Declaratory Ruling 01-1

RE: POLICY AND PROCEDURE FOR REGISTERED NURSES DISPENSING PRESCRIPTION AND OVER THE COUNTER DRUGS AND DEVICES IN PUBLIC HEALTH CLINICAL PRACTICE SETTINGS

INTRODUCTION

On April 28, 1999, Diane Matuszak, MD, MPH, Deputy Director, Office of Food Protection and Community Health Services, petitioned the Board of Physician Quality Assurance to issue a declaratory ruling to allow physicians in public health clinics to delegate the authority to dispense medications to public health nurses.

On April 28, 1999, the board of Physician Quality Assurance voted to proceed to issue a declaratory ruling for dispensing by public health nurses. The Board of Physician Quality Assurance delegated responsibility for consideration of the petition to the Practice of Medicine committee to study the request and make a recommendation regarding registered nurses dispensing prescription and over the counter drugs and devices in public health clinical practice settings. The Practice of Medicine Committee considered the petition and made a recommendation that the Board of Physician Quality Assurance issue a declaratory ruling.

The Board of Physician Quality Assurance is authorized to issue a declaratory ruling pursuant to State Government Article § 10 – 301 et seq. and code of Maryland regulations 10.32.16 Petition for Declaratory Ruling.

RULING

The Board of Physician Quality Assurance ruled that a physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

BACKGROUND

1.0 PURPOSE

To establish a uniform standard of practice to guide registered nurses in the delegated function of dispensing drugs in public health practice setting in local health department throughout Maryland.

2.0 **POLICY**

Upon approval by the Board of Physician Quality Assurance, a physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

3.0 **DEFINITIONS**

A. **"Adulterated Drug"** means a drug that:

(1) Contains any "putrid, filthy or decomposed substance";

(2) Has been produced, packaged or held under unsanitary conditions where it might become contaminated;

(3) Has been placed in a container that might render the contents injurious;

(4) Does not have the identity, strength, quality or purity it is purported to posses;

(5) Has been:

(a) Mixed or paced in a way to reduce its quality or strength; or

(b) Substituted in whole or in part; or

(6) Does not otherwise meet the requirements of Health-General Article, §21-216, Annotated Code of Maryland.

B. **"Approved Formulary"** means a listing of the drugs or devices approved by the Committee on Nurse Dispensing and reviewed at least annually that a registered nurse may dispense in local health departments in accordance with this Policy and Procedure. Drugs will be dispensed to local health department patients in need of communicable disease, alcohol and drug abuse, and family planning and reproductive health services. A drug may be added to the approved formulary between reviews by filing a request for approval by the Committee on Nurse Dispensing. For a new or amended formulary to be approved by the Committee on Nurse Dispensing, it must include at least the following information on the drugs to be dispensed:

(1) Drug name;

(2) Vendor or manufacturer;

(3) Dosage strength;

(4) Quantity in a standard order, and

(5) Specified, recommended or suggested use.

The request for approval will be reviewed by the Committee on Nurse Dispensing. Registered nurses **may not** dispense controlled, dangerous substances except for methadone which may be dispensed to patients in a registered maintenance program.

C. **"Approved Training"** means initial and on-going training for registered nurses that must be approved by the Department of Health and Mental Hygiene, Board of Nursing, and Board of Pharmacy. The training will be designed to "train the trainer," thereby allowing registered nurses to receive standardized training so that they may return to their local health departments to train other registered nurses. The training curriculum must include instruction in accordance with this Policy and Procedure regarding the following:

(1) Drugs and devices that a trained nurses may dispense according to this Policy and Procedure:

(2) Steps in dispensing;

(3) Local health department dispensing policies and procedure

(4) Storage, packaging, labeling and disposal of drugs and devices;

(5) Inventory;

(6) Drug interaction management:

(7) Patient consultation;

(8) Record keeping;

(9) Legal aspects of dispensing;

(10) Procedures for minimizing general medication errors; and

(11) Reviews of pharmacology, therapeutics, and side effects of drugs on the approved formulary.

