

CEO LETTER Vol. 4, No. 10
E- Communication
Important News

December 9, 2005

TO: Members of The NPA

SUBJECT: Sample Drug Distribution Policy

The NPA has successfully reversed a policy calling for NPs to provide a copy their collaborative agreement to pharmaceutical companies as a condition of receiving sample drugs for patient distribution. Over the past several years, Nurse Practitioners in New York have frequently encountered difficulties in receiving sample drugs from pharmaceutical companies due to misunderstandings related to compliance requirements surrounding the Prescription Drug Marketing Act (PDMA). As previously reported in several of our member communications (as well as in the 3rd Edition of our Practice Issues Guide), The NPA had developed a compliance strategy for members to utilize with pharmaceutical representatives requesting to either see a copy of your collaborative agreement, or have your collaborating physician sign a form attesting to it. This is due to the PDMA standards requiring verification of licensure to the provider in which the sample is being issued. Since NPs are currently required to have a collaborating agreement as a condition of licensure to practice in NYS, many pharmaceutical representatives were instructed to follow company policy in requesting to see or be furnished with some form of proof that the agreement exists.

Most recently, The NPA learned of a company that provides PDMA compliance clearinghouse services to pharmaceutical companies as a client service: J. Knipper & Co. Due to their understanding of PDMA requirements, they had instituted a statewide practice of requesting that NPs furnish them with a copy of their collaborative agreement as a condition of receiving drug samples. Upon learning of this, The NPA intervened as wrote a letter to their Vice President, Sampling and Regulatory Affairs pointing out the Association's position that this practice was inappropriate and unnecessary from a compliance standpoint. We outlined our compliance methodology which we believe does not require any direct interaction between NP and pharmaceutical representative in order to meet PDMA compliance standards for sample distribution: least of not which that involving the sharing ones collaborative agreement with an external third party.

The NPA's position is that the collaboration agreement is a proprietary document between the Nurse Practitioner and Collaborating physician. The State Education Department (SED) agreed with this position along with the Association's assertion that that verification of NP practice authority in NYS can be determined by a reliance on State Education Department data of licensed NPs with prescriptive authority. As previously outlined to members, this has been our position from day one.

In meetings with J. Knipper representatives, The NPA explained the process by which NPs become certified and credentialed with SED and convinced the company to change its policy upon verification of this information by SED which they did (see attached letter). Should members encounter any further problems receiving sample drugs from pharmaceutical companies, please keep this letter on file and refer the representative to it. Should any further issues persist beyond that, as always, please refer them to The NPA.

Sincerely,

Seth M. Gordon

Seth M. Gordon
President/CEO

November 7, 2005

Ihab Ghaly
Vice President
Sampling and Regulatory Affairs
J. Knipper and Company, Inc.
Lakewood, NJ 08701

Dear Mr. Ghaly:

Seth Gordon, President and CEO of The Nurse Practitioner Association in New York, has communicated with me about an issue of concern to the over 12,000 Nurses Practitioners (NPs) certified by the New York State Education Department. As I understand the situation, your agency's compliance division has determined that sample drug distribution to NPs will be limited to those NPs who verify their practice authority by providing your agency with a copy of their collaborative practice agreements.

Lawrence Mokhiber, the Executive Secretary to the New York State Board of Pharmacy, informs me that the intent of the Prescriptive Drug Marketing Act is to allow for the distribution of sample drugs to any practitioner who has prescriptive privileges as recognized by the licensing/certifying authority within that jurisdiction. The New York State Education Department's Office of the Professions has that responsibility in this State.

Our licensure/certifying responsibility relies on verification of graduation through primary documentation review from appropriately accredited educational entities. This responsibility is viewed as a primary mission of our Department and is thus performed internally, not by an outside agency with which we contract. Please be assured that this review of each licensee's credentials is thorough and detailed. Moral character requirements must be met. A collaborative practice agreement must be verified. A practice protocol must be identified and agreed to by the Department. Once all of these requirements are met, and we have determined that appropriate pharmacology course content has been completed, including a course specific to writing prescriptions in New York State, then, and only then, do we license/certify an applicant and provide them with an "F" designation that indicates that they have prescriptive privileges. Receiving a copy of the collaborative practice agreement is thus unnecessary, and additionally incomplete, as this document will not verify the "F" designation of a licensee.

I urge you to review your agency's policy so that verification of authority can be determined by a reliance on State Education Department data. This information is readily available and easily retrievable by accessing our web site at www.op.nysed.gov and following the prompts to Online License Verifications on the top menu bar, then to the List of Professions, and finally to the individual licensee's name.

I hope this is helpful. If additional information is needed please contact me at the above letterhead address, by phone at 518-473-0134, or by e-mail at bzittel@mail.nysed.gov.

Sincerely,



Barbara Zittel, R.N., Ph.D.
Executive Secretary

cc: Lawrence Mokhiber