nabp
National Association of Boards of Pharmacy
700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

December 9, 2002

Richard M. Campanelli, JD
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F, HHH Building
Washington, D.C. 20201

RE: HIPAA Privacy Rule: Impact on State Board of Pharmacy Inspections and Prescription Monitoring Programs

Dear Mr. Campanelli:

The National Association of Boards of Pharmacy (NABP) is the professional organization that represents state boards of pharmacy in all regions of the United States, the Virgin Islands, Puerto Rico, eight provinces of Canada, four states in Australia, and New Zealand. NABP was established in 1904 to develop uniform standards and procedures for pharmaceutic licensure and for the transfer of licensure. Over the past 98 years, NABP has been repeatedly called upon to develop programs and services to assist the state boards in their charge to protect the public health, safety, and welfare.

It is in this capacity that we write to you asking how Section 167.528 of the final privacy rule (45 CFR §167.528) will impact inspections conducted by state boards of pharmacy, as well as controlled substance prescription monitoring programs run by state boards of pharmacy or other designated state agencies. Section 164.528 reads as follows:

> *Section 164.528: Accounting of disclosures or protected health information*
> *(a) Standard: right to an accounting of disclosures of protected health information.*
> *(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:*
> *(i) To carry out treatment, payment and health care operations as provided in §164.506;*
> *(ii) To individuals of protected health information about them as provided in §164.502;*
> *(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;*
> *(iv) Pursuant to an authorization as provided in §164.508;*
> *(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;*
> *(vi) For national security or intelligence purposes as provided in §164.512(k)(2);*
> *(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);*
> *(viii) As part of a limited data set in accordance with §164.514(e); or*
> *(ix) That occurred prior to the compliance date for the covered entity.*

Although it seems clear that covered pharmacies must account for disclosures made of protected health information to pharmacy board inspectors, it is unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds or even thousands of hard copy prescriptions and/or computerized files in one inspection. The amount of time it would take to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to conduct thorough inspections. Furthermore, such a requirement will adversely affect patient care as pharmacies divert time away from patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. Guidance from your office supporting the position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute a disclosure for which an accounting is then required would be appreciated to alleviate these concerns.

On a similar note, many states now have prescription monitoring programs, which require pharmacies to report to a designated state agency, oftentimes the board of pharmacy, the filling of certain designated controlled substances on a monthly or twice-monthly basis. Again, the documentation of each reporting does not enhance the patient confidentiality provisions but could, in fact, hamper investigatory operations to curb or stop drug diversion. The required documentation would also adversely affect patient care as pharmacies divert time away from patient care activities to complying with this accounting requirement.

If we can provide any background information to assist you in supporting the position that these health oversight activities should not be included in the accounting of disclosures requirement found in Section 164.528 of the final privacy rule, please feel free to contact me at 847/698-6227 or ceo@nabp.net.

Sincerely,
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh
Executive Director/Secretary

CC/mm

cc: NABP Executive Committee
2002-2003 Task Force on Privacy

DEPARTMENT OF HEALTH & HUMAN SERVICES
Voice - (202) 619-0403 TDD - (202) 619-3257 Fax - (202) 619-3818
Http://www.hhs.gov/ocr/

OFFICE OF THE SECRETARY

Director
Office for Civil Rights
200 Independence Ave., SW Rm 506F
Washington, DC 20201

April 1, 2003

Dr. Carmen Catizone
National Assoc. of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068

Dear Dr. Catizone:

Thank you for your letter regarding the requirements of the health information privacy regulation (Privacy Rule) issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA). The Secretary and I are committed to protecting the privacy of health information through implementation of the Privacy Rule. At the same time, the Department is undertaking a broad range of efforts to assist covered entities in voluntarily complying with their obligations under HIPAA.

We have considered your request that we interpret the definition of disclosure to exclude the standard investigatory quick viewing or skimming review of prescription files, as well as the regular filing of certain designated controlled substances. We are must advise that the definition of disclosure at 45 CFR section 164.501 clearly encompasses the provision of access to protected health information, even when that access is only to skim the file. The "skimming" of patient files by state investigators is a disclosure of protected health information, and such disclosures must be included in an accounting of disclosures if requested by a patient.

The accounting requirements are designed to permit individuals to learn the non-health care purposes for which their protected health information was disclosed by covered entities. The Privacy Rule excepts from the accounting certain disclosures, including those authorized by the individual and disclosures for treatment, payment, and health care operations purposes, because individuals already know of these disclosures, or typically expect that those disclosures occur. By contrast, individuals are less likely to have similar knowledge or expectations about disclosures that covered entities may make to comply with law.

With respect to the accounting standard, we note that, like other privacy standards, it is designed to be flexible and scalable. Thus, the Rule does not require that disclosures be tracked individually; rather, a covered entity is free to design a system that efficiently permits an accounting to be provided upon an individual's request. It would be sufficient to prepare a standard checklist of such disclsoures, which could then be completed and provided to those individuals who request an accounting. The Rule permits this or other simplified means of providing the required accounting.

We thank you for your thoughtful suggestion on how to improve the operation of the Privacy Rule and hope our comments are helpful in assisting your members with their compliance efforts. Additional information, guidance, and technical assistance materials to facilitate compliance with the Privacy Rule are available on our web site: http://www.hhs.gov/ocr/hipaa/. As the Privacy Rule is implemented, the Department will continue to carefully monitor its impacts to assure that the Rule does not have any unintended negative effects on patient access to quality health care. If we find that the Privacy Rule is indeed causing problems in this regard, we will consider proposing modifications to the Rule. In addition, we will continue to publish guidance and technical assistance materials to ensure covered entities have the tools they need to implement the Privacy Rule in an effective and efficient manner.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Richard M. Campanelli, J.D.
Director
Office for Civil Rights