



## Ohio Respiratory Care Board

77 S. High Street, 16<sup>th</sup> Floor  
Columbus, Ohio 43215-6108

Telephone: (614) 752-9218  
Complaint Line: (800) 338-9888  
Fax: (614) 728-8691  
Website: [www.respiratorycare.ohio.gov](http://www.respiratorycare.ohio.gov)

# Practice Statement

Written in cooperation with the Ohio State Board of Pharmacy, the Ohio State Medical Board, and the Ohio Board of Nursing

## Regarding the Use of Protocols to Administer Medication in the Practice of Respiratory Care

February 8, 2005

It has been brought to the attention of the Ohio Respiratory Care Board (hereinafter, "Board") that medications administered during the course of respiratory care treatment in the inpatient setting are often delivered with the use of some form of protocol ordered by authorized prescriber treatment directives. Based upon the Board's review of such protocols (following consult with the Ohio Boards of Pharmacy, Medicine, and Nursing), the Board determined that many of those protocols involving medication administration by a respiratory care therapist failed to comply with Ohio Board of Pharmacy rules regulating the administration of medications by protocol. The Board of Pharmacy has the jurisdiction to adopt these rules governing the administration of medication by authorized prescribers. Rules governing the use of such protocols are not new and have been in place for several years. However, because of concerns that various medical practices were not in compliance with Ohio law, the Boards of Pharmacy, Medicine, Nursing, and Respiratory Care are attempting to inform licensees of their legal obligations with respect to the use of protocols or some other form of drug treatment directives, such as pre-printed orders.

For the purpose of medication administration, Ohio Board of Pharmacy Rules [Ohio Administrative Code rule 4729-5-01 (L) (1), (2), and (3)] permit "protocols" to be used in only three circumstances:

1. Emergency situations when the services of a prescriber are not immediately available,
2. Administration of biologicals or vaccines for the purpose of preventing diseases, and
3. Administration of approved drugs pursuant to a definitive set of Ohio Board of Pharmacy approved written treatment guidelines that meet specified criteria.

In other words, many so-called protocols or drug treatment directives referencing respiratory care ordered by authorized prescriber treatment directives reviewed earlier this year by the Ohio Respiratory Care Board appeared to allow respiratory care therapists to determine drugs, dose, and frequency of medication administration based upon the assessment performed by the therapist without receipt of a specific order from an authorized prescriber. This type of protocol or drug treatment directive not only appeared to violate Ohio Administrative Code rule 4729-5-01 (L) (1) and (2), but may have constituted inappropriate delegation of medical treatment by the ordering prescriber and/or the unauthorized practice of medicine, which is a felony in Ohio.

To comply with Ohio law, the Ohio Respiratory Care Board suggests two alternatives to the current approach for non-emergency cases:

(1) Re-write protocols for drug treatment directives that do not currently meet the requirements of Ohio law as “pre-printed order” sets for authorized prescribers, as defined in O.A.C. 4729-5-01 (J).

**Rule 4729-5-01 (J) O.A.C. defines a pre-printed order 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 pre-printed order.” \*\*\***

- A. Patient-specific order: Medication orders must be specific for each patient under the prescriber’s care. In other words, a medication order cannot be written to treat a number of patients meeting the prescriber’s treatment criteria. Each patient must be specifically diagnosed and assessed. Orders must be specific for each individual patient under the prescriber’s care.
- B. Definitive set of drug treatment directives: The medication order must state the drug, dose, and frequency of administration. These parameters may be determined through defined objective measures, if those measures are documented in the context of the order. Objective measurements must specify the associated treatment criteria and medication. Therapist following the prescriber’s order may assess and score the patient according to the defined measurement criteria and implement the associated treatment. Changes in the treatment that deviate from the authorized treatment path must be confirmed by the prescriber resulting in a new order for therapy.
- C. Prescriber: An individual authorized under Ohio Law to diagnose and prescribe medications in the State of Ohio. In most instances, this person is a licensed medical physician. On occasion, therapy may be ordered by an advanced practice nurse working under a standard care arrangement with a licensed physician. The prescriber must sign the order.
- D. Conditions set forth in the pre-printed order: The patient-specific order must reflect the assessment criteria based on objective measurements and the corresponding treatment for the measures. The assessment criteria may include a sliding-scale response (treatment) based upon the determined measures.

Or,

(2) Obtain a valid, patient-specific order (verbal or written) from an authorized prescriber before implementing drug treatment directives, therapy or therapeutic changes and document it as part of the patient record. The order must be patient, medication, dose, and frequency specific.

## Common Questions

**1. How much authority can be delegated for respiratory care through drug treatment directives utilizing pre-printed orders?**

Drug treatment directives, when written as a pre-printed order set, should be designed to delegate, but not delegate beyond the scope of a licensee's authority or competence. Such delegation should be clear, effective, safe and reasonable medical treatment appropriate for delegation to non-prescribers. For example, a prescriber cannot delegate the authority to diagnose as a part of carrying out written treatment directives. Respiratory therapists are reminded to practice within the scope of practice defined by the Ohio General Assembly under Section 4761.01 of the Ohio Revised Code. Therapists can be sanctioned by the Ohio Respiratory Care Board for practicing beyond the authority vested in them by the law or therapists could be charged with practicing a profession, such as medicine, without a valid license. Such unlicensed practice is a criminal offense in Ohio.

**2. Should pre-printed orders for medications address specific drug response?**

Yes, the treatment pathway should address expected response to treatment. Specifically, the treatment pathway must address treatment that fails to produce a desired effect or a deteriorating patient condition. Prescriber feedback and communications should be clearly defined. Therapists must have clear requirements to contact the ordering prescriber when treatment fails to produce the expected outcome or a patient's condition deteriorates.

**3. What if a prescriber chooses not to utilize a pre-printed order to administer medications for respiratory care treatment?**

It is within the prescriber's scope of authority to choose another acceptable course of treatment for patients under their care. If the prescribed treatment is contraindicated, inaccurate, or harmful, a therapist must communicate these concerns with the ordering prescriber and not carry out such an order until the concerns are adequately resolved to the satisfaction of both the provider and the therapist carrying out the treatment directive.

**4. What if the prescriber chooses to continue ordering non-patient specific protocol? An example of such an order might be: "Respiratory Care to assess and treat per protocol."**

Many drug treatment directives currently used by health organizations to order medications for respiratory care that the Ohio Respiratory Care Board has reviewed do not appear to meet the legal definition of a "protocol" as it is used by the Pharmacy Board in Ohio Administrative Code rule 4729-5-01. Any order that does not contain specific instruction on the administration of the drug, including drug name, route of administration, dose, and frequency of administration, is not a valid order and should not be carried out by the respiratory care provider. Practice outside the aforementioned rules is grounds for discipline for licensees and depending on the facts and violation may result in criminal prosecution.

Again, drug treatment directives are acceptable methods of providing care, if, and only if:

- (1) The written directive is formatted as a pre-printed order that establishes the prescriber authorized assessment criteria and objective measures that lead to a treatment pathway. The

assessment outcome/scoring must lead to a patient- specific definitive set of drug treatment directives. These treatment directives must establish the specific medication, medication dose, method of administration, and frequency of administration. Any deviation by the treatment provider from the pre-printed order must be authorized by a prescriber by written or verbal order and documented in the patient record; or

- (2) The written directive is used as a means to obtain a valid, patient-specific order from an authorized prescriber. Upon assessing a patient using pre-established and accepted criteria for therapy, respiratory care therapists must obtain a valid prescriber's order before implementing or changing therapy. The order must be patient, medication, dose, and frequency specific.