificate to prescribe holder, or a pilot program APN) can initiate or adjust medications.** A list of approved nurse prescribers (CTP holders and pilot program APNs) is available on the Board of Nursing website at: www.state.oh.us/nur/AdvPractice.htm.

The Pharmacy Board rule on protocols (4729-5-01(K) and (L)(1)(2) O.A.C., *provided below*) permits reliance on protocols in **only 3 situations**:

1. Emergencies,
2. Administration of biologicals for the purpose of preventing diseases, and
3. Administration of vaccines for the purpose of preventing diseases.

For purposes of enforcing Rule 4729-5-01(K) and (L)(1)(2) O.A.C.:

(K) "Standing order" will mean the same as the term "protocol".

(L) "Protocol" is defined as:

- (1) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber as defined in rule 4729-5-15 of the Administrative Code and have been approved by the state board of pharmacy to be used by certified or licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or
- (2) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber as defined in rule 4729-5-15 of the Administrative Code and have been approved by the state board of pharmacy to be used by certified or licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases.

Protocols should not be confused with **preprinted orders**, which are permitted in inpatient settings by **Rule 4729-5-01(J) O.A.C.:**

(J) "Preprinted order" is defined as a patient-specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the O.A.C.

Protocols submitted for approval to the Pharmacy Board may be reviewed with the Medical Board or Nursing Board, as appropriate, prior to any approval by the Pharmacy Board.

A detailed list of frequently asked questions regarding the application of this rule follows, for your convenience.

Frequently Asked Questions Regarding Protocols

Q: When is it appropriate to use protocols?

A: A protocol may only be used in a true emergency, or for biologicals or vaccines administered to individuals for the purpose of preventing diseases. For all other situations, all orders must be patient-specific with well defined parameters for administration, and authorized by the prescriber prior to implementation. The parameters to be used include: (1) description of the intended recipients, (2) drug name and strength, (3) specific instructions of how to administer the drug, (4) dosage, (4) frequency, and (5) a signature of the authorized prescriber. The administration of drugs that are not patient-specific or authorized by the prescriber prior to implementation would be the unauthorized practice of medicine, which is a **felony** in this state.

Enforcing the appropriate use of protocols as described above is not intended to address or limit the practice of Certified Registered Nurse Anesthetists or Anesthesiologist Assistants administering anesthesia in accordance with statute and rule. This information is also not meant to disrupt the consultative agreement between pharmacist, physician and patient.

Q. What is an example of a "true emergency?"

A: For purposes of this rule, examples of "true emergencies" would be cases such as heart attacks, severe burns, cyanide poisonings, electrocutions, or severe asthmatic attacks. Examples of non-emergencies would be earaches, stomachaches, or infections.

Q. What is an example of a biological or vaccine administered to an individual for the purpose of preventing disease?

A: For purposes of this rule, examples of biologicals or vaccines administered to individuals for the purpose of preventing diseases would be flu vaccines, tetanus toxoids, hepatitis B vaccines, or PPD tuberculosis tests. Note that vaccines such as typhoid oral vaccine that must be taken over a several day time period cannot be dispensed by a nurse who is not authorized to prescribe. These drugs must be dispensed by an authorized prescriber to his or her own patients or by a pharmacist pursuant to a prescription.

Q: How should protocols be written?

A: The protocol from the authorized prescriber must:

- Specifically define the intended audience;

- List the drug name and strength of the product; and
- For the purposes of emergency protocols, give specific instructions on how to administer the drug, how much to administer, and how often the drug should be administered; for purposes of biologicals or vaccines, give specific instructions for the use of the drug.

In addition, the authorized prescriber must sign the protocol. The authorized prescriber may have a more detailed protocol or may word the protocol any way the authorized prescriber wishes as long as it contains the required details noted above.

For example, a protocol to be used an emergency situation might be:

"EPINEPHRINE 1:1000. When a patient has a severe allergic reaction or goes into anaphylactic shock as a result of an insect sting or a drug reaction, inject 0.3 ml SC. If necessary, may repeat this dose every 10-15 minutes no more than two times until appropriate medical care can be sought or until symptoms subside."

An example of a protocol to be used for biologicals or vaccines might be:

"FLU VACCINE. All patients, or patients at risk, will be offered the opportunity to receive this year's flu vaccine. The patient will first read and sign an information sheet which will be placed in the medical record. Once the document is understood and signed, the patient will receive an injection 0.5ml IM of the flu vaccine. All injections will be given in accordance with CDC guidelines."

Q: How does a non-prescriber adjust or initiate medications in an inpatient setting?

A: Pharmacy Board Rule 4729-5-01 O.A.C. addresses the adjustment or initiation of medications in inpatient settings through use of preprinted orders. A preprinted order is defined as a patient-specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the order. Preprinted orders may be used only for inpatients. Because the preprinted order is patient-specific and is prescribed by an authorized prescriber who has examined the patient, these are not protocols and are therefore appropriate for use in an inpatient facility.

Q: What is the difference between "dispense" and "administer"?

A: The Pharmacy Board defines "dispense" as "the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug." (4729-5-01 (B) O.A.C.) "Administer" is defined in the Revised Code as "the direct application of a drug, whether by injection, inhalation, ingestion, or any other means to a person or an animal." (3719.01(A) O.R.C.) To easily remember the difference between the two in practice, you may use this simplified distinction: "Administration" means "*here's a dose, take it NOW.*" "Dispensing" means "*here's a dose, take it LATER.*" "Dispensing" is limited to pharmacists and authorized prescribers. "Administration" may be performed by a nurse pursuant to the order of an authorized prescriber.

Q: May an authorized prescriber have certain drugs regularly available to give to a particular patient, employee or student?

A: Yes, an authorized prescriber may have stock drugs available for his or her use only, or to have available to give a direct order to a health care professional for administration to a particular patient, employee, or student, including prescription drugs. This occurs often in an occupational health or school setting. These drugs must be documented on a list. Prescription drugs in this list may include such items as antibiotics, non-steroidal anti-inflammatories (e.g. Naprosyn), and any other drug the authorized prescriber wishes to have available. No prescription drug may be purchased or stored at a site unless it is on this drug list. To store a drug at a site, an individual must be licensed to do so by the state Pharmacy Board.

Q. How should this list of drugs to be regularly stored on the premises be written?

A. A qualifying statement must precede the list and the list must be signed and notarized by an authorized prescriber.

An example of documentation of a list of drugs to be regularly kept on the premises might be:

"The drugs listed below will be purchased and stored at this facility for my use only or for use when I give a direct order to a health care professional to administer such drug to a specific patient."

<u>Drug Name</u>	<u>Strength</u>	<u>Dosage Form</u>	<u>NDC number</u> (on drug container)
Amoxil	500 mg	capsule	000029-6007
Atarax	10 mg	tablet	000049-5600
Bacteriostatic Sodium Chloride		solution	0333-08
Heparin Lock Flush		solution	0008-523
Naprosyn	500 mg	tablet	018930-0277
Neosporin		ointment	000081-0732
Ophthalmic Otobiotic Otic		solution	000085-0847

Q. Can the drugs on a list of drugs to be regularly stored on the premises be administered using protocols?

A. No, these drugs may not be administered using protocols, unless their use falls within one of the exceptions listed above. The administration must be patient-specific and authorized by the prescriber prior to implementation. To administer a listed drug using protocols would be the unauthorized practice of medicine, which is a **felony** in this state.

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