Task Force on Collaborative Practice Agreements

Members Present:
Sharlea M. Leatherwood, Chair (MO); Michael J. Ayotte (VA); Winifred A. Landis (IN); Jeffery Lindoo (MN); C. Ann Perry (GA); Charles R. Young (MA).

Others Present:
Joseph A. Whaley, Jr., Executive Committee Liaison; Carmen A. Catizone, NABP Executive Director/Secretary; Melissa Madigan, NABP Staff.

Introduction:
The Task Force on Collaborative Practice Agreements (TFCPA) met December 3, 1998, at the Marriott Suites Hotel in Rosemont, Illinois. The Task Force was established by the NABP Executive Committee in response to recent increases in the number of prescribers and pharmacists entering into collaborative practice agreements and requests that boards of pharmacy define the elements of an appropriate collaborative practice agreement.

Charge of the Task Force on Collaborative Practice Agreements
Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

- Review the available literature and information pertaining to collaborative practice agreements between prescribers and pharmacists.
- Develop national model guidelines for writing and implementing uniform collaborative practice agreements that can be utilized by the state boards of pharmacy.

TFCPA Recommendation #1
The Task Force on Collaborative Practice Agreements recommends to the Executive Committee and the Committee on Law Enforcement/Legislation that the following language be adopted for incorporation into the NABP Model State Pharmacy Act and Model Rules.

Article I
Title, Purpose, Definition
Section 105. Definitions.

(g) “Collaborative Pharmacy Practice” is that Practice of Pharmacy whereby a one or more Pharmacists has jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol whereby the Pharmacist may perform certain patient care functions authorized by the Practitioner or Practitioners under certain specified conditions and/or limitations.
(h) “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice for the purpose of Drug Therapy Management of patients.

…

(r) “Drug Therapy Management” means the review of Drug therapy regimen(s) of patients by one or more Pharmacists for the purpose of evaluating and rendering advice to one or more Practitioners regarding adjustment of the regimen. Decisions involving Drug Therapy Management shall be made in the best interest of the patient. “Drug Therapy Management” may include:

(1) Implementing, modifying, and managing Drug therapy according to the terms of the Collaborative Pharmacy Practice Agreement;
(2) Collecting and reviewing patient Drug histories;
(3) Obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration;
(4) Ordering and evaluating the results of laboratory tests directly relating to Drug therapy, when performed in accordance with approved protocols applicable to the practice setting; and
(5) Such other patient care services as may be allowed by law.

“Pharmacist’s Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement” means those duties and limitations of duties placed upon one or more Pharmacists by the collaborating Practitioner or Practitioners, the Board, and applicable law, and includes the limitations implied by the specialty practiced by the collaborating Practitioner or Practitioners.

Model Rules for Pharmaceutical Care
Section 3. Pharmacy Practice.

Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement
A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The existence and termination of such Agreement shall be reported to the Board and such Agreements shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist’s Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct Drug Therapy Management activities approved by the Practitioner. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner’s current practice. Patients who receive services from one or more collaborating Pharmacists shall receive notification of receipt of such services.

(2) Contents
The Collaborative Pharmacy Practice Agreement shall include:

(a) Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(b) The types of Drug Therapy Management decisions that the Pharmacist is allowed to make, which may include:
(i) A detailed description of the types of diseases, Drugs, or Drug categories involved, and the type of Drug Therapy Management allowed in each case;
(ii) A detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting Drug Therapy Management; and
(iii) A detailed description of the activities the Pharmacist is to follow in the course of conducting Drug Therapy Management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;
(c) A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes where Drug Therapy Management by the Pharmacist has occurred and to intercede where necessary;
(d) A provision that allows the Practitioner to override a collaborative practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
(e) A provision that allows either party to cancel the agreement by written notification;
(f) An effective date; and
(g) Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as the date of signing.
Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3) Initiation of the Collaborative Pharmacy Practice Agreement
The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate Drug Therapy Management for any particular patient.

(4) Documentation of Drug Therapy Management
Documentation of Drug Therapy Management must be kept as part of the patient’s permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to received it. Documentation of drug Therapy Management shall be considered Confidential Information.

(5) Review
At a minimum, the written agreement shall be reviewed and renewed, and, if necessary, revised every year.

[NOTE: the above new subsections would be inserted with sequential relettering of all subsequent subsections.]

Background:
Task Force members listened to a brief presentation by American College of Clinical Pharmacy (ACCP) Executive Director Robert Elenbaas and Immediate Past President Jerry Bauman regarding ACCP’s position on collaborative practice agreements, and later discussed their charge to develop national guidelines for writing and implementing uniform collaborative practice agreements for use by state boards of pharmacy. They agreed that the best way to fulfill their charge was to create model regulations addressing the issue.
To assist in developing the model regulations, members looked to several sources of information, including current state pharmacy laws and regulations, as well as the information provided by Drs. Elenbaas and Bauman. The Task Force felt that the Idaho State Board of Pharmacy’s regulations on collaborative practice encompassed much of what they wanted to include in the model regulation; therefore, they were used as a blueprint.

A “brainstorming” session brought issues and concerns regarding state regulation of collaborative pharmacy practice to the forefront. Topics that members felt needed to be addressed in a model regulation included:

- Contents of collaborative pharmacy practice agreements;
- Practitioner override authority;
- Board approval of agreements;
- Pharmacists’ documentation of care;
- Patient consent/notification;
- Confidentiality of patient information;
- Periodic review of agreement;
- Pharmacist competence/qualifications to provide drug therapy management services; and
- Quality assurance review of practice.

Task Force members concurred on a majority of these topics and incorporated their determinations into the model recommendation. Members agreed that certain key elements should be included in collaborative pharmacy practice agreements so that such agreements may guide both the pharmacists’ and collaborating practitioners’ decisions and conduct. Key elements incorporated included a description of the pharmacists’ activities, a method describing a practitioner monitoring methods, and a practitioner override clause.

Members also agreed that it should not be necessary for boards of pharmacy to take on the responsibility for approving agreements or even requiring their submission, but that boards should require parties to notify them of the existence of such agreements and to keep a copy at the practice site. On this issue, members concluded that the individual practitioners, were the persons most qualified to approve the agreements, noting that minimal government involvement in the practice of the pharmacist and collaborating practitioner was the most desirable. In order for the board to have some handle on the situation, however, it was determined that agreements should be made available for board inspection upon request. Regarding the issue of pharmacist competence to provide drug therapy management services, Task Force members concluded that the subject should not be addressed in the model regulations. They agreed that the determination of competence should be left up to the individuals who are party to the agreement. Members felt certain that most, if not all, collaborating practitioners would only delegate certain aspects of their patient care authority upon demonstration by the pharmacist of his or her abilities to provide such care. Further, members felt that the majority of pharmacists would not take on the responsibility for providing such care without being competent to do so.

**TFCPA Recommendation #2**

The Task Force on Collaborative Practice Agreements recognized that the issue of quality care assurance is not still developing and, at present, cannot be addressed with regard to collaborative pharmacy practice. The Task Force recommends that the NABP Executive Committee closely
follow this issue and, should it be determined that language addressing the subject should be incorporated into the model regulation, take further action at that time.

**Background:**

Task Force members were uncertain at this time of how to address the issue of quality care assurance. Members noted that most states addressing collaborative pharmacy practice in their laws or regulations did not include a provision on this subject. It was noted, however, that at least one state placed the responsibility for quality assurance on the “Principal pharmacist and practitioner” and that ACCP urged that an “appropriate body” be responsible for such activities.

Member postulated that collaborative practice activities would likely be subject to quality assurance review via physician peer-review processes. Additionally, they suggested that those parties practicing in institutional settings would follow the quality assurance policies, guidelines, and/or requirements of the institution. The Task Force felt it was premature to make a recommendation regarding those parties who practice in ambulatory settings and who may not be subject to quality assurance review. Members observed that the work of NABP’s Task Force on Patient Outcomes Regulation should be reviewed before a recommendation was made.