Members Present:
Jeanne Gilligan Furman (MD), chair; Michael J. Ayotte (VA); Reuben R. Dixon (LA); Ryan C. Lee (UT); Karen Ryle (MA).

Members Not Present:
Gay Dodson (TX); Patricia F. Donato (NY).

Others Present:
Howard Anderson (ND), executive committee liaison; Carmen Catizone, Melissa Madigan, NABP staff.

Introduction:
The Task Force on Transition of Pharmacy Regulation from the Dispensing Process to Outcomes met December 12, 2002, at the Hyatt Rosemont Hotel in Rosemont, Illinois.

Review of the Task Force Charge
Task Force members reviewed their charge and, proposing no changes, accepted it as follows:
Assess the current status of NABP’s Regulating for Outcomes initiative and prepare recommendations for the Executive Committee that assist states in transitioning their current regulations from a focus on dispensing to patient care outcomes with specific attention to patient outcome data, expanded role of the technician, automation, e-prescribing systems, centralized prescription filling systems, continuous quality improvement programs, and pharmaceutical care provisions.

Recommendation 1: Move Forward with Regulating for Outcomes
The Task Force recommends that NABP and the state boards of pharmacy move forward with implementing the regulating for outcomes concept by: 1) reviewing regulating for outcomes literature for currency and making any needed updates; 2) surveying the state boards of pharmacy to gauge their position and status with regards to regulating for outcomes and their assessment of the barriers that prevent the adoption of the regulating for outcomes concepts; and 3) working with other pharmacy groups to develop practice criteria and standards necessary to implement outcomes regulation.

Background:
Task Force members questioned why there has been limited “buy in” by the state boards of pharmacy into the regulating for outcomes concept since its release several years ago, noting that, although some boards have adopted the continuous quality improvement portion of the regulating for outcomes concept and others have redirected their disciplinary focus to error mitigation and systems for identifying root causes of errors to prevent recurrences, many boards have not done so and still take a punitive approach to medication errors. Suggested reasons for the lack of acceptance included the enormity and complexity of the concept; the lack of guidance on how to incorporate outcomes regulations into actual pharmacy regulation procedures; the fact
that practice models and settings do not support the concept; and the lack of nationally recognized and accepted practice criteria and standards that can be used by boards and the pharmacy profession as a basis for determining practice success.

Members felt a review of the materials for currency, coupled with a survey and the development of national criteria and standards might give the concept a “jump start” with regards to its acceptance by boards and the profession. It was suggested that a review and update be taken on by David Brushwood, who worked with NABP to initially develop the regulating for outcomes concept. The survey would be a modified version of the one distributed to boards of pharmacy by NABP in 1997, which sought board input on responsibility for the outcomes of drug therapy and approaches that might be taken to regulate for pharmaceutical care outcomes. Additional information will be collected on what, if any, portions of the outcomes regulations boards have adopted, and any perceived barriers to the adoption of such regulations (e.g., expense, resistance from profession, lack of usefulness, lack of protection from discovery, etc.). The development of criteria and standards would take place with input of the practitioner organizations, and would attempt to identify successful patient outcomes in each of the various practice settings and methods that could be used to measure outcomes. Once all these tasks are completed and the information is collected and analyzed, the next steps can then be determined and may include a second meeting of the Task Force.

**Recommendation 2: Develop a Guidance Report for Boards on Outcomes Regulation**

Once the review and survey are completed and the criteria and standards developed, as indicated in Recommendation #1, the Task Force recommends that NABP develop a guidance document for boards of pharmacy on how to implement outcomes regulation.

**Background:**

Task Force members agreed that among the barriers preventing the implementation of the regulating for outcomes strategy are the sheer enormity and complexity of the concept. The complexity of the regulating for outcomes concept seems to prevent its implementation by presenting an insurmountable challenge that lacks a clear and definable starting point. A guidance document identifying an appropriate starting point and order of implementation, where the most critical concepts are phased in first (e.g., continuous quality improvement programs), would provide boards with much needed advice on this issue.

**Recommendation 3: Develop White Paper on Regulating for Outcomes**

The Task Force recommends that NABP develop a white paper or report on the current status of outcomes regulation in the states and within the profession, assessing and documenting the progress that has been made and projecting successful strategies for future implementation. The analysis should include examples of how state boards implemented regulating for outcomes approaches and the impact on the practice of pharmacy and patient care.

**Background:**

Members felt that an analysis of outcomes regulation might provide the explanation and exposure NABP needs to further the acceptance of the regulating for outcomes approach. It was noted that certain states have put forth significant efforts to further the concept of quality care.
and quality improvement, including Massachusetts, Florida, California, and Texas, and that any report developed by NABP should document their efforts to assist other states.

**Recommendation 4: Amend Model Act**

The Task Force recommends the following changes to the NABP Model State Pharmacy Act and Model Rules:

**Model State Pharmacy Act**

**Article I Title, Purpose, and Definitions**

…

**Section 105. Definitions.**

…

(i) “Certified Pharmacy Technician” means personnel registered with the Board as defined in Article III of this Act, and allowed, under the supervision of a Pharmacist, to perform the activities involved in the Practice of Pharmacy, except that a Certified Pharmacy Technician may not perform the following activities: drug utilization review; clinical conflict resolution; prescriber contact concerning Prescription Drug Order clarification or therapy modification; Patient Counseling; Dispensing process validation; receive new Prescription Drug Orders when communicating telephonically or electronically unless the original information is recorded so the Pharmacist may review the Prescription Drug Order as transmitted.

**Model Rules for Pharmaceutical Care**

…

**Section 2. Personnel.**

A. Duties and Responsibilities of the Pharmacist-in-Charge

…

(2) The Pharmacist in Charge has the following responsibilities:

(a) Developing quality assurance programs for Pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect Drug diversion.

…

(c) Establishing policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices. Quality assurance programs shall be designed to prevent and detect Drug diversion.

…

Section 3. Pharmacy Practice.
I. Continuous Quality Improvement Programs

(1) Each Pharmacy shall establish a Continuous Quality Improvement Program. As a component of its Continuous Quality Improvement program, each Pharmacy shall assure that periodic meetings are held by staff members of the Pharmacy to consider the effects on quality of the Pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Pharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients. Incidents of medication errors shall be reported to an error reporting program designated by the Board. For those Persons utilizing a drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.

J. Collaborative Pharmacy Practice

(2) Contents.

The Collaborative Pharmacy Practice Agreement shall include:

... 
(d) A description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes.

Background:

Members reviewed the Model Act to determine if the additions included with the introduction of the regulating for outcomes approach were still applicable. The Task Force particularly noted that the Model Act language allowing for increased technician responsibility, requiring medication error reporting to a national error-reporting program, and adding some sort of quality improvement efforts within collaborative practices with prescribers would enhance the provision of quality patient care and should be addressed within the Model Act.

Recommendation 5: Update “Transfer of Prescription Drug Order”

The Task Force recommends the Committee on Law Enforcement/Legislation review the “Transfer of Prescription Drug Order” section in the Model Rules for Pharmaceutical Care for currency in an effort to further enhance outcomes regulation.

Background:

While scanning through the Model Rules for Pharmaceutical Care, members noted that this section is outdated in that it does not seem to accommodate for the electronic maintenance of prescription records and requires access and notation of prescription transfer on the prescription hard copy, unnecessary efforts that take pharmacists away from patient care activities.

Recommendation 6: Support for NABP’s Continuing Professional Development Program
The Task Force supports NABP’s commitment to improved patient outcomes through efforts designed to ensure professional competency.

**Background:**

The Task Force agreed that NABP’s Continuing Professional Development program will contribute to positive patient outcomes by providing pharmacists with a competency assessment mechanism to discover their strengths and weaknesses and directing them to continuing education programs designed to improve their knowledge and skills in designated areas.

**Recommendation 7: Support for NABP as an Accrediting Resource for Boards of Pharmacy**

The Task Force was apprised of NABP serving as an accrediting resource for boards of pharmacy seeking to rely on accreditation of pharmacies or pharmacists for certain specialized practices.

**Background:**

With pharmacy practice becoming more specialized and focused on patient outcomes and the need for specialized knowledge and skills increasing, the need for specialized accreditation seems to be emerging. For example, injury as a result of deficient compounding practices invariably evokes the need for accreditation of pharmacies and pharmacists in a compounding specialty; the inability to obtain needed medications perhaps evidences the need for accreditation of limited distribution pharmacies; and poor patient outcomes or the inability to demonstrate positive patient outcomes may demonstrate the need for accreditation in good patient outcomes. With resources to the boards of pharmacy dwindling, NABP can provide boards with assurance that these issues are addressed by pharmacists and pharmacies to interested boards.