Introduction:


Review of the Task Force Charge

The Task Force reviewed its charge and proposed no changes to it. As derived from NABP Resolution No. 90-12-94, the charge of the Task Force on Standards for Enteral and Parenteral Care is to:

1. explore the tasks and responsibilities of providing enteral and parenteral care; and
2. develop and propose changes to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to establish quality standard of care outcomes.

Recommendation TFSEPC #1

The Task Force is concerned that the distribution of legend drugs and devices directly from manufacturers to patients without the monitoring and pharmaceutical care functions provided by pharmacists presents a danger to the public health. The Task Force recommends that the NABP Executive Committee share the concerns of the Task Force with any and all state and federal regulatory authorities including, but not limited to, the Health Care Financing Administration (HCFA), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA), and would urge
the NABP Executive Committee to share this information with the state boards of pharmacy.

**Background:**

The Task Force members received a detailed presentation on practices that involve the delivery of legend drugs and legend devices to home peritoneal dialysis patients directly from the manufacturer without benefit of pharmacist involvement or potential for intervention when necessary. The Task Force expressed concern that such deliveries of legend drugs and legend devices to home care patients directly from the manufacturer may violate federal and state drug laws. While the Task Force recognized that the continuous evolution of patients’ needs requires innovation by practitioners and regulators alike, they remained concerned that quality of care issues and legislatively mandated requirements to protect patient safety are being overlooked in the apparent interests of cost containment.

**Recommendation TFSEPC #2:**

The Task Force on Standards for Enteral and Parenteral Care recommends that the Model Rules for Sterile Pharmaceuticals found within the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* be amended as follows: *(Note: The changes made by the Task Force to the Model Rules for Sterile Pharmaceuticals are indicated with underlining and strikeout markings to identify the Task Force’s proposed changes to add or remove language from the Model Rule.)*

Model Rules for Sterile Pharmaceuticals

Section 1. Scope and Purpose

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; to provide standards 2) the preparation, labelling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a Prescription Drug Order; and 3) product quality and characteristics. The primary focus of these Rules is the assurance of product quality and characterizes, such as sterility and potency, that would be association with environmental quality, preparation activities, and checks and tests carried out in the Pharmacy. These standards are intended to apply to all sterile products, including but not limited to injectables and ophthalmics, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor’s office).

Section 2. Definitions

(a) - (e) No changes.

(f) “Sterile Pharmaceutical” means any dosage form devoid of viable microorganisms, a dosage form free from living microorganisms (aseptic).

(g) “Product Quality and Characteristics” include: sterility, potency associated with environmental quality, preparation activities, and checks and tests.
(h) “Positive Patient Outcomes” include the cure or prevention of disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process so as to improve the patient’s quality of life.

Section 3. Policy and Procedure
A policy and procedure manual shall be prepared and maintained for the Compounding, Dispensing, Delivery, Administration, storage and use of Sterile Pharmaceutical Prescription Drug Orders.
(a) The policy and procedure manual shall include a quality assurance program for the purpose of monitoring patient care and pharmaceutical care outcomes, adverse drug reactions, personnel qualifications, training and performance, product integrity, equipment, facilities, infection control, and guidelines regarding patient education.
(b) The policy and procedure manual shall be current and available for inspection by a Board of Pharmacy-designated agent.

Section 4. Physical Requirements
(no change)

Section 5. Records and Reports
(no change)

Section 6. Delivery Service
(no change)

Section 7. Disposal of Cytotoxic and/or Hazardous Wastes
(no change)

Section 8. Emergency Kit
When sterile pharmaceuticals are provided to home care patients, the Dispensing Pharmacy may supply the nurse or patient with emergency Drugs, if the physician has authorized the use of these Drugs by a protocol, in an emergency situation (e.g., anaphylactic shock).

Section 9. Cytotoxic Drugs
(no change)

Section 10. Patient Education and Training
If appropriate, the Pharmacist must demonstrate or document the patient’s training and competency in managing this type of therapy provided by the Pharmacist to the patient in the home environment. A Pharmacist must be involved in the patient training process in any area that relates to Drug Compounding, Labeling, Administration, storage, stability, or compatibility, or disposal. The Pharmacist must be responsible for seeing that the patient’s competency in the above areas is reassessed on an ongoing basis.
Section 11. Quality Assurance / Compounding and Preparation of Sterile Pharmaceuticals

Only recommended change by Task Force is in the wording of the Section title.

Section 12. Quality Assurance and Pharmaceutical Care Outcomes

There shall be a documented, ongoing quality assurance control program that monitors patient care and pharmaceutical care outcomes, including but not limited to the following:

(a) Routine performance of Prospective Drug use Review and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;

(b) Patient monitoring plans that include written outcomes measures and systems for routine patient assessment, (Examples include infection rates, rehospitalization rates, and the incidence of adverse drug reactions);

(c) Documentation of patient training as specified in Section 10; and

(d) Appropriate collaboration with other health care professionals.

Background:

The Task Force discussed and recognized pharmacists’ increasing responsibilities and opportunities to positively impact patient care in today’s changing health care environment. In light of this evolving scenario, the Task Force maintained that there is a need for the regulation of pharmacy practice to include the outcomes of pharmaceutical care as well as the process, and that the proper performance of these functions should be assured through quality assurance programs and documentation procedures.