D. **"Authorized Physician"** means a physician licensed in Maryland, employed by the Department of health and Mental Hygiene or a local health department who has applied for and received authorization from the Board of Physician Quality Assurance to delegate dispensing authority to certain registered nurses who work in local health department clinical practice settings.

E. **"Board of Pharmacy"** means the Board established under Health Occupations Article, §12-201, Maryland Annotated code, to regulate the licensure, continuing education and practice of licensed pharmacists in Maryland.

F. **"Board of Physician Quality Assurance"** means the Board established under Health Occupations Article, §14-201, Maryland Annotated code, to regulate the licensure, continuing education, and practice of licensed physicians in Maryland.

G. **"Board of Nursing"** means the Board established under Health Occupations Article, §8-201, Maryland Annotated Code, to regulate the licensure, continuing education, and practice of licensed registered nurses in Maryland.

H. **"Committee on Nurse Dispensing"** means a committee convened by the Department of Health and Mental Hygiene and composed on one representative designed by the Secretary and one representative from each of the Boards of Pharmacy, Nursing, and Physician Quality Assurance, a representative from the Maryland Council of Public Health Nurse Directors, and a volunteer pharmacist from the community as nominated by the Board of Pharmacy.

I. **"Department"** means the Department of Health and Mental Hygiene.

J. **"Designated Trainer"** means a health care professional licensed under the Health Occupations article of the Annotated Code of Maryland, which may include an authorized physician, a program physician, a pharmacist, a registered nurse, or any combination of these professionals, who has been approved by the Committee on Nurse Dispensing to provide training on dispensing drugs.

K. **"Device"** means an item used in the diagnosis, treatment, or prevention of disease. Devices may include prescription items such as diaphragms or non-prescription items such as spacers. Device does not include any:

(1) Surgical or dental instrument;

(2) Physical therapy equipment;

(3) X-ray apparatus; or

(4) Component part or accessory of any of these items.

L. **"Dispense"** means the procedure which results in the receipt of a prescription or non-prescription drug or device by a patient or patient's agent which include:

(1) Interpreting an authorized prescriber's prescription for a drug or device;

(2) Selecting and labeling of the drug or device prescribed; and

(3) Measuring and packaging of the drug or device in accordance with State and Federal laws.

M. **"Drug Inventory Log"** means an administrative form on which the following must be recorded:

(1) Date received and quantity in each delivery to a local health department site of a particular drug;

(2) Quantity of the drug that is dispensed with each prescription;

(3) Quantity of the drug remaining in the clinic's stock; and

(4) Prescription number and date that the drug is dispensed.

N. **"Drug References"** means up-to-date printed information on drug use, actions, adverse reactions, and interactions with other drugs.

O. **"Interpretation"** means:

(1) Correctly identifying the drug prescribed; and

(2) Preparing a label which accurately reflects the instructions for use given on the prescription, such as form, dosage, route, and frequency of dosing.

P. **"Misbranded Drug"** means a drug whose:

(1) Label is false or misleading in any way;

(2) Label does not meet requirements for labeling under the State law;

(3) Label does not carry the established name of the drug;

(4) Label bears the name of a drug which is not what the container holds;

(5) Packaging is in violation of the Federal Poison Prevention Packaging Act of 1970; or

(6) Label does not otherwise meet the requirements of Health-General Article, §21-217, Annotated Code of Maryland.

Q. **"Patient Profile"** means a computerized or hard copy format which lists the following information:

(1) Patient's name, address, and date of birth;

(2) Patient's allergies, medical problems, and medications;

(3) Prescription number;

(4) Name, strength, quantity, directions for administration, and manufacturer of drug; and

(5) Date that the drug is dispensed.

R. **"Physician Delegation Documentation Log"** means an administrative form which certifies that the authorized physician has delegated dispensing authority to specified registered nurses in compliance with the Policy and Procedure. The log must be signed and dated by an authorized physician annually.

S. **"Prescription Log"** means an administrative form on which each act of dispensing must be recorded in sequential order by prescription number. The information that must be recorded for each set of dispensing includes the following:

(1) Prescription number, which should be sequential and without duplication;

(2) Brand or generic name of the drug;

(3) Name of the manufacturer or distributor of the drug;

(4) Quantity dispensed;

(5) Dosage strength;

(6) Date of dispensing;

(7) Lot or serial number assigned to drug dispensed;

(8) Identification of the dispenser;

(9) Records of refills, including date of refill and dispenser;

(10) Name of the patient to whom the drug was dispensed; and

(11) Expiration date.

T. **"Registered Nurse"** means an individual who is licensed by the Maryland Board of Nursing to practice registered nursing.

4.0 RESPONSIBILITIES

A. **The authorized physician is responsible for:**

(1) Complying with the Board of Physician Quality Assurance requirements for delegation of dispensing authority;

(2) Delegating dispensing authority only to registered nurses who have successfully completed a training program approved by the Committee on Nurse Dispensing created under this Policy and Procedure;

(3) Signing the authorized Physician Delegation Documentation Log;

(4) Assessing the potential for adverse affects if the prescribed medication is taken by a patient who is allergic to an ingredient in the prescribed medication or if the prescribed medication is taken concurrently with other medications being taken by the patient.

B. **The Health Officer or designee is responsible for :**

(1) Assuring that authorized physicians and registered nurses who dispense drugs in local health department settings are aware of and in compliance with this Policy and procedure;

(2) Assuring competency of registered nurses who dispense drugs by providing continuing training relevant to dispensing and an annual review of the Approved Training curriculum;

(3) Conducting n annual review of dispensing related activities of registered nurses who dispense drugs;

(4) Obtaining the approval of the Committee on Nurse Dispensing for each local health department's formulary and any changes or additions to that formulary;

(5) Obtaining the approval of the Committee on Nurse Dispensing for each designated trainer used by the local health department;

(6) Authorizing a registered nurse to dispense only after the registered nurse has successfully completed training and received the delegation of dispensing authority from an authorized physician;

(7) Assuring that the Division of Drug Control is slowed to enter and inspect the premises at all reasonable hours;

(8) Reviewing the training curriculum approved by the Committee on Nurse Dispensing;

(9) Ensuring that written authorization or release of information is signed by the patient or the patient's authorized agent;

(10) Ensuring that adequate safeguards are in place to maintain the confidentiality of patient's drug records;

(11) Restricting access to the patient's drug records to only the following persons:

(a) An adult patient for whom the prescription was written or the patient's legally appointed guardian;

(b) An emancipated minor patient for whom the prescription was written;

(c) An unemancipated minor for whom the prescription was written, when the minor's consent was sufficient to authorize treatment for the minor's condition;

(d) A parent or legally appointed guardian for an emancipated minor for whom the prescription was written, when the minor's consent is not sufficient to authorize treatment for the minor's condition;

(e) The prescriber who issued the prescription;

(f) The licensed practitioner who is treating the patient for whom the prescription was written;

(g) A pharmacist who is providing pharmacy services for this patient for whom the prescription was written;

(h) A person with signed authorization for release of the information from the patient or the patient's legally appointed guardian;

(i) A person authorized by subpoena, court order, or statue;

(j) A third party responsible for providing or paying for medical expenses for the patient for whom the prescription was written with the patient's written authorization;

(k) A member or designated employee of the Board of Pharmacy or Maryland State Division of Drug Control;

(l) The executor, or spouse or administrator of a deceased patient for whom the prescription was written;

(m) Researchers as approved by the Department of Health and Mental Hygiene's Institutional Review Board.

(12) Assuring that no additional fee is charged for dispensing drugs or devices;

(13) Assuring that a licensed pharmacist is available for consultation; and

(14) Assuring that up-to-date references are available to registered nurses who dispense medications.

C. **The Board of Pharmacy is responsible for:**

(1) Selecting pharmacists with community health experience to assist with the development of the Approved Training Curriculum;

(2) Selecting a licensed pharmacist with community health experience who may provide consultation; and

(3) Reviewing and assuring, as needed, that this Policy and Procedure is in compliance with the Pharmacy Practice Act.

D. (1) **The registered nurse is responsible for:**

(a) Successfully completing the approved training;

(b) Complying with this Policy and procedure;

(c) Assuring that this delegated dispensing authority in **not** redelegated to other individuals;

(d) Assuring that all drugs and devices dispensed pursuant to this Policy and Procedure are not adulterated drugs or misbranded drugs;

(e) Maintaining medication related records and files in a manner that ensures the confidentiality of patient's drug records and is consistent with State and Federal laws and regulations;

(f) Following the drug storage and inventory procedures in this Policy and Procedure;

(g) Dispensing only to patients of the local health department;

(h) Dispensing only at designated health department sites;

(i) Maintaining access to suggested drug references;

(j) Maintaining competency related to dispensing; and

(k) Consulting with a licensed pharmacist, when appropriate, to answer questions that arise regarding drug or medication therapy.

(2) **The registered nurse shall strictly adhere to the follow steps when dispensing a prescribed product:**

(a) Reading the prescription order. The registered nurse shall:

(i) Verify that the drug is on the approved formulary;

(ii) Verify that the prescription order includes at least the following information:

1. Date of issue;
2. Name and address of patient;
3. Name, address, and telephone of prescriber;
4. Name, strength, dosage form, and quantity of drug prescribed;
5. Stop date for refills, if authorized;
6. Route of administration, if applicable; and
7. Directions for use.

(iii) Verify that prescription or prescription orders are signed by the physician within four working days;

(iv) Check the patient profile for pertinent information, including information on allergies, concurrent prescription drugs, and over the counter medication; and

(v) Determine that the prescription is not outdated and not to be filled if more than 120 days after issue, in accordance with Health Occupations Article, §12-503, Annotated Code of Maryland.

(b) Selecting the medication. The registered nurse shall:

(i) Select the appropriate drug or device in accordance with the prescription order;

(ii) Select the prescribed product in the correct dosage;

(iii) Inspect the prescribed product for defects;

(iv) Measure out appropriate quantity if unit of uses are not available;

(v) Double check accuracy before returning drug to stock; and

(vi) Note in the patient chart and on the patient profile the brand, manufacturer or distributor of the product dispensed.

(c) Selecting the proper container. The registered nurse shall:

(i) Package drugs and devices dispensed pursuant to this Policy and Procedure in suitable safety-closure containers unless the patient requests in writing that no safety container by used;

(ii) Select the appropriate container based on quantity, storage requirements, and need for child-resistant container;

(iii) Use a new container whenever refilling the prescription; and

(iv) Dispense relevant substances in safety packaging in accordance with the Poison prevention Packaging Act of 1970.

(d) Complying with other drug packaging requirements. The registered nurse shall act in conformity with the following provisions:

(i) The prescriber or patient may request that non-safety closures be used. The patient may give a blanket waiver regarding all of the patient's prescriptions. This request must be in writing and signed by the patient or authorized agent.

(ii) The prescriber may not give blanket authorization for the use of non-safety closures;

(iii) New packages must be used when refilling prescriptions. However, when glass containers are used, replacing the cap with a new one complies with the poison prevention packaging requirements.

(iv) The manufacturer's original package, with appropriate labeling, may be dispensed directly to the consumer if it carries a safety closure.

(e) Labeling container. The registered nurse shall comply with the following provisions when dispensing both prescription and non-prescription drugs:

(i) Drugs and devices dispensed pursuant to the Policy and Procedure shall be properly labeled (including necessary

auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;

(ii) A drug dispensed by filling or refilling a written or oral prescription of a legally authorized prescriber must bear a label with the following contents:

1. Local health department name, address and telephone number;
2. Patient name;
3. Clinic name and address;
4. Phrase "Dispensed by….., R.N. and initials" with the name of the dispenser appearing in the blank;
5. Lot number and date of dispensing of the prescription;
6. Prescriber's name;
7. Directions for use, including route of administration;
8. Name and strength of the drug, with the label showing the brand name of the drug, or in the absence of a brand name, the established generic name of the drug and the manufacturer or distributor of the drug;
9. Expiration date in accordance with Health-General Article, §12-505, Annotate Code of Maryland;
10. Any appropriate special handling instruction regarding proper storage of the drug or device;
11. Refills, if authorized; and
12. Prescription number.

(iii) Plastic containers or dispenses for oral contraceptives must be labeled with patient information leaflets attached; and

(iv) A medication supplied by the manufacturer with patient information leaflets must be dispensed with leaflet intact.

(f) Giving medication to patient. The registered nurse shall:

(i) Determine if the patient or patient's agent is to receive the medication;

(ii) Determine what information should be provided regarding correct use of the medication;

(iii) Determine the level of understanding of the patient or patient's agent for printed and verbal instructions;

(iv) Provide educational information about drugs in a format that the patient or patient's agent can comprehend;

(v) Give the medication to the patient or patient's agent; and

(vi) Deliver the drug or device to the patient at home, only if necessary, following Federal, State and local laws and regulations.

(g) Counseling patient on use. The registered nurse shall:

(i) Explain the proper procedure for taking or administering the drug, based of the patient's or caregiver's ability to understand;

(ii) Describe to the patient or patient's agent any side effects of the dispensed drug and how to minimize them;

(iii) Explain the precautions regarding food or other drugs that might interact adversely with the drug being dispensed;

(iv) Explain the proper storage conditions for the drug;

(v) provide appropriate written information as necessary;

(vi) Explain the steps to be taken when a dose is missed; and

(vii) Explain any special considerations.

(h) Retaining record of dispensing. The registered nurse shall retain prescription records for five years in accordance with Health Occupations Article, §12-403 (b)(13)(1), Annotated Code of Maryland. A prescription profile containing a record of each act of dispensing must be made in addition to the original prescription of

chart order. Records shall include, but are not limited to, the following:

(i) Name of the patient to whom the drug is dispensed;

(ii) Brand name, if any, or the established name and the manufacturer or distributor of the drug product that is dispensed;

(iii) Quantity dispensed;

(iv) Date of dispensing;

(v) Lot or serial number assigned to the drug dispensed;

(vi) Identification of the disperser (e.g., initials);

(vii) Records of refills, to date, including date of refill and the name of the dispenser; and

(viii) Prescription number.

E. **The designated trainers are responsible for:**

(1) Developing and presenting the approved training curriculum in accordance with this Policy and Procedure and a self-instruction manual to registered nurses seeking dispensing authority; and

(2) Conducting pre-training and post=training tests to registered nurses seeking dispensing authority.

F. **The Department of Health and Mental Hygiene is responsible for:**

(1) Convening a Committee on Nurse Dispensing to review and approve:

(a) The formulary for each local health department where a physician delegates dispensing of drugs or devices to a registered nurse;

(b) The training curriculum required for registered nurses to whom dispensing of drugs and devices has been delegated by a physician;

(c) The designation of trainers requested by each local health department; and

(d) The forms used to document required information and actions as stated in this Policy and Procedure.

(2) Including representatives of the following as members of the committee on Nurse Dispensing:

(a) Board of Pharmacy;

(b) Board of Nursing;

(c) Board of Physician Quality Assurance;

(d) Department of Health and Mental Hygiene;

(e) Member of the Maryland Council of Public Health Nursing Directors; and

(f) A volunteer pharmacist from the community.

5.0 **OTHER**

A. **Prescription Drug Storage and Inventory**

(1) Receipt of Drug

(a) Shipments of drugs received at the local health department must be handled in accordance with this Policy and Procedure. Staffs are required to:

(i) Visually examine the package for identification and refuse acceptance of potentially adulterated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents; and

(ii) Sign the packaging invoice confirming the quantity and date that the drugs were received.

(b) Staff who receive drugs in the local health department are required to maintain inventories and records of all transactions regarding receipt and distribution of prescription drugs. A copy of the packaging invoice will be used to generate a Drug Inventory Log (sample attached) or similar local form, if desired.

(c) Upon receipt of drugs, staff shall:

(i) Reject all shipments of drugs not listed on the approved formulary;

(ii) Complete sections 1 through 7 of the Drug Inventory Log upon acceptance of the drug shipment;

(iii) Immediately store drugs in an appropriate and secure dispensing area;

(iv) Complete sections 8, 9, and 10 of the Drug Inventory Log upon sending the drug to the clinic;

(v) Complete section 11 of the Drug Inventory Log upon receipt of the drug; and

(vi) make a photocopy of the Drug Inventory Log and maintain for initial inventory control.

(2) Secured Drug Storage and Inventory

(a) All drugs must be secured in a locked substantially constructed cabinet, storage closet, or refrigerator;

(b) Only designated staff shall possess access to the locked storage closets and refrigerators;

(c) The cabinet or storage closet must be a room temperature (68° - 77° F), in an area of adequate light, and maintained in a clean and orderly condition;

(d) All drugs that require refrigeration must be stored a 2°-8° C (35°-46° F) to maintain biologic potency. All biologic storage refrigerators must be secured and have a 24 hour a day electronic monitoring alarm device to prevent biologic loss due to inappropriate storage or equipment failure. Refrigerators must be used only for the storage of biologicals and drugs;

(e) Drugs must be stored according to manufacturer's recommendation and in a manner that ensures proper rotation of stock. Expired drugs or devices must be removed from stock each month. Document on the bottom of the Drug Inventory Log must reflect whether drugs were returned to the supplier or disposed. If disposed, the disposal process must meet requirements of State and Federal Laws.

(f) In the event that drugs stocked at the Local health Department become outdated (expired), the staff shall take the following actions:

(i) Verification of the drug to be discarded must be established by comparing the expiration dates listed in the Drug Inventory Log with the actual date stamped on the drug container;

(ii) Expired drugs must be gathered, counted, and returned to the supplier or reverse distributor for partial credit, if possible, or properly disposed. This disposal must be witnessed and two licensed registered nurses must sign the Drug Inventory Log attesting to having witnessed the disposal. The date, lot numbers, and reasons for disposal must also be noted. Controlled substances must be gathered, counted, and returned to the Drug Enforcement Agency (DEA) for disposal;

(iii) If a drug cannot be returned, the preferred method for disposal is incineration at an approved biomedical waste disposal site. For small quantities only, acceptable methods for drug disposal are double flushing or pouring of liquids down a drain;

(iv) Following disposal, the Drug Inventory Log related to the eliminated drugs must be removed from the active files, but retained for a minimum of five years.

(3) Recalls

(a) Drug recall notices must be reviewed by the Department and forwarded to the appropriate program manager at the local health departments. The program manager shall immediately arrange for removal of a recalled drug from distribution and return it to the manufacturer in accordance with the recall instructions. A copy of the recall letter must be returned to the Department with either:

(i) Documentation that no such product is on site; or

(ii) Documentation that the product was returned to the supplier.

(b) Notation of a recall must also be made on the Drug Inventory Log and retained for a minimum of five years.

(c) In the event of a Class 1 (patient level) Recall, the program manager or designee must contact all patients that received the affected lot. The records documenting the contact with patients and returns shall be maintained on-site for at least two years following the recall.

CONCLUSION

The mission of the Board of Physician Quality Assurance is to protect the citizens of Maryland through the effective licensure and discipline of physicians and allied health practitioners under its jurisdiction. The Board of Physician Quality Assurance recognizes that the practice of medicine develops and evolves over time. The Board of Physician Quality Assurance reviews and considers developments in the practice of medicine within the context of its duty to protect the public. A physician employed by the Department of Health and Mental Hygiene or a local health department may delegate dispensing authority to certain registered nurses who have received approved training to dispense drugs and devices in a safe and legal manner.

_____ _____

Samir R. Neimat, Chairman Date

EFFECTIVE DATE

The effective date of the Administrative Policy and procedure is _____.

_____ _____

Date Department of Health and Mental Hygiene

_____ _____

Date Health Officer

_____ _____

Date Authorized Physician

_____ _____

Date Director of Nurses

Rev. 7/25/01