



PRACTICE STATEMENT

Position on the Administration of Medications by Routes (or Purposes) Not Approved by the FDA Nursing Practice Statement NP 70

Developed: 5/94

Revised: 1995, 2016

The American Nurses Association *Code of Ethics for Nurses* states that the nurse has authority, accountability, and responsibility for nursing practice; makes decisions; and takes action consistent with the obligation to promote health and to provide optimal care (Provision 4).

Occasionally nurses are asked to administer medications by routes or for purposes other than what is approved by the Food and Drug Administration (FDA). Some of these non-FDA-approved routes or purposes have been utilized in many settings for many years; others are limited to a specific region or even a specific physician's preference. In addition, some non-approved routes or purposes have been widely published in journals citing risks and benefits while others have no documented effectiveness. For instance, although amitriptyline is approved to treat depression it is commonly prescribed to treat chronic nerve pain without FDA- approval.

Registered nurses should use the following guidelines for the administration of medication or other therapeutic prescriptions by routes or for purposes not approved by the FDA. The registered nurse has a legal obligation to question or clarify the order with the prescribing practitioner. If the clarification or explanation given by the practitioner is not satisfactory and the nurse believes that the implementation of the prescribed therapy would be detrimental to the patient, the nurse has the right to refuse to carry out the order. Prior to refusal, the nurse should attempt to resolve the issue through other avenues, such as resolution with top level nursing management.

When there is a question of appropriate route or purpose of medication administration, agencies must have a system in place where these issues can be addressed. To provide safe care to clients, institutions should have an organized system of communicating to nurses which drugs they can administer by a route or for a purpose different from that approved by the FDA. Each agency must have developed and adopted policies and procedures for all medications and other therapies that are given by alternative routes or for purposes other than those approved by the FDA. A pharmacy and therapeutics committee would be helpful for this purpose. The committee would do a thorough review of the literature, and possibly their own study, to determine the safety aspects of the medication or other therapy. The committee would also develop educational materials for the staff including a nursing and drug manual with agency-approved drugs, doses, routes, and purposes. Each agency would establish a mechanism for report, follow-up and documentation of each situation.

Advanced Practice Registered Nurses with Prescriptive Authority

OHIO REVISED CODE 4723.50 (A) (B) (1)

Administrative rules for prescribing drugs and therapeutic devices.

- (A) In accordance with Chapter 119 of the Revised Code, the board of nursing shall adopt rules as necessary to implement the provisions of this chapter pertaining to the authority of clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners to prescribe drugs and therapeutic devices and the issuance and renewal of certificates to prescribe.

The board shall adopt rules that are consistent with the recommendations the board receives from the committee on prescriptive governance pursuant to section 4723.492 of the Revised Code. After reviewing a recommendation submitted by the committee, the board may either adopt the recommendation as a rule or ask the committee to reconsider and resubmit the recommendation. The board shall not adopt any rule that does not conform to a recommendation made by the committee.

- (B) The board shall adopt rules under this section that do all of the following:

(1) Establish a formulary listing the types of drugs and therapeutic devices that may be prescribed by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

The Committee on Prescriptive Governance (CPG)

FORMULARY 2015

CTP holders are responsible for keeping informed and responding to FDA issued safety alerts and recalls. Appropriate responses include, but are not limited to timely and specific communications with patients regarding prescribed drugs. Timely information including recalls, warnings, safety alerts and patient information is available on the Food and Drug Administration (FDA) website at: <http://www.fda.gov/oc/oha/default.htm>

Off-Label Use:

A drug may be prescribed for purposes other than FDA indications when the purpose is supported by current peer review literature (to be produced by the CTP holder upon request), which emanates from a recognized body of knowledge – OR – identified as the standard of care as provided in the standard care arrangement, approved and documented by the collaborating physician, and is consistent with the Formulary.

REFERENCES FOR POSITION ON THE ADMINISTRATION OF MEDICATIONS BY ROUTES (OR PURPOSES) NOT APPROVED BY THE FDA:

- A. Ohio law and rules regulating the practice of nursing
- B. Ohio law and rules regulating APRNs with Prescriptive Authority
- C. The Committee on Prescriptive Governance (CPG) Formulary 2015: Off-label use

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