



**Ralph E. Progar**

Vice President of Pharmacy Relations

January 22, 2003

Carole L. Clarke, Esquire  
Legal Counsel, State Board of Pharmacy  
116 Pine Street  
Third Floor  
Harrisburg, Pennsylvania 17101

Dear Attorney Clarke:

Thank you for including Eckerd in the Board of Pharmacy's effort to amend the Pharmacy Act. Our suggestions and comments are as follows:

**§ 27.1. Definitions**

*Practice of pharmacy* -- We would suggest that Lines 2 and 3 be reconfigured to read "implementation of medical orders or prescriptions for the provision of pharmacy services" and delete "or prescription drug orders". Rationale: Retail Pharmacy fills prescriptions not drug orders, and "pharmacy services" could define both medical orders or prescriptions.

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JAN 27 2003

**§ 27.201. Written Protocol**

(a) (3) Is it legal and/or professional for a physician to "refer" patients to a "pharmacist for drug therapy"?

DOS LEGAL COUNSEL

Call if I can provide additional information. I may be reached at 412/967-8735.

Sincerely,

Ralph E. Progar, R.Ph.  
Vice President of Pharmacy Relations

REP/dk

CC: Rich Smiga



PENNSYLVANIA ACADEMY  
OF FAMILY PHYSICIANS

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DOS LEGAL COUNSEL

November 8, 2004

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Harrisburg

Carole A. Clarke, Counsel  
State Board of Pharmacy  
PO Box 2649  
Harrisburg, PA 17105-2649

VIA FACSIMILE AND US MAIL

Dear Ms. Clarke:

On behalf of the PA Academy of Family Physicians (PAFP), please accept these written comments on the proposed amendments to the State Board of Pharmacy's (Board) Drug Therapy and Injectable Medications, Biologicals and Immunizations Regulations. The PAFP believes that these regulations are generally consistent with the authorizing law, Act 102 of 2002. However, we have several clinical concerns dealing with the proposed reporting timeframes.

Specifically, Section 27.301(a)(5) and (6) (Written protocol) allows up to 72 hours for documentation of a pharmacist drug therapy change to be placed in the patient's medical record and up to 72 hours for notification of medication dose, duration or frequency changes to be made to the patient's physician. It would seem important that staff in an institution in addition to the physician should have immediate notice of a drug therapy change. While facility regulations and individual physicians through their written protocols may provide for much shorter timeframes, the regulations appear somewhat inconsistent with good medical documentation practices. Indeed, the General Assembly provided guidance in this area at Section 511(a) of the Mcare Act: "Entries in patient charts concerning care rendered shall be made contemporaneously or as soon as practicable." 40 P.S. § 1303.511(a). For these reasons, the PAFP requests that the 72 hour timeframe be shortened.

Section 27.405 (Recordkeeping) requires records of injectable drug administrations to be maintained for only two years. Two years is the recordkeeping requirement for pharmacy dispensing. However, inasmuch as the injection of drugs into a patient implicates the patient's medical condition, the PAFP believes it more appropriate for the regulations to adopt the seven-year recordkeeping requirement applied to medical records.

Finally, Section 27.406 (Notification requirements) provides for notification of the physician within 72 hours of the administration of an injectable medication if done under the physician's order, and notification within 14 days if the injection was done under a written protocol. We have not uncovered any explanatory rationale provided for either of these timelines. Neither of the notification periods seems to be consistent with good medical care; both appear to be too long, particularly where injections are not being given in a health care facility. For these reasons and those cited above, the PAFP believes that both of these timeframes should be shortened.

Thank you for this opportunity to provide the PAFP's comments on these proposed regulations. We appreciate the time and effort that must have gone into their development and further hope that the Board looks favorably on our requested revisions. Should you have questions or concerns, please do not hesitate to contact me at 570-321-3156 or [timfpmd@aol.com](mailto:timfpmd@aol.com).

Sincerely,

Handwritten signature of Timothy Heilmann, MD, in cursive script.

Timothy Heilmann, MD  
PAFP President

th/ALM/AJS

Cc: The Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee  
The Honorable Lisa M. Boscola, Democratic Chair, Senate Consumer Protection and Professional Licensure Committee  
The Honorable Thomas P. Gannon, Chairman, House Professional Licensure Committee  
The Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee



Original: 2437

508 North Third Street, Harrisburg, PA 17101-1199  
phone: 717-234-6151 fax: 717-236-1618 website: [www.PApharmacists.com](http://www.PApharmacists.com)

October 26, 2004

Pennsylvania State Board of Pharmacy  
Post Office Box 2649  
Harrisburg, PA 17105

RE: Regulation #16A-5412 (#2437)

Dear Board Members:


The Pennsylvania Pharmacists Association is writing in support of the proposed regulations (numbers referenced above) for Drug Therapy and Injectable Medications, Biologicals, and Immunizations.

PPA commends the Board for their complete research and study that went into the development of these regulations and to thank the Board for involving and soliciting input from practitioners in the process of this development. The result is a comprehensive, effective, and appropriate set of regulations for expanding the scope of practice for pharmacists in the Commonwealth.

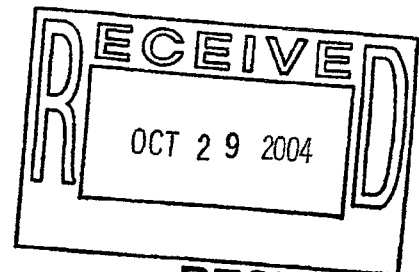
Pharmacists are the medication experts in the healthcare field and their services should be appropriately utilized and compensated. Pharmacists are also among the most trusted and certainly the most accessible. Permitting these regulations to become final will only help to advance Pennsylvania healthcare.

Once again, we would like to thank all of the Board members, Board Counsel, and the Board's Executive Secretary for their efforts in the development of these regulations.

Sincerely,

  
Patricia A. Epple, CAE  
Executive Director

cc: Independent Regulatory Review Commission



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DOS LEGAL COUNSEL

November 1, 2004

Ms. Carole Clarke  
Counsel  
State Board of Pharmacy  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Dear Ms. Clarke:

This letter is in response to the proposed rulemaking titled "Drug Therapy and Injectable Medications, Biologicals and Immunizations.

The first issue I would like to address is the continuing education requirement for pharmacists who decide to undertake the administration of injectables. It is my feeling that 2 out of 30 hours is not a sufficient amount of time considering the complexity of some of these formulations. When administered, an injection is not reversible. Any subsequent effects due to an error may have more of an adverse impact on the patient, which may not be treatable. Keeping the pharmacists prepared by setting more stringent continuing education requirements would greatly benefit the profession as well as the safety of the patient.

The second issue I would like to address is a provision regarding an "Emergency Situation" such as a small-pox outbreak. It is my feeling that such a threat should be addressed in the document. There are multiple pharmacies in every community in our state that can act as an immediate infrastructure for the administration of injectable medications, biologicals and immunizations should there arise a need. It is my opinion that pharmacists who are able to administer injectables should be allowed to do so freely (i.e. without a physician order) in emergency situations only. Emergency situations would clearly be needed to be designated as such by the Governor if the time comes. This would greatly improve the time it takes the citizens of the state to receive a vaccine if needed as well as ease the demand of the government clinics.

Any consideration or comments the Board may have will greatly be appreciated. Thank you.

Sincerely,



Louis F. Puzano, Jr.  
Temple University School of Pharmacy  
Doctor of Pharmacy Candidate

Original: 2437

IRRC

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**From:** Jewett, John H.  
**Sent:** Friday, October 29, 2004 3:57 PM  
**To:** IRRC  
**Cc:** Stephens, Michael J.; Pagan, Elena V.; Wyatte, Mary S.; Sandusky, Richard M.  
**Subject:** FW: Proposed Regulation #16A-5412 (#2437), Drug Therapy and Injectable Medications, Biologicals and Immunizations, State Board of Pharmacy

Please file this email and its attached document under "proposed comments" for #2437.

-----Original Message-----

**From:** Patricia Epple [mailto:pepple@papharmacists.com]  
**Sent:** Friday, October 29, 2004 3:54 PM  
**To:** Jewett, John H.  
**Subject:** RE: Proposed Regulation #16A-5412 (#2437), Drug Therapy and Injectable Medications, Biologicals and Immunizations, State Board of Pharmacy

Thank you for this reminder – We did send in comments. I am attaching a copy

*Pat*

Patricia A. Epple, CAE  
Executive Director  
Pennsylvania Pharmacists Association  
508 North Third Street  
Harrisburg, PA 17101-1199  
717-234-6151 Ext. 106  
fax: 717-236-1618  
pepple@papharmacists.com  
www.papharmacists.com

*PPA has recently redesigned our website - please visit it!*




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**From:** Jewett, John H. [mailto:jjewett@IRRC.STATE.PA.US]  
**Sent:** Tuesday, October 26, 2004 11:15 AM  
**To:** pepple@papharmacists.com; tkl@papharmacists.com; pshp@usip.edu  
**Cc:** Stephens, Michael J.  
**Subject:** Proposed Regulation #16A-5412 (#2437), Drug Therapy and Injectable Medications, Biologicals and Immunizations, State Board of Pharmacy

On October 9, 2004, the State Board of Pharmacy published a notice of proposed rulemaking in the *Pennsylvania Bulletin* for the regulation referenced in the subject line. The notice of proposed rulemaking is available on the web at [www.pabulletin.com](http://www.pabulletin.com) in Vol. 34, No. 41. A copy of the link to this notice at the *Pennsylvania Bulletin* web site is attached.

The Board is inviting the public to submit written comments on this proposed regulation. Written comments on the regulation may be addressed to the Board (See "Public Comment" in the preamble of the notice). The last day of the public comment period for this regulation is November 8, 2004. Please "cc: IRRC" on any written comments and reference the regulation numbers on your comments: #16A-5412 (#2437). Formal written comments may be

sent to IRRC at the mailing address, fax number or email address ([irrc@irrc.state.pa.us](mailto:irrc@irrc.state.pa.us)) listed below. Written comments sent to IRRC will be included in IRRC's public record file.

Thanks for your time and consideration. I hope this information is helpful. If you, other members of your organization or other interested parties have informal comments or questions, please contact me at (717) 783-5475 or via email. John Jewett, IRRC

**INDEPENDENT REGULATORY REVIEW COMMISSION**  
333 Market Street, 14<sup>th</sup> Floor, Harrisburg, PA 17101  
Phone: (717) 783-5417, Fax: (717) 783-2664  
E-mail: [irrc@irrc.state.pa.us](mailto:irrc@irrc.state.pa.us), Website: [www.irrc.state.pa.us](http://www.irrc.state.pa.us)

<http://www.pabulletin.com/secure/data/vol34/34-41/1855.html>



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508 North Third Street, Harrisburg, PA 17101-1199  
phone: 717-234-6151 fax: 717-236-1618 website: www.PApharmacists.com

October 26, 2004

Pennsylvania State Board of Pharmacy  
Post Office Box 2649  
Harrisburg, PA 17105

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INDEPENDENT REGULATORY  
REVIEW COMMISSION

RE: Regulation #16A-5412 (#2437)

Dear Board Members:

The Pennsylvania Pharmacists Association is writing in support of the proposed regulations (numbers referenced above) for Drug Therapy and Injectable Medications, Biologicals, and Immunizations.

PPA commends the Board for their complete research and study that went into the development of these regulations and to thank the Board for involving and soliciting input from practitioners in the process of this development. The result is a comprehensive, effective, and appropriate set of regulations for expanding the scope of practice for pharmacists in the Commonwealth.

Pharmacists are the medication experts in the healthcare field and their services should be appropriately utilized and compensated. Pharmacists are also among the most trusted and certainly the most accessible. Permitting these regulations to become final will only help to advance Pennsylvania healthcare.

Once again, we would like to thank all of the Board members, Board Counsel, and the Board's Executive Secretary for their efforts in the development of these regulations.

Sincerely,

Patricia A. Epple, CAE  
Executive Director

cc: Independent Regulatory Review Commission



Original: 2437

**Long Term Care Pharmacy Alliance**

March 5, 2003

Carole L. Clarke  
Counsel  
State Board of Pharmacy  
Department of State Legal Office  
116 Pine Street  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Dear Ms. Clarke:

I am writing on behalf of the Pennsylvania Chapter of the Long Term Care Pharmacy Alliance (LTCPA), in response to your letter sent to Bradley Shopp from Triad Strategies, LTCPA's representative in Harrisburg. In your letter to Mr. Shopp, which was dated January 24, 2003, you requested comments on the draft Annex which the State Board of Pharmacy is considering proposing pertaining to the amendment of the Pharmacy Act by Act 102 of 2002.

While I understand that we have passed the date by which you asked that comments on the draft be submitted, the Pennsylvania Chapter of LTCPA has decided to forward you its position that our membership does not have any opposition or suggested amendments to the proposed Annex. Because the Board of Pharmacy will not meet until March 11, we hope that it is not too late to have our comments entered into the record.

Thank you for soliciting the comments of the Pennsylvania Chapter of LTCPA and I apologize for the delay in responding. If you have any questions or comments regarding our position, please do not hesitate to contact Mr. Shopp at (717) 238-2970, extension 234.

Sincerely,

A handwritten signature in black ink that reads "John Walker". The signature is written in a cursive style with a small flourish at the end.

John Walker  
President  
Pennsylvania Chapter LTCPA

## DRUG THERAPY MANAGEMENT

### § 27.201. Written Protocol

(a) The written protocol between a licensed physician and a pharmacist shall be in writing and shall contain:

(1) A statement identifying the individual physician responsible for authorizing drug therapy management.

(2) A statement identifying the individual pharmacist authorized to perform the drug therapy management.

(3) A statement requiring that drug therapy regimens be initiated by a licensed physician for patients referred to a pharmacist for drug therapy.

(4) A statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:

(i) A statement of the ailments or diseases involved within the physician's scope of practice, and types of drug therapy management authorized.

~~(5)~~ A statement of the functions and tasks the pharmacist shall follow in the course of exercising drug therapy management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall occur as soon as possible after each intervention in the patient medical record and shall also be recorded in the pharmacist's records.

24hrs

~~(6)~~ A statement that establishes an appropriate time frame, not to exceed seventy-two hours, within which the licensed pharmacist must notify the licensed physician of any changes in dose, duration or frequency of medication prescribed.

24hrs

~~(7)~~ A provision for notification of the role of the pharmacist by a licensed physician to each referred patient whose drug therapy management may be affected by the agreement.

Patient right to refusal

~~(8)~~ The signatures of the licensed physician(s) and licensed pharmacist(s) who are entering into the written protocol, and the dates when signed.

~~(9)~~ A statement allowing for the termination of the agreement at the request of any party to it at any time.

(b) The written protocol shall be available as follows: