Committee on Pharmacy Practice

Members Present:

Howard B. Bolton (LA), *Chairman;* Judith S. Christensen (IN); Ralph G. Deitemeyer (KY); William P. Larson (AK); James Lill (VT); Milton Moskowitz (MD); Maureen Sandison (WA).

Others Present:

T. Donald Rucker, *Professor Emeritus, University of Illinois at Chicago College of Pharmacy;* David R. Work (NC), *Executive Committee Liaison;* Beth Aylward, Mary Jo Hunst, and Bart Clark, *NABP Staff.*

Introduction:

The 1990-91 Committee on Pharmacy Practice met January 25-26, 1991 at NABP Headquarters in Park Ridge, Illinois. The Committee reviewed its charge, and proposed no changes to it.

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 centers, 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 settings 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.

Resolution CPP#1:
Compounding and Manufacturing

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 medication 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 the 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 discussed recent incidents that prompted concern from FDA regarding the "compounding" and/or "manufacture" of pharmaceuticals. Committee members discussed the difference between both practices and agreed that, while the difference between the two is sometimes ambiguous, compounding is an essential part of the practice of pharmacy and must remain the jurisdiction of state boards of pharmacy.

The Committee recommends strongly that the Executive Committee of NABP contact FDA immediately to clarify the boards' position, and that NABP work with FDA to resolve this issue by defining the practice of compounding more definitively, and by providing model standards to state boards of pharmacy.

Resolution CPP #2:
Medicaid Prudent Pharmaceutical Purchasing Provisions (MPPP)

WHEREAS, the enactment of the Medicaid Prudent Pharmaceutical Purchasing Provisions (MPPP), including provisions for Drug Utilization Review, has significant impact on pharmacy practitioners and regulators, and

WHEREAS, pharmacists are health care professionals qualified to undertake the Drug Utilization Review requirements of the legislation, and

WHEREAS, state boards of pharmacy must play a key part in developing and implementing standards for Drug Utilization Review,

THEREFORE BE IT RESOLVED that NABP take and maintain the **lead** role in appointing a task force consisting of representatives from state boards of pharmacy, the pharmacy profession, the profession and regulators of medicine, and the scientific community to develop such standards, and

BE IT FURTHER RESOLVED that the aforementioned task force work with Senator David Pryor (AR) and his staff to assist in the implementation of the MPPP, and make recommendations to HCFA and state Medicaid officials regarding implementation and enforcement of the Drug Utilization Review provisions of MPPP.

Background:

After a comprehensive presentation from Dr. T. Donald Rucker concerning the implications for boards of pharmacy posed by the retrospective and prospective Drug Utilization Review provisions of the MPPP, the Committee discussed this new legislation at length. It is clear that the implications of this legislation are dramatic for both the profession of pharmacy and its regulators, and the Committee agrees that state boards of pharmacy and NABP must assume a leadership role, working closely with the medical and scientific communities. Enactment of MPPP has provided a unique and timely opportunity for NABP and pharmacy regulators, and it is imperative to act immediately.

The Committee expressed many concerns about the MPPP implementation process, including reservations about how closely the medical and scientific communities will be willing to work with state boards of pharmacy and NABP; that uniformity among the states is key to the successful implementation of the program; and that the legislation cannot possibly be fully and effectively implemented within the two-year deadline.

Rather, planning a step-by-step basis to achieve maximum benefits should be encouraged. The Committee added that the manner in which the requirements of this legislation are presented to the profession of pharmacy is critical to its success, that it should be presented as an important opportunity for pharmacy to play a larger and even more critical role in pharmaceutical care.

The Committee expressed further concern about the cost of implementing MPPP to state boards of pharmacy, and recommends that NABP speak with Senator Pryor and/or his staff regarding financial assistance from the federal government. They suggest that once a task force is appointed, input be sought in planning for the point-of-sale equipment provisions of the legislation from organizations that already have extensive experience in Medicaid claims processing. They agree that the composition of a uniform final database is critical to the success of such a widespread effort.

Regarding the development of standards for Drug Utilization Review, the Committee suggests that hospitals, which have had such standards in place for many years, should serve as a valuable resource to the task force.

In addition to the above Resolution, the Committee also recommends to the Executive Committee that a presentation of the scope and impact of this legislation be made to all state boards of pharmacy in the form of educational programming.

The Committee asserts that NABP and state boards of pharmacy must take and maintain the lead in developing and implementing the MPP's DUR provisions.

Recommendation CPP #1: Pharmacist Workloads as Related to Public Safety

The Committee recommends that the Executive Committee of NABP sponsor or solicit sponsorship for a study on pharmacists' current workloads in the various practice sites, in an effort to determine if and how they impact on public safety.

Background:

The Committee discussed this issue both generally and in regard to various practice sites, including community pharmacy, hospital and other institutional pharmacy, long-term care, etc. They agree that a pharmacist's workload in any setting could affect the public's safety, and that this is an issue of general concern to all state boards of pharmacy.

Additionally, pharmacist workloads relate directly to many other key issues that boards are currently considering, including patient counseling, technicians/support personnel, manpower, and implementation of the Medicaid Prudent Pharmaceutical Purchasing Provisions and its Drug Utilization Review provisions.

The Committee feels that it is impossible to determine what impact current pharmacist workloads have on public safety until more comprehensive data is available regarding workloads in the various practice sites.

The Committee asserts that while each individual pharmacist has the professional ability and obligation to work in a manner so as not to endanger the public he or she serves, it is necessary to determine what current workloads entail before further consideration can be give by either professional organizations or by the boards themselves.

Recommendation CPP #2: Quality Assurance Programs

The Committee on Pharmacy Practice recommends to the NABP Executive Committee subcommittee responsible for review and update of the *Model State Pharmacy Practice Act and Model Regulations* that the concept of outcome-oriented quality assurance programs for all aspects of pharmacy practice, as an aid to pharmacists in monitoring pharmaceutical care, be included in the *Model Act* wherever it most appropriately fits.

Background:

In discussing the issue of medication errors, the Committee agreed that it is imperative that pharmacists, as part of their professional practice, have in place a reliable mechanism by which to monitor types and numbers of medication errors, and pharmaceutical care in general.

Since quality assurance programs have proven to be helpful in all settings, they suggested that pharmacists in every practice setting have the responsibility to develop a comprehensive, outcome-oriented quality assurance plan to monitor pharmaceutical care in that setting, and that this aspect of pharmacy practice should be included in the *Model Act.*

Recommendation CPP #3: Distribution of Drugs Directly from Manufacturer to Patient

The Committee on Pharmacy Practice recommends to the NABP Executive Committee that it forward a letter to FDA in opposition to the direct distribution of drugs from the manufacturer to the patient without the utilization of a pharmacy and/or pharmacist, and also opposing the FDA endorsement of any closed system of distribution of pharmaceuticals. NABP should also request that FDA establish a policy to address these concerns.

Background:

The Committee reviewed NABP Resolution 86-7-90, which states the NABP membership's opposition to direct drug distribution by drug manufacturers to the patient. The Committee reaffirmed the Resolution, stating that direct distribution to the patient from the manufacturer circumvents critical services that pharmacists are trained and expected to provide, and which are in place to protect the patient.

Critical services provided by pharmacists that such a distribution system bypasses include patient counseling, drug utilization review, as well as monitoring.

Recommendation CPP #4: Military Service of the United States

The Committee on Pharmacy Practice recommends to the NABP Executive Committee subcommittee charged with reviewing and updating NABP's *Model State Pharmacy Practice Act and Model Regulations* that they consider including in the *Act* language which would enable state boards of pharmacy to exempt pharmacists serving in the military of the United States from meeting licensure renewal requirements during times of national emergency.

Background:

The Committee discussed problems that have arisen related to licensure requirements as a result of the war with Iraq. The Committee felt that it was important for state boards, during times of national emergency, to have the authority to exempt military service personnel from any or all licensure renewal requirements as deemed appropriate by the board.

While each state should determine which requirements are appropriate, fees and continuing education were mentioned by the Committee as possible items for exemption.

Recommendation CPP #5: FAX Regulations

The Committee on Pharmacy Practice recommends to the Executive Committee that DEA be asked to consider permitting faxing or other electronic transmission of Schedule III, IV, and V prescriptions, directly from the prescriber to the pharmacy, in the best interest of the patient and to guard against diversion, since the pharmacists is ultimately responsible for verifying the authenticity of any prescription. They suggest that DEA be asked to confirm this practice in a letter from the Agency.

The Committee further recommends to the NABP Committee on Law Enforcement/Legislation that they consider allowing the faxing or other electronic transmission of Schedule III, IV, and V prescriptions in the model FAX regulations they will be drafting at their February 1-3, 1991 meeting.

Background:

The Committee discussed DEA's position on the faxing of controlled substance (III-V) prescriptions, and did not find it consistent with other methods of transmitting prescriptions, e.g. telephone. The Committee feels that in many ways, faxed prescriptions are for a superior to prescriptions communicated by telephone.

With a faxed prescription, a pharmacist can usually verify the source of the fax, will have a facsimile signature from the prescriber, and will have a written record of the prescription. In the case of prescription called in by phone, pharmacists are not required to maintain any documentation as a back-up from the prescriber.

With a faxed prescription, pharmacists can maintain a copy of the faxed document as back-up. In general, the Committee believes that technological advances can assist in the safe practice of pharmacy, and that they should be utilized to do so when indicated.

Recommendation CPP #6: Anabolic Steroids

The Committee on Pharmacy Practice requests that the NABP Executive Committee contact DEA and ask them to coordinate the effective dates of both their Anabolic Steroids Control Act of 1990, and the resulting regulations which DEA is not obligated to promulgate. The Committee recommends that the effective dates for both the legislation and the regulations be identical.

The Committee also suggests to the NABP Executive Committee subcommittee charged with the review and update of the *Model State Pharmacy Practice Act and Model Regulations* that it consider whether changes are needed to NABP's current Model Law on Anabolic Steroids in light of the federal legislation, and if this Model is still needed.

Background:

Chairman Bolton informed the Committee that as written, the Anabolic Steroids Control Act of 1990, which became effective in February 1991, calls for DEA to promulgate additional regulations within 45-180 days that will exempt this legislation many of the drugs it currently includes. As a result, pharmacies will be required to inventory, as controlled substances, all drugs included in the legislation in time for the February 1991 effective date. Ninety days later, DEA will publish a list of **exemptions** from the current list, requiring pharmacies to re-inventory the drugs at the time. The Committee feels that this is redundant and cumbersome, and believes that DEA should be asked to make both effective dates coincide.

Recommendation CPP #7: Self-Administration of Medications

The Committee on Pharmacy Practice recommends to state boards of pharmacy that pharmacists be allowed to utilize innovative prescription packaging which would improve and enhance patient compliance, as long as such packaging meets board-approved standards.

Background:

Member Moskowitz brought to the attention of the Committee that some states do not currently allow the use of "medpak" self-administration packaging for multiple medications to improve patient compliance. The Committee agreed that medpaks can improve patient compliance, especially in the elderly or handicapped. It also acknowledged that health care costs may be reduced if patients are not required to be institutionalized simply because they are unable to comprehend and comply with complicated drug therapies. The Committee felt strongly that while medpaks may be valuable tools in pharmaceutical care, all such packaging should meet board-approved standards for packaging.

Recommendation CPP #8: Mission of Pharmacy

The Committee on Pharmacy Practice recommends to the NABP Executive Committee that it review the various "Mission Statements" that currently abound for pharmacy, and that they select or draft one for incorporation into the *Model State Pharmacy Practice Act and Model Regulations,* if appropriate. They further recommend that the term "pharmaceutical care" should replace the term "pharmacy services" or other such terms.

Background:

In conjunction with many of the areas it addressed, the Committee discussed the fact that a "Mission Statement" for pharmacy is being considered and developed by the profession, and felt that if appropriate, such a statement would be useful to include in the *Act.*

Recommendation CPP #9: Amendment of the "Definition of Pharmacy Practice"

The Committee on Pharmacy Practice recommends to the NABP Executive Committee subcommittee charged with review and update of the *Model State Pharmacy Practice Act and Model Regulations* that the "Definition of the Practice of Pharmacy" in the *Model Act* be amended as proposed by the 1989-90 Committee on Pharmacy Practice.

Background:

The Committee reviewed the current definitions as well as changes proposed last year, and agreed that the changes proposed last year are still appropriate and necessary.