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JOINT REGULATORY STATEMENT
Regarding the Use of Protocols to Initiate or Adjust Medications
May 2014

This statement should not be construed as a 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, in a variety of settings, as a means to have unauthorized individuals initiate or adjust medications. **Only an authorized prescriber (Physician; Advanced Practice Registered Nurse with a certificate to prescribe; or Physician Assistant with a certificate to prescribe and physician delegated prescriptive authority and, if applicable, consistent with the policies of the health care facility) can initiate or adjust medications.** Advanced Practice Registered Nurses who hold a certificate to prescribe are listed on the Board of Nursing license verification website at: www.nursing.ohio.gov. Physician Assistants who hold a certificate to prescribe are listed on the Medical Board license verification website at: www.med.ohio.gov.

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

1. Emergencies;
2. Administration of biologicals for the purpose of preventing diseases;
3. Administration of vaccines for the purpose of preventing diseases;
4. Administration of vitamin K for the prevention of vitamin K deficient bleeding in newborns; and
5. Administration of erythromycin for prevention of ophthalmia neonatorum.

For the purposes of enforcing Rule 4729-5-01(K) and (L) 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.

(3) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering vitamin K for prevention of vitamin K deficient bleeding in newborns; or

(4) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering erythromycin for prevention of ophthalmia neonatorum; or

(5) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to

implementation. To be considered for approval by the board, the treatment guidelines must meet the following requirements:

(a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.

(b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

(i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;

(ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;

(iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;

(iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;

(vi) Can be performed without requiring the exercise of medical judgment;

(vii) Will lead to results that are reasonably predictable and safe;

(viii) Can be performed safely without repeated medical assessments;

(ix) If performed improperly, would not present a danger of immediate and serious harm to the patient.

A protocol may be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol.

Protocols submitted for approval by the state board of pharmacy may be reviewed with the appropriate health care related board prior to any approval by the state board of pharmacy.

Protocols should not be confused with **preprinted orders**, which are permitted in inpatient setting 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.

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

Frequently Asked Questions Regarding Protocols

Q1: 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, (5) frequency, and (6) 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, authorized prescriber and patient.

Q2: What about the October 2008 CMS memorandum concerning the use of "standing orders"?

A: The CMS policy interprets federal regulation 42 CFR 482.23(C)(2). The CMS policy is not fully consistent with Pharmacy Board Rule 4729-5-01, O.A.C. Because federal regulation 42 CFR 482.23(C)(2) includes the proviso that orders for drugs and biologicals must be in accordance with State law, orders for drugs and biologicals in the hospital setting in Ohio must be in compliance with Pharmacy Board Rule 4729-5-01, O.A.C.

According to Pharmacy Board Rule 4729-5-01(K), O.A.C., a "standing order" is a protocol that has been approved by the Pharmacy Board and which may only be used in an emergency situation or for the administration of biologicals or vaccines. A "standing order" is generally not applicable to the inpatient setting. However, Pharmacy Board Rule 4729-5-01(J), O.A.C. authorizes the use of a "pre-printed order" in the inpatient setting. A "pre-printed order" is a patient-specific, definitive set of drug treatment directives for use in the inpatient setting. To meet the requirements of Pharmacy Board Rule 4729-5-01(J), O.A.C., the patient must have been examined by the prescriber and the prescriber must have determined that the drug therapy is appropriate pursuant to the conditions set forth in the pre-printed order before the pre-printed order may be implemented.

Q3: Can a nurse administer Vitamin K and erythromycin ointment to a newborn according to a protocol?

A: Pharmacy Board rule 4729-5-01(L)(3)(4) O.A.C. does allow for the administration of these medications according to a protocol.

Q4: What is an example of a "true emergency?"

A: For the 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.

Q5: 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.

Q6: 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 in an emergency situation might be:
"EPINEPHERINE 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."

Q7: How does a non-prescriber adjust or initiate medication in an inpatient setting?

A: Pharmacy Board Rule 4729-5-01 O.A.C. addresses the adjustment or initiation of medication 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.

Q8: 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.

Q9: 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, 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.

Q10: 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"

Drug Name	Strength	Dosage Form	NDC number (on drug container)
Amoxil	500mg	Capsule	000029-6007
Atarax	10mg	Tablet	000049-5600
Bacteriostatic Sodium Chloride		Solution	0333-08
Heparin Lock Flush		Solution	0008-523
Naprosyn	500mg	Tablet	018930-0277
Neosporin Ophthalmic		Ointment	000081-0732
Otobiotic Otic		Solution	000085-0847

Q11: Can the drugs on a list of drugs 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.

Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO
BOARD OF PHARMACY

Resolution: Influenza Outbreak Management in Long-Term Care Facilities by Emergency Protocol

Adopted: 2/7/2018

The Board hereby recognizes that a long-term care facility's administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel according to the Center for Disease Control and Prevention's "Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities[1]" constitutes an emergency and may be administered via protocol pursuant to paragraph (L)(1) of rule 4729-5-01 of the Ohio Administrative Code.

For questions regarding this resolution, please review the following frequently asked questions. Other questions not addressed here may be emailed to the Board by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) Who can administer influenza antiviral treatment and chemoprophylaxis in accordance with a protocol?

A1) Rule 4729-5-01 of the Ohio Administrative Code requires the administration to be by licensed health care professionals. This does not include medical assistants or other unlicensed personnel.

Q2) The rule states the protocol must be approved by the Board of Pharmacy. How do I obtain approval?

A2) No prior approval is necessary. The resolution above serves as the approval. Please be advised that any deviation from the CDC Guidance or the requirements of the rule could result in disciplinary action against the long-term care facility's terminal distributor license.

Q3) Who must authorize the protocol?

A3) The protocol must be authorized by a prescriber. This should be a prescriber employed by the long-term care facility, such as the facility's medical director.

[1] https://www.cdc.gov/flu/professionals/infectioncontrol/ltc-facility-guidance.htm

Q4) Can a protocol for influenza outbreak management be used by a hospital or other facility in accordance with this resolution?

A4) No. The resolution is intended for long-term care facilities. Hospitals may adopt emergency protocols or other protocols in accordance with rule 4729-5-01 of the Ohio Administrative Code and the Joint Regulatory Statement issued by the Medical, Nursing and Pharmacy Board.

Q5) What must be included in the protocol?

A5) A protocol from an authorizing prescriber must include the following:

(1) Specifically define the intended audience;

(2) List the drug name and strength of the product;

(3) Give specific instructions on how to administer the drug, how much to administer, and how often the drug should be administered; and

(4) Any other requirements as specified in the CDC's "*Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities*."

The authorizing prescriber may have a more detailed protocol or may word the protocol any way the prescriber wishes as long as it contains the required details noted above.

Q6) The resolution permits the use of protocols for the administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel. Who is included in the definition of health care personnel?

A6) It is up to the authorizing prescriber to determine what long-term care facility staff members meet the definition of health care personnel.