Original: 2405

**Karen Nishi**
Director, Regulatory Affairs

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CardinalHealth

July 6, 2004

RECEIVED

JUL 07 2004

HEALTH LICENSING BOARDS

Ms. Melanie Zimmerman
Executive Secretary
Pennsylvania State Board of Pharmacy
Bureau of Professional and Occupational Affairs
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: Comments regarding 49 PA Code Chapter 27 Section 27.204 – Proposed new section to establish rules applicable to the operation and maintenance of automated medication systems.

Dear Ms. Zimmerman:

On behalf of Cardinal Health, Inc. and our Pyxis Automation and Information Division, we want to thank you for the opportunity to comment on the proposed regulations for Technology and Automation. We know the Board has put many long hours into drafting these proposed regulations. We are encouraged to see that we as pharmacists are looking to automated systems as a tool to help us expand our role as clinicians and providers of pharmaceutical care.

In reviewing the proposed rules, we found a provision in the rules that is unclear and may be unworkable in practical application. As such, we respectfully submit our comments in an attempt to have the Board better refine and improve the proposed language.

Our comment concerns the following provision found in 49 PA Code Chapter 27.204 Automated Medication Systems (d) (6):

*(d) When an automated medication system is used to fill prescriptions or medication orders, it must be operated according to written policies and procedures of operation. The policies and procedures of operation must: ...*

(6) *Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or qualified support personnel acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.*

The proposed language for stocking and removal of medications from an automated medication system would limit the access of such systems to only a pharmacist and qualified support personnel under the supervision of a licensed pharmacist. Healthcare professionals such as nurses, physicians, and those individuals authorized to legally administer drugs would be prohibited from accessing an automated medication system.

We would recommend the following revision to 49 PA Code Section 27.204 (d) (6):

(6) Set forth methods that ensure the access for stocking and removal of medications from an automated medication system is limited to licensed pharmacists, qualified support personnel acting under the supervision of a licensed pharmacist, or a person legally qualified to administer drugs. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

We thank you again for the opportunity to comment on these proposed rules.

Sincerely,

Karen Nishi

Karen Nishi
Director of Regulatory Affairs

**ORIGINAL: 2405**

-----Original Message-----
**From:** Patricia A. Epple [mailto:pepple@papharmacists.com]
**Sent:** Thursday, July 01, 2004 1:29 PM
**To:** Smith, James M.
**Subject:** RE: Regulation #16A-5410 - State Board of Pharmacy - Technology and Automation

Mr. Smith -

Thank you for providing the Pennsylvania Pharmacists Association with notification of the publication of these regulations. Our association has reviewed these regulations and fully supports their intent to update the Boards regulations to meet today's practice demands. We have no objections or concerns to express on these regulations and look forward to this becoming final.

Again, we appreciate the opportunity to offer comment.

Pat Epple

Patricia A. Epple, CAE
Executive Director
**Pennsylvania Pharmacists Association**
508 North Third Street
Harrisburg, PA 17101-1199
Telephone: 717-234-6151 ext. 106
Fax: 717-236-1618
E-Mail: Pepple@papharmacists.com
Website: www.papharmacists.com



-----Original Message-----
**From:** Smith, James M. [mailto:jsmith@irrc.state.pa.us]
**Sent:** Wednesday, June 30, 2004 11:04 AM
**To:** v.elliot@usip.edu; Patricia A. Epple; mspeck@haponline.org; dmccoy@pamedsoc.org
**Cc:** Stephens, Michael J.
**Subject:** Regulation #16A-5410 - State Board of Pharmacy - Technology and Automation

On June 19, 2004, the State Board of Pharmacy published the above proposed regulation in the Pennsylvania Bulletin which may be of interest to you. A copy can be obtained online at www.pabulletin.com/secure/data/vol34/34-25/1066.html

The close of the public comment period before the Board is July 19. Our comments are due by August 18. If you have any questions, please give me a call at 717-783-5439 or send an email.

Thanks,
Jim Smith
Regulatory Analyst
Independent Regulatory Review Commission

Original: 2405

(2)

DEPARTMENT OF HEALTH
... in pursuit of good health

RECEIVED
JUL 06 2004
HEALTH LICENSING BOARDS

June 30, 2004

(717) 783-8665

Commonwealth of Pennsylvania
Department of State
Board of Pharmacy
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649

Attn: Melanie Zimmerman, Executive Director

Dear Mrs. Zimmerman:

I am writing in response to the Pennsylvania Board of Pharmacy's (Board) proposed regulatory amendments published in the June 18, 2004 issue of The Pennsylvania Bulletin. The Bureau of Community Program Licensure and Certification is responsible for oversight of the Commonwealth's Drug, Device, & Cosmetic Program. The Drug, Device, & Cosmetic Program is responsible for assuring compliance with the registration and reporting requirements of the Pennsylvania Controlled Substances, Drug, Device, & Cosmetic Act and Regulations (35 P.S. § 780-101 et seq., 28 Pa. Code Chapter 25).

We have reviewed the Board's proposed regulations and feel it is important to notify the Board that the proposed amendments may conflict with certain sections of the Pennsylvania Code. In particular, §25.53 relating to prescription orders, subsection (b) requires prescribers to handwrite "brand necessary", and subsection (d) requires controlled substances to be written in indelible ink, pencil or typewriter. Also, §25.56 relating to prescription record keeping subsections (a) and (b) require prescription records of controlled substances I and II to be maintained separately and controlled substances II-V to be marked with a red "C".

We are not opposed to the proposed amendments, since they would allow pharmacy practices to be more current with today's electronic environment. We further realize the primary regulatory oversight of pharmacies lies with the Board. However, since we have not changed our regulations, registrants and consumers may be confused by any conflict between the two regulations. Therefore, we request that the Board either amend the proposed regulations or address any differences between the two regulations in the preamble.

We would be willing to consider the Board's comments and recent amendments if we update our regulations at a later date. If you have any questions regarding our comments, please feel free to contact me. Thank You.

Sincerely,

Carol A. Williams

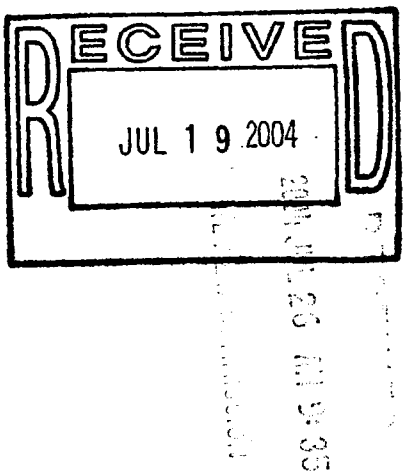
Carol A. Williams
Director
Bureau of Community Program Licensure
And Certification

Original: 2405

(4)

**PSHP**
Pennsylvania Society of
Health-System Pharmacists

*Pharmacists dedicated to safe and proper medication use in organized health care settings*




July 16, 2004

Melanie Zimmerman
State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman,

The following are comments made on behalf of the Pennsylvania Society of Health-System Pharmacists regarding the proposed *technology and automation* amendments to the board of pharmacy regulations, published in the Pennsylvania Bulletin on June 19, 2004. Overall, PSHP has no significant objections to the proposed changes in either Annex. Below are our specific comments and recommendations for the board's consideration.

General Provisions
*27.1 Definitions*

The term "automated medication system" excludes compounding, however, many inpatient pharmacies utilize automated compounding systems such as, automix / micromix machines, syringe fillers, etc. Would the proposed definition prohibit the use of these systems from a central location to fill or prepare intravenous medications, or the batching of products for use in a centralized pharmacy?

While the various definitions of a pharmacy are understood in a retail or a mail order environment, can it be assumed that "the pharmacy" in an institution would include any site within the institution considered to be part of the pharmacy license? For example, the central pharmacy and all satellites may be part of one license with the "HP" designation, and some or all may contain "automated medication systems". Will each of these be designated as one of the defined pharmacy terms provided in the proposed definitions, or will an institutional pharmacy be considered as one entity?

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**Technology and Automation**
*27.201 Electronically transmitted prescriptions*
The term "prescription" is used throughout this section. Is it the intent of the board to include "orders" in this definition? If so, this could prove to be a problem within institutions related to electronic transmission of patient-specific orders for controlled substances. The intent is for outpatient prescriptions, it seems.

*27.202 Computerized record keeping systems*
*(d)* the section allows prescriptions to be filled during system down times, "if the number of refills authorized by the prescriber has not been exceeded". How can the number of refills be verified unless the patient brings the original prescription vial / container with them to the pharmacy, or if the patient is phoning in their refill?

Has the Board considered providing the minimum contingency plans to be required in case of a system failure? From a pharmaceutical care perspective, important system checks may be bypassed during computerized or electronic down times including patient allergies, drug interactions, insurance verification, confirmation of the "five rights or rules of medication administration" (right patient / drug / dose / route / time), patient compliance history, and medication efficacy/safety.

Finally, does the Board plan to reference the requirements of patient confidentiality contained in the Health Insurance Portability and Accountability Act of 1996 (HIPPA) in these amendments, or has that been dealt with in a separate part of the Board of Pharmacy regulations?

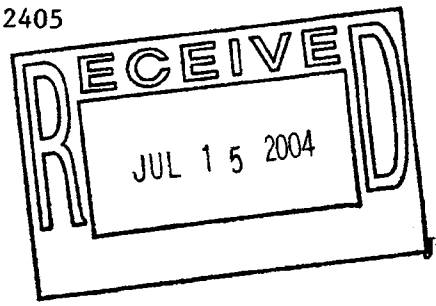
We appreciate your consideration of our comments and questions. If you have any questions, please contact me at (215) 596-8997, or v.elliot@usip.edu.

Sincerely,

Victoria E. Elliott, R.Ph., MBA, CAE
Executive Vice President, PSHP

(5)

Original: 2405




WebMD

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Columbus, OH 43215
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Fax: 614.462.5470

July 14, 2004

Melanie Zimmerman, Executive Secretary
Pennsylvania State Board of Pharmacy
2601 North Third Street
Harrisburg, PA 17110

Re: Proposed New 49 Pa. Code § 27.201—Electronically Transmitted Prescriptions: Formal Comments of WebMD Corporation

Dear Executive Secretary Zimmerman:

I am writing in my capacity as Senior Vice President and Regulatory Counsel for WebMD Corporation ("*WebMD*") and its WebMD Practice Services Division. WebMD appreciates the opportunity to submit comments concerning the amendments proposed by the Pennsylvania State Board of Pharmacy (the "*Board*") to 49 Pa. Code Chapter 27, specifically proposed § 27.201—Electronically Transmitted Prescriptions.

WebMD Practice Services is the nation's leading provider of integrated physician practice management systems, serving physicians nationwide. Most of these physicians use the WebMD Practice Services' practice management software marketed under The Medical Manager® brand ("*The Medical Manager*"). The Medical Manager system incorporates a wireless component, ULTIA™, to provide practitioners with portable access to their patient and practice information, including The Medical Manager Prescription Writer System (the "*Prescription Writer*").

The Prescription Writer supports computer generated prescription orders for non-controlled substances that can be printed in the practitioner's office for delivery to the patient or transmitted electronically to the pharmacy of the patient's choice.[1] Prescriptions are electronically created according to the SCRIPT standard of the National Council for Prescription Drug Programs (the "*NCPDP*")[2] and are transmitted, pursuant to the execution of the prescribing practitioner's electronic signature, from the practitioner's computer to a pharmacy's computer or to a pharmacy's facsimile machine ("*e-Fax prescription*") over the secure Electronic Data Interchange ("*EDI*") Network of ProxyMed, Inc.

---

[1] The Prescription Writer requires computer generated prescriptions for Schedule II through V controlled substances to be printed locally and executed with the prescribing practitioner's handwritten signature.

[2] The NCPDP, an ANSI-accredited Standards Development Organization, consists of over 1350 members who represent chain and independent pharmacies, consulting companies and pharmacists, database management organizations, federal and state agencies, health insurers, health maintenance organizations, mail service pharmacy companies, pharmaceutical manufacturers, pharmaceutical services administration organizations, prescription service organizations, pharmacy benefit management companies, professional and trade associations, telecommunication and systems vendors, wholesale drug distributors, and other parties interested in electronic standardization within the pharmacy services sector of the health care industry. ANSI is the American National Standards Institute, a private, non-profit organization (501(c)(3)) that administers and coordinates the U.S. voluntary standardization and conformity assessment system.

The Board should note that an e-Fax prescription is neither an original written prescription nor a copy produced by scanning an original written prescription. It is an electronic record that takes physical form for the first time when it prints on the pharmacy's facsimile machine. WebMD's e-Fax prescription contains verifiable evidence of a documented electronic signature associated solely with the authorized prescriber who created the prescription. However, because the SCRIPT standard does not support bit-mapped images, this electronic signature is not a visual representation of the prescriber's handwritten signature. Despite the absence of a bit-mapped signature, WebMD would note that its electronic signature technology and security systems comply with the Pennsylvania Electronic Transactions Act[3] and the federal Electronic Signatures in Global and National Commerce Act.[4]

***General Comments***

WebMD recognizes the Board's deep commitment to improving patient outcomes while protecting the public health and safety. WebMD believes that electronic prescribing technology can make a critical contribution toward achieving those goals by delivering secure, complete, legible, clinically appropriate and formulary adherent prescriptions to Pennsylvania pharmacists, thereby reducing administrative inefficiencies, medication errors and overall healthcare costs.

WebMD fully recognizes the complexity of establishing a reasonable and operationally viable regulatory environment for electronic prescriptions. WebMD commends and supports the Board's efforts in proposing regulations that provide explicit authority for pharmacists to dispense pursuant to the receipt of electronically transmitted prescriptions (i.e., which does not include those transmitted by telephone or by facsimile machine) that comply with specified standards. Although proposed 49 Pa. Code § 27.201 will provide guidance for creating and transmitting lawful prescriptions electronically, WebMD believes it can be improved by three significant additions: (a) recognition for e-Fax prescriptions (computer-to-facsimile machine); (b) guidance as to how a prescriber's generic substitution instructions are communicated in electronically transmitted prescriptions; and (c) authorizing prescribers' use of secure EDI networks to route electronically transmitted prescriptions to the pharmacy of the patient's choice.

WebMD believes the following specific recommendations will contribute toward providing Pennsylvania's consumers, prescribers and pharmacists the benefits of a promising technology.

***Specific Comments***

1. <u>The Proposed Regulation Should Provide Recognition for E-Fax Prescriptions (Computer-to-Facsimile Machine Transmissions).</u>

The e-Fax prescription is the most commonly transmitted computer-generated prescription in the U.S. Today, less than one percent of all electronic prescriptions are transmitted computer-to-computer. Of the remaining ninety-nine percent (99%) of electronically created prescriptions, roughly one half are sent computer-to-facsimile machine using facsimile simulation software (either resident at the prescriber's computer system or at an EDI network

[3] 73 P. S. §§ 2260.101–2260.5101.

[4] 15 U.S.C. §§ 7001-7006, 7021, and 7031.

switch) and one half are printed locally for delivery to the patient. To the best of WebMD's knowledge, few if any prescriptions are electronically transmitted via e-mail.

Accordingly, WebMD would recommend that proposed 49 Pa. Code § 27.201(a) be amended to read as follows:

> (a) For the purposes of this section, an electronically transmitted prescription means the communication of original prescriptions or refill authorizations ~~to the pharmacist~~ by electronic means, to include computer-to-computer, computer-to-facsimile machine ~~of data base exchange~~ or e-mail transmissions (which does not include prescription orders transmitted by telephone or facsimile machine) ~~of original prescriptions or refill authorizations,~~ which have been sent directly from an authorized licensed prescriber or an authorized agent to the pharmacy of the patient's choice and which have not been altered, accessed, viewed, screened or manipulated by an intervening entity or person unless authorized by law.

2. The Proposed Regulations Should Clarify How Generic Substitution Instructions Are Communicated in Electronically Transmitted Prescriptions.

28 Pa. Code § 25.53 provides explicit guidance regarding how a prescriber must indicate generic substitution instructions with respect to oral and written prescriptions. If an oral prescription, substitution is permissible unless the prescriber expressly indicates to the pharmacist that the brand name drug is necessary and substitution is not allowed.[5] Prescriptions issued in writing (i.e., paper-based) must bear a signature line for the prescriber's handwritten signature at the bottom of the form and be imprinted with the words "substitution permissible."[6] Additionally, the written prescription form must be imprinted with the following directions: "IN ORDER FOR A BRAND NAME PRODUCT TO BE DISPENSED, THE PRESCRIBER MUST HANDWRITE 'BRAND NECESSARY' OR 'BRAND MEDICALLY NECESSARY' IN THE SPACE BELOW."[7]

However, proposed 49 Pa. Code § 27.201 does not provide specific guidance for how prescribers are to communicate generic substitution instructions in electronically transmitted prescriptions. WebMD would respectfully note that the existing requirements for written prescriptions cannot be applied to electronic prescriptions: were handwritten signatures and/or handwritten instructions required for electronically transmitted prescriptions, applicable provisions of the Pennsylvania Electronic Transactions Act would make such requirements unenforceable.[8]

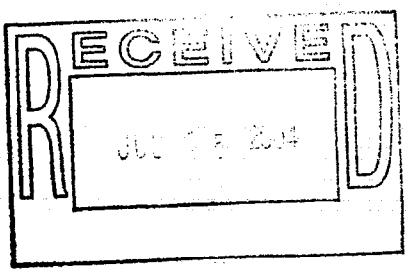
Further, even though bit-mapping technology can be used to replicate handwritten signatures and instructions (to include handwritten initials, check marks and abbreviations), few if any electronic prescribing software programs employ technology that meets the implicit requirement that such handwriting be created contemporaneously with the creation of the prescription. Finally, bit-mapping technology cannot be employed in electronic prescriptions

[5] 28 Pa. Code § 25.53(c).

[6] *Id.* § 25.53(b).

[7] *Id.*

[8] 73 P.S. § 2260.303(a) and (d).



transmitted computer-to-computer because the SCRIPT standard format does not support graphical images.[9]

In sum, requiring electronic prescriptions to comply with the same requirements for communicating drug product selection instructions in written prescriptions is neither reasonable nor enforceable. To accommodate the requirements of the Pennsylvania Electronic Transactions Act and the limitations of electronic prescribing technology, WebMD would respectfully recommend that proposed 49 Pa. Code § 27.201 be amended to provide guidance to pharmacists and authorized prescribers on how drug product selection instructions may be separately addressed in electronic prescriptions.

For example, the Texas Board of Pharmacy's requirements for communicating generic substitution instructions in written prescriptions are almost identical to Pennsylvania's requirements, to include requiring prescribers to handwrite the phrase "brand necessary" or "brand medically necessary" on the face of the prescription form in order to prohibit substitution.[10] However, where electronic prescriptions are concerned, Texas pharmacy regulations appropriately do not require handwriting; instead, the regulations require that, to "prohibit substitution, the practitioner or practitioner's agent shall note 'brand necessary' or 'brand medically necessary' in the electronic prescription drug order.[11]

WebMD would respectfully recommