Committee on Pharmacy Practice

Members Present:
Howard B. Bolton (LA), Chairman; William A. Fitzpatrick (MO); Michael W. Noel (AZ); Jerry D. Pyle (TX); William H. Randall, Jr. (NC); Marian L. Roberts (IA); E. George Roentsch (NH).

Institutional Practice Subcommittee Members Present:
Patricia DeLaPointe (MN), Chairman; Maureen Sandison (WA); Joseph A. Whaley, Jr. (GA).

Others Present:
Morris Lederman (MA), Executive Committee Liaison; Carmen A. Catizone, Executive Director; Bart Clark, NABP Staff Liaison; Sharon Stach, Staff Liaison, Institutional Practice Subcommittee; Mary Jo Hunst, NABP Staff.

Introduction:

Review of the Task Force Charge:
The charge of the Committee on Pharmacy Practice remains as follows:

1. Study and report on current issues affecting pharmacy practice and regulation in all settings, including but not limited to pharmacies (community and institutional), home health care enters, health maintenance organizations, pharmaceutical manufacturers, wholesalers, etc.;
2. Study and report on the responsibilities and roles of the pharmacist in practice as they pertain to regulation of, and setting of, standards for the profession;
3. Study and report on new developments in the practice of pharmacy that affect the regulation of the profession; new health care centers, robotics, new drug delivery systems, etc.;
4. Assist the Executive Committee in its relations with other regulatory agencies, pharmacy organizations, pharmaceutical manufacturers, drug wholesalers, and other practice-related organizations and agencies; and
5. Recommend to the Executive Committee, for referral to the Committee on Law Enforcement/Legislation, the development of model regulations for important practice areas.

Recommendation CPP #1:
The Committee on Pharmacy Practice recommends to the Executive Committee that the Committee on Law Enforcement/Legislation further examine the issue of compounding versus
manufacturing as the Committee on Pharmacy Practice reiterates support for the 1991 Resolution CPP#1, Compounding and Manufacturing, which stated:

**WHEREAS**, the compounding of medication pursuant to or in anticipation of a prescription or medication order is part of the practice of pharmacy; and

**WHEREAS**, state boards of pharmacy are responsible for the development and enforcement of legislation, rules, and regulations related to drug distribution and the practice of pharmacy in the interest of public safety; and

**WHEREAS**, pharmacists must always have the prerogative to compound medications pursuant to, or in anticipation of, a prescription or drug order;

**THEREFORE BE IT RESOLVED** that NABP assert strongly to FDA that compounding is a necessary and essential component of the practice of pharmacy and, as such, the boards of pharmacy must maintain primary jurisdiction over the compounding of medications in pharmacies; and

**BE IT FURTHER RESOLVED** that NABP will work cooperatively with FDA to establish clear and concise guidelines to differentiate between pharmacy compounding and manufacturing, and that NABP will work toward defining and developing model standards for pharmacy compounding for use by state boards of pharmacy.

**Background:**

The Committee, in discussing recent developments in the interactions of NABP and the FDA pertaining to manufacturing and compounding and the definitions of these activities as they appear in the current draft of the **NABP Model State Pharmacy Practice Act**, wanted to reiterate their belief that compounding activities should remain an integral part of the practice of pharmacy under the jurisdiction of the state boards of pharmacy.

**Recommendation CPP #2:**

The Committee on Pharmacy Practice recommends to the Executive Committee that they, through follow-up by NABP staff, obtain clarification and a report on the status of the exemption list of anabolic steroid-containing preparations, which is not yet forthcoming from the U.S. Drug Enforcement Administrations (DEA).

**Background:**

The Committee discussed the fact that the DEA was to have made public a list of anabolic steroid-containing preparations which are to be exempt from inclusion in the schedules of the 1991 amendment to the Controlled Substances Act of 1970. This list, containing drug products eligible for exemption from Controlled Substance schedules within 90 days of the passage of this amendment, would assist both pharmacists and state boards of pharmacy in assuring compliance with these new provisions.

**Recommendation CPP #3:**
The Committee on Pharmacy Practice recommends to the Executive Committee that, in view of NABP’s position in favor of mandatory patient counseling and the upcoming requirements for patient counseling contained in the OBRA '90 legislation, state boards of pharmacy be strongly encouraged to adopt patient counseling regulations.

**Recommendation CPP #4:**
The Committee on Pharmacy Practice recommends to the Executive Committee that it encourage state boards of pharmacy to require a portion of the continuing education requirement for pharmacist licensure renewal be obtained in programs designed to enhance the patient counseling skills of pharmacists.

**Background:**
The Committee discussed the need for states to soon adopt patient counseling regulations in that the OBRA ’90 patient counseling requirements for Medicaid recipients will take effect January 1, 1993. Also, because pharmacists will be required to perform this patient-serving activity, it seemed appropriate that they be required to obtain a portion of their continuing education credits in coursework that would enhance their skills in this area.

**Recommendation CPP #5:**
The Committee on Pharmacy Practice recommends to the Executive Committee that the Committee on Law Enforcement/Legislation examine issues pertaining to licensure and non-dispensing activities included in the *NABP Model State Pharmacy Practice Act* definition of the practice of pharmacy (such as patient counseling) which take place in settings other than within a pharmacy facility.

**Background:**
The Committee discussed the need for state boards to retain jurisdiction over the practice activities of pharmacists, whether or not these activities take place within a pharmacy facility. Examples discussed included pharmacist/patient counseling services operation by 1-900 telephone numbers and the activities of consultant pharmacists who do not supply medications to long-term care facilities.

**Recommendation CPP #6:**
The Committee on Pharmacy Practice recommends to the Executive Committee that, whereas the prospective Drug Utilization Review (pro-DUR) requirements of the OBRA ’90 legislation will ultimately enhance patient care and the protection of the public health, NABP should strongly encourage the U.S. Health Care Financing Administration (HCFA) to make the funding available for the necessary electronic claims processing equipment and computer software.

**Background:**
The Committee discussed the need for both the standardization of equipment and software compatibility and for the Federal funding necessary to assure timely implementation of systems needed to facilitate compliance with the OBRA ’90 pro-DUR requirements.
Recommendation CPP #7:
The Committee on Pharmacy Practice recommends to the Executive Committee that the Committee on Law Enforcement/Legislation include the standardized reports of controlled substances utilization in the NABP Model State Pharmacy Practice Act as an example of a reporting format which states may choose to require.

Background:
The Committee commended the American Society for Automation in Pharmacy (ASAP) for their efforts toward encouraging standardization by developing the Controlled Substances Utilization Report format. The Committee discussed the advantages to both pharmacists and state boards of pharmacy if a standardized controlled substances reporting format requirement were universally adopted by state boards of pharmacy. These advantages include increasing the efficiency of pharmacy inspectors in reviewing pharmacies’ records and potential savings in the cost of software development, which would be passed on to pharmacies.

Institutional Practice Subcommittee

Recommendation IPSC #1:
The Subcommittee recommends to the Committee on Pharmacy Practice that, after follow-up by NABP staff to obtain clarification from the developers of the proposed Nuclear Pharmacy Inspection Form on select sections, the form be accepted for inclusion as an Exhibit in the revised Model Act.

Background:
The Subcommittee reviewed and discussed the proposed Nuclear Pharmacy Inspection Form and found it to be quite thorough and complete. Concern was raised that certain sections need not be included, such as those referring to checking DEA registration and storage of Schedule II medications, and that there was no provision for checking for a dosimetry badge policy. The Subcommittee offered some suggestions for minor changes in the wording of the form, but had no strong objections to it as a whole.

Recommendation IPSC #2:
The Subcommittee recommends to the Committee on Pharmacy Practice that the DEA and FDA be contacted, and if no policy is already in place, that the DEA and FDA permit the pharmacist, when approached by patients or their representatives, to assist in the destruction of any discontinued, outdated, or unused medications.

Background:
The Subcommittee continues to be concerned about the possibility of drug diversion and the potential for public harm from drugs dispensed for use in a hospice or home care setting. The Subcommittee feels the potential for public harm can be reduced if the medications can be
destroyed. The Subcommittee further feels that the pharmacist is a reasonable member of the health care team to assist in the destruction.

**Recommendation IPSC #3:**

The Subcommittee recommends to the Committee on Pharmacy Practice that the following changes be made to the proposed Model Rules for Institutional Pharmacy.

Section 2. Definitions
(a) Institutional Facility means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to:
   (1) Hospital;
   (2) Convalescent Home;
   (3) Nursing Home;
   (4) Extended Care Facility;
   (5) **Mental Health Facility**
   (6) Rehabilitation Center;
   (7) Psychiatric Center;
   (8) **Developmental Disability Center**;
   (9) Drug Abuse Treatment Center;
   (10) Family Planning Clinic;
   (11) Penal Institution;
   (12) Hospice;
   (13) **Public Health Facility**;
   (14) **Athletic Facility**.
(b) Institutional Pharmacy means the physical portion of an Institutional Facility…

**Background:**

The Subcommittee felt that the list of examples either needed to be expanded as listed above, or shortened by grouping the examples under more general headings. Additionally, the Subcommittee believes that the definition of Institutional Pharmacy as found in the current draft of the Model rules for Institutional Pharmacy needs to be clarified by including the term physical in order that the definition not be confused with a definition of Institutional Pharmacy Practice.

**Recommendation IPSC #4:**

The Subcommittee recommends to the Committee on Pharmacy Practice that the following change be made in the Section 5(b) of the current draft of the Model Rules for Institutional Pharmacy and that the comment which follows also be included.

Section 5. Drug Distribution and Control.
(b) The use of the patients’-own medication, brought into an Institutional Facility, should be discouraged. Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such…

Section 5(b). Comment

The use of patients’-own medications in an Institutional Facility should be discouraged in order to safeguard patient health and safety. The Institutional Facility Pharmacy may be able to positively identify the medication brought in by the patient, but would not be able to assure that the medication had not been tampered with, otherwise adulterated, or that it had been stored under proper conditions. Discouraging the use of patients’-own medications in an Institutional Facility is not meant to preclude patient self-medication programs that may be established.

**Recommendation IPSC #5:**

The Subcommittee recommends to the Committee on Pharmacy Practice that the following changes be made to the proposed Model Rules for Pharmaceutical Care. Section I. Adverse Drug Reactions, should be changed to:

**I. Significant Drug Errors**

Significant Drug Errors shall be reported to the prescribing Practitioner and in writing to the Board of Pharmacy immediately upon discovery. Appropriate entry on the patient’s record shall also be made.

**Background:**

Discussion among the Subcommittee members revealed concern that use of the term “Adverse Drug Reactions” would be inappropriate in that this term already has a meaning in contemporary practice which may lead pharmacists to believe that they will be required to report to the Board such reactions as nausea, vomiting, rash, etc. Reporting of such reactions to the Board could result in Boards being deluged with information while providing for no protection of the public health, safety, and welfare. However, reporting of Significant Drug Errors, would alert state Boards to situations or pharmacists that present a danger to the public health, safety, and welfare. Such reporting would be consistent with assisting Boards in their mission to protect the public health, safety, and welfare.