



Committee on Law Enforcement/Legislation

Members Present:

J. Floyd Ferrell, Jr., *Chairman*, (TN); Leo Blais (RI); Clovis S. Burch (LA); Bernard Corchnoy (PA); Frank M. Cole (AR); Galen Jordre (SD); William P. Larson (AK).

Others Present:

Roslyn Scheer (MD), *Executive Committee Liaison*; Carmen A. Catizone, *Executive Director*; Bart Clark, *NABP Staff*.

Introduction:

The 1991-92 Committee on Law Enforcement/Legislation met February 14, 1992 at NABP Headquarters in Park Ridge, Illinois. The Committee reviewed its charge and proposed no recommendations to amend or change it.

The charge of the Committee on Law Enforcement/Legislation remains as follows:

1. Review and comment on existing legislation and regulations for the practice of pharmacy and related areas within pharmacy, including impaired pharmacists;
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by members of the Association, or from reports of the other committees of the Association;
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Recommendation CL/L #1:

Standardized Pharmacy Reports

The Committee on Law Enforcement/Legislation recommends that state boards of pharmacy adopt the following Standardized Pharmacy Compliance Reports developed by a special committee of representatives from NABP and the American Society for Automation in Pharmacy (ASAP):

Report #1: Nightly Drug Print-Out (*as amended*)

Report #2: C/S Audit Report (*by drug*)

Report #3: Drug Audit Report (*by prescriber*)

Report #4: Drug Audit Report (*by pharmacist*)

Report #5: Patient Profile (*as amended*).

The Committee reviewed the remaining Standardized Pharmacy Compliance Reports:

Report #6: Drug Purchases

Report #7: C/S Purchase Report (*by schedule*)

Report #8: C/S On-Hand Inventory Report

Report #9: DEA Registration Number Report.

The Committee acknowledged that Standardized Report #'s 6-9 were valuable and could help states standardize their compliance procedures. However, the Committee did not feel that states need to adopt the reports at this time. Therefore, the Committee made no recommendations regarding the adoption of the reports by state boards of pharmacy.

Background:

The project to standardize certain pharmacy computer functions (reports, labeling, etc.) was initiated in November 1989 by representatives of NABP and ASAP. A special subcommittee composed of representatives from NABP and ASAP was organized. Paul Boisseau, Executive Director of the New Hampshire Board of Pharmacy and Secretary/Treasurer of the NABP Executive Committee; Peter Grasso, Chief Compliance Officer for the New Hampshire Board of Pharmacy; Bill Lockwood, Executive Director of ASAP; and Louis B. Phipps, Director of Pharmacy Services for QS/1 Pharmacy Systems, co-chaired the committee. The special committee developed an interactive workshop that was presented at the 1990-91 District III, IV, and VI meetings and designed prototypes for standardized reports has also been forwarded to the Drug Enforcement Administration (DEA) for comment.

The Committee on Law Enforcement/Legislation reviewed the reports, making the recommendations noted above. The Committee took care to ensure that the reports and report formats complied with federal requirements. It was agreed that standardization among the states was necessary and that the special committee had done an outstanding service for the state boards. A complete copy of the reports, as amended by the Committee, is attached to this report.

Recommendation CL/L #2:

NABP's Clearinghouse for Wholesale Distributors

The Committee recommends that state boards of pharmacy utilize the NABP Clearinghouse for Whole Distributors to assist in the licensure, disciplinary reporting, and inspection of wholesale distributors (PDMA).

Background:

In 1987, Congress enacted the Prescription Drug Marketing Act of 1987 (PDMA) requiring states to license and regulate wholesale distributors involved in the distribution of prescription drugs in interstate commerce. The PDMA also required that the FDA develop guidelines for states to license wholesale distributors. NABP worked closely with the FDA to develop these guidelines. The final guidelines adopted by the FDA mirrored the NABP guidelines, officially known as the NABP Model Regulations for Licensure of Wholesalers, developed by the 1990-91 Committee and approved by the membership at the 87th Annual Meeting.

NABP staff reported to the Committee that the NABP Wholesaler Clearinghouse is near completion and will be operational by March, 1992. The application form for the Clearinghouse has been reviewed by the FDA, the state boards of pharmacy, wholesale distributors, and representatives of the National Wholesale Druggists Association (NWDA). The application incorporates the minimum requirements for licensure application delineated in the FDA Guidelines. The NABP Clearinghouse will assist wholesale distributors licensed in one state who need to acquire licensure in additional states obtain licensure in all states where the application will be accepted. The NABP Clearinghouse eliminates the need to prepare separate, often repetitive, applications for each jurisdiction. NABP's service will also include corrections, changes, and updates in information. The wholesale distributor will submit the information to NABP, who, in turn, will send the information to all states where the distributor is licensed. NABP will also handle renewal for those manufacturers or state boards of pharmacy that request this service.

The Committee discussed the legal basis for states to license out-of-state wholesalers. It was agreed that the state boards of pharmacy possess the authority to license out-of-state wholesalers. It was further agreed that there was a need to license out-of-state wholesalers in order to protect the public from the inherent danger of the shipping of thousands (perhaps millions) of medication doses into states. NABP Counsel has repeatedly opined that the regulation of out-of-state wholesales by state boards of pharmacy would not be a burden on interstate commerce, especially if the guidelines developed by NABP are enacted.

Recommendation CL/L #3:

NABP Task Force on OBRA '90

The Committee on Law Enforcement/Legislation recommends that state boards of pharmacy officially recognize that patient counseling and prospective drug use review (DUR) are inherent parts of the practice of pharmacy and regulated by the state boards of pharmacy through state pharmacy practice acts. The Committee further recommends that state boards of pharmacy adopt the Model Regulations for Patient Counseling and Prospective DUR, developed by NABP and its Task Force to implement OBRA '90.

Background:

In 1990, Congress passed the Omnibus Budget Reconciliation Act (OBRA '90), amending the 1965 Medicaid Law to condition federal Medicaid payments for outpatient drugs on states developing drug use review programs (DUR) and patient counseling requirements. NABP actively participated in the drafting of OBRA '90's language defining patient counseling and DUR. In fact, NABP's Model Regulations for Patient Counseling were included almost verbatim in OBRA '90.

Shortly after the passage of OBRA '90, NABP organized, in response to a resolution passed by the membership and at the urging of other national pharmacy organizations, a task force to assist states in the implementation of the patient counseling and DUR provisions of OBRA '90. The Task Force included representatives from the Joint Commission of Pharmacy Practitioners (JCPP), the United States Pharmacopeial Convention (USPC), the Food Marketing Institute (FMI), the Health Care Financing Administration (HCFA), state Medicaid agencies, Senator Pryor's office, and the American Medical Association (AMA).

The Task Force was successful in preparing model regulations for patient counseling and prospective DUR that could be used by the state boards of pharmacy. The packet was reviewed and enforced by the Committee for states to utilize when developing regulations to implement the patient counseling and prospective DUR provisions of OBRA '90.

Resolutions C/L #1:

Distinguishing Pharmacy Compounding from Manufacturing of Drugs

The Committee recommends that state boards of pharmacy adopt the following definitions for distinguishing between pharmacy compounding and the manufacturing of drugs:

Compounding means the preparation, mixing, assembling, packaging, or labeling of a drug or device (i) as a result of a practitioner's Prescription Drug Order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice or, (ii) for the purpose of, as an incident to research, teaching, chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of Prescription Drug Orders based on routine, regularly observed patterns.

Manufacturing means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices. Manufacturing also includes the preparation and promotion and marketing of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

Background:

The Committee reviewed recent events surrounding the distinction between pharmacy compounding and the manufacturing of drugs. NABP has been working with the FDA and other national pharmacy organizations since October of 1991 to define these two practices. In recent months, the FDA has issued a number of regulatory letters to pharmacists asserting that the activities engaged in by these pharmacists was manufacturing. In November of 1991, NABP released draft definitions of compounding and manufacturing for comment. It has received back comments from the state boards, national pharmacy organizations, pharmacists, and national compounding companies. The comments have all indicated a need for the definitions to be broadened so as not to interfere with the practices of pharmacy and medicine.

The Committee reviewed these comments as well as information of allegations against some firms engaged in manufacturing, but maintaining that they are engaged in compounding as defined and appropriated licensed to do so by the state boards of pharmacy where domiciled. NABP has repeatedly asked the FDA to release draft compliance policy guidelines defining manufacturing for public comment so that state boards of pharmacy and pharmacists can understand the distinction being made by the FDA. NABP is also concerned that the language of the regulatory letters issued by the FDA seems to encroach upon the constitutional authority of state boards of pharmacy to regulate the practice of pharmacy. The FDA appears anxious to bring enforcement actions to ensure the safe and effective use of a new drug and thus assume broad authority to promulgate regulations that are reasonably related to the public health purposes of the Food, Drug, and Cosmetic Act. NABP is **very** concerned that the initiatives

undertaken by the FDA in this regard are circumventing the authority of state boards of pharmacy and do **not** have standing under the Act.

Resolution CL/L #2:

Pharmacist Phone Consultation Services

WHEREAS, the Committee on Law Enforcement/Legislation recognizes that the practice of pharmacy is defined to include the provision of pharmaceutical care services by the pharmacist, such as but not limited to, patient counseling; and

WHEREAS, pharmaceutical care services are being provided in settings other than traditional practice sites; and

WHEREAS, state boards of pharmacy are responsible for protecting the health and welfare of the public and regulating the practice of pharmacy;

THEREFORE BE IT RESOLVED that state boards of pharmacy regulate the practice of pharmacy in all settings where pharmaceutical care is being provided through licensure and appropriate regulations.

Recommendation CL/L #4

The Committee further recommends that state boards of pharmacy ensure that individuals engaged in the practice of pharmacy in non-traditional settings are licensed to practice and conform with applicable state laws protecting the patients to whom pharmaceutical care is being provided.

Background:

The Committee discussed the emerging practice of pharmacists providing phone consultation to patients via 1-900 phone service numbers. The Committee expressed concern that states may not have adequate safeguards in place to ensure that the public is protected from wrong information or individuals purporting to be knowledgeable about medications and devices and misleading the public. At the minimum, the Committee agreed that if information about medications is being provided to patients as occurs in the practice of pharmacy, such individuals should be licensed by the state boards of pharmacy where such practices are located. The Committee discussed the need to license these individuals in the states where the patient is located or the information service is provided, but did not reach consensus.