Task Force on Patient Compliance and Intervention Programs

Members Present:
Carl D. Lyons, Chair (OK); Anthony W. Alexander, Jr. (NJ); C. Richard Allen (GA); Karen H. Kiessling (WA); R.T. “Tenny” Moss, Jr. (SC); and Janet H. Shipton (MO).

Others Present:
Carmen A. Catizone, NABP Executive Director/Secretary; Janice Teplitz, NABP Staff.

Introduction:
The Task Force on Patient Compliance and Intervention Programs (TFPCIP) met November 20, 1998, at the Marriott Suites Hotel in Rosemont, Illinois. The Task Force was established by the NABP Executive Committee in response to public concern about the need for such programs to assure confidentiality of patient-identifiable information and the promotion of improved medication-use behaviors, while prohibiting inappropriate and potentially damaging activities that may prove detrimental to patient health.

Charge of the Task Force on Patient Compliance and Intervention Programs
Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

- Review the “Patient Compliance and Intervention Programs Guidelines” developed by NABP and the comments that have been submitted in response to those Guidelines.
- Recommend to the Executive Committee whether such Guidelines should be incorporated into the NABP Model State Pharmacy Act and Model Rules.

Background:
A draft version of the “Patient Compliance and Intervention Programs Guidelines” was developed by NABP in response to concerns from its member boards of pharmacy, practicing pharmacists, professional pharmacy organizations, industry, and the public regarding organizations that use patient compliance and intervention programs for the primary purpose of attempting to switch patient drug regimens for economic or financial gain.

Elensys, a patient information management company recently highlighted in the Washington Post and other media, assisted NABP in preparing the first version of the Guidelines. Elensys representatives provided NABP with an overview of their company and the programs they manage for independent and chain pharmacies and manufacturers. They explained that the patient intervention programs managed by Elensys adhere to strict patient confidentiality guidelines and do not utilize “switch” programs. Their willingness to share the operating guidelines for these programs resulted in draft Guidelines that NABP subsequently sent for comment to the state boards for comment to the state boards of pharmacy, professional pharmacy organizations, and other interested groups June 1998. A copy of the draft was also posted for comment on the NABP Web site.
At its November meeting, Task Force members reviewed the draft Guidelines as well as the comments that had been submitted to NABP.

**TFPCIP Recommendation #1**

The Task Force on Patient Compliance and Intervention Programs recommends that the NABP Executive Committee accept the revised Guidelines, which have been renamed “Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs.” Task Force members believe that the new title more accurately describes the purpose of the Guidelines, which is to assure the confidentiality of patient-identifiable information as managed by patient compliance and intervention programs.

**Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs**

Section 1: Purpose

The purpose of these Guidelines is to provide pharmacists and patients with the appropriate direction and information for the design, implementation, and participation in “Patient Compliance and Intervention Programs.” Such Guidelines are needed in the interest of public health to protect the confidentiality of patient information, and prohibit contact with the patient that is inappropriate and potentially detrimental to the patient’s health.

Patient Compliance and Intervention Programs promote improved medication-use behaviors, such as compliance, appropriate monitoring, and self-reporting increased patient knowledge; and improved therapy options. It shall be a violation of these Guidelines for third-party programs/PBMs to attempt to, or cause, a switch of a patient’s medication, or direct a patient away from a course of therapy solely for economic or financial gains or incentives.

Section 2: Definitions.

a) “Confidential Information” means information accessed, maintained by, or transmitted to the Pharmacist in the patient’s records or which is communicated to the patient as part of Patient Counseling, which is privileged and may be released only to the patient or, as the patient directs, to those Practitioners, other authorized health care professionals, and other Pharmacists where, in the Pharmacist’s professional judgment, such release is necessary to protect or to improve the patient’s health and well-being; and to such other Persons or governmental agencies authorized by law to receive such Confidential Information, regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

b) “External Entities” means those organizations that exist outside of the pharmacist/patient relationship, such as third-party insurance carriers, benefit management systems, and marketing systems.

c) “Non-confidential Information” means information that is not Confidential Information as defined in this Guidance document.

d) “Patient Compliance Program” is defined as any formal activity that uses Non-confidential and/or Confidential Information to contact the patient or caregiver through, but not limited to, phone, print, or electronic media in order to improve the patient’s compliance with his or her prescribed medication therapy. In addition, Patient
Compliance Programs can involve information provided to the patient so as to educate that patient on his or her disease state.

e) “Patient Intervention Program” is defined as any formally activity that uses Non-confidential and/or Confidential Information to contact the patient or caregiver through, but not limited to, phone, print, or electronic media in order to discuss, inform, and/or affect a patient’s therapy or choice of medications. If the program information is mailed, delivery systems should be utilized which allow for return of the material if not deliverable, and a system to ensure that the information will only be delivered to the designated patient or caregiver. For example, if the contact is via the U.S. Postal Service, the information should be mailed first class.

Section 3: Confidentiality of Data Patient Compliance and Intervention Programs must be conducted in such a manner so as to ensure and protect the confidentiality of patient information and data. The unauthorized release or disclosure of such information may constitute a violation of State Practice Acts and Rules. The Pharmacist is responsible for providing services on behalf of, or at the direction of, a pharmacy or pharmacist in Patient Compliance and Intervention Programs. The pharmacy is responsible for the security and integrity of any patient information, confidential and non-confidential, and must abide by all relevant regulations applicable to the pharmacy or pharmacist.

The following minimal safeguards must be in place for Patient Compliance and Intervention Programs:

a) Information/data accessed, transmitted, stored, analyzed, or purged must use methods that are generally recognized as secure by experts qualified by training and experience;

b) Any correspondence with a patient or caregiver must be documented, traceable, recordable, and easily accessible by board of pharmacy inspectors or other authorized law enforcement officials;

c) Information/data maintained outside the pharmacy’s internal system(s) must adhere to the same security requirements as the pharmacy’s internal system(s), including, but not limited to, access, storage, audibility, and release of data;

d) Confidential patient information/data must be maintained in a manner to protect against such an unauthorized release of such information;

e) Procedures must be in place to ensure that purged information/data cannot be misused or placed into active operation without appropriate authorization;

f) Internet connectivity or remote access tied directly to systems containing patient data must be on a secure basis only;

g) Confidential Information must only be accessed by the Pharmacist(s) or by individuals under the direct supervision of the Pharmacist(s);

h) Patient-identifiable information must be utilized only to implement a program(s) approved by a Pharmacist, and cannot be distributed or provided to any third party(ies) other than the entity implementing the program with, or on behalf of, the pharmacy or claim adjudication; and

i) All personnel with access to Confidential Information or patient-identifiable information must sign and retain on file current confidentiality and non-disclosure agreements.

Section 4: Patient Participation

Patient Compliance and Intervention Programs must focus on the patient and should inform patients about the program’s purpose and use of information/data. A patient may have the option
to participate in any such program and, if deciding to participate, withdraw at any time the patient feels it necessary to do so. Programs designed to change a patient’s medication or medication therapy without the informed consent of the patient and prescriber are prohibited and in violation of the State Practice Act and Rules.

a) The patient should be provided with the source of the contact, including but not limited to the pharmacy/pharmacist’s name, address, and phone number; and
b) Nothing in this section or Guideline supercedes the procedures for drug recalls.

Section 5: Pharmacist Participation

A Pharmacist must oversee and approve all Patient Compliance and Intervention Programs. Pharmacists involved in the programs, either through contact with the patient or caregiver, or the design, implementation, management, and analysis of the program(s), are required to be educated about the existence and objectives of the program. Pharmacists in contact with the patient(s) or caregiver(s) are responsible for the accuracy and appropriateness of the information being presented and the list of participating patients.

a) Program information, along with the therapies included in the program(s), must be regularly communicated to pharmacists involved in the program(s); and
b) Results of the program(s) must be communicated to all pharmacists involved.

Section 6: Utilization of Non-confidential Information/Data

Only Non-confidential Information/Data should be provided to entities other than the patient or caregiver for research purposes or analysis. The unauthorized release or use of Confidential Information/Data or any patient/identifiable information/data may constitute a violation of State Practice Acts and Rules.

Section 7: Measurement and Analysis of Program(s)

Patient Compliance and Intervention Programs may include methodologies to measure the outcome of the program(s) in relation to patient care and the performance of the pharmacy/pharmacist. The following minimum guidelines must be observed when measuring and analyzing the program outcomes:

a) Analysis and aggregate data reports should not include any patient-identifiable information;
b) Study design, measurement, and analysis must adhere to accepted research and study designs; and
c) Reports prepared or published must provide accurate and statistically correct information.

Background:

Task Force members agreed that it was important for NABP to endorse strong guidelines that could be used by the state boards of pharmacy and other interested entities, including the U.S. Congress, in the development of legislative and regulatory initiatives to effectively protect the patient from inappropriate patient compliance and intervention programs that may have, as their primary focus, economic gain or incentives. They noted that expanded standards of practice and the increasingly sophisticated computer software programs designed to assist in their implementation could produce immense databases containing an ever-widening range of confidential patient information. Task Force members worried that while security for such patient-identifiable information could be assured in the closed loop of a pharmacy, the potential
for security breach increases significantly once the data becomes externally accessible. To guard against internal or external security breaches, the Task Force agreed that all personnel with access to the confidential or patient-identifiable information should be required to sign confidentiality and non-disclosure agreements, which would be kept on file with the employing entity.

Of further concern was the quality and quantity of information provided to patients prior to making a decision to enroll in a patient compliance and intervention program. Task Force members strongly agreed that no patient should be automatically enrolled in such a program. Patients should be fully informed about all aspects of the program at the outset before any enrollment action is taken. Furthermore, the decision of whether or not to participate in such programs must rest solely with the patient.

**TFPCIP Recommendation #2**

The Task Force on Patient Compliance and Intervention Programs recommends to the NABP Executive Committee that the Committee on Law Enforcement/Legislation consider adding the Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs as an addendum to the *NABP Model State Pharmacy Act and Model Rules* as follows:

**Model Rules for Pharmaceutical Care**

Section 3. Pharmacy Practice

N. Patient Compliance and Intervention Programs

Patient Compliance Intervention Programs designed to promote improved medication-use behaviors, such as compliance, appropriate monitoring, and self-reporting; increased patient knowledge; and improved therapy options shall comply with established Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs. *(See Appendix F for Model Guidelines for the Confidentiality of Patient Records as They Relate to Patient Compliance and Intervention Programs.)*

**Background:**

Task Force members agreed it was important to incorporate the Guidelines as a component of the *Model Act* so that boards of pharmacy and other interested parties could review them and adopt or modify the language to suit the requirements of their respective jurisdiction and constituencies. They further concluded that given the rapidly changing environment that supports patient compliance and intervention programs, the boards of pharmacy would be better served by offering the Guidelines as an addendum to the NABP Model Rules on Pharmaceutical Care. Unlike model regulations, which may be difficult to amend, Guidelines can be easily changed to meet evolving needs. Guidelines also allow state boards greater flexibility in determining how they will be used.

**TFPCIP Recommendation #3**

The Task Force on Patient Compliance and Intervention Programs recommends that the NABP Executive Committee advise state boards of pharmacy to pursue actions necessary to ensure
compliance with the “Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs.” Such compliance action should not be limited to pharmacists and pharmacies, but should also be required of state and/or federal regulation of pharmacy benefit managers, pharmaceutical care organizations, and other related entities.

**Background:**

Task Force members agreed that regulation of these entities is necessary to ensure uniformity and compliance throughout the system. They expressed concern that while PBMs often perform the same tasks as those performed in pharmacies, they are often unregulated by the state boards of pharmacy because they do not dispense drugs. The Task Force supported the need for regulation of these external entities and agreed that state boards of pharmacy should consider licensing them as pharmacies.

**TFPCIP Recommendation #4**

The Task Force on Patient Compliance and Intervention Programs recommends that the NABP Executive Committee provide a copy of the “Guidelines for the Confidentiality of Patient Records as It Relates to Patient Compliance and Intervention Programs” to Senator Robert F. Bennett (UT), sponsor of S.2609, the Medical Information Protection Act of 1998, which was introduced in the Senate October 9, 1998.

**Background:**

Task Force members noted that the Guidelines could serve as an important resource for not only the state boards of pharmacy, but for many federal and state agencies wrestling with the problem of confidentiality of patient records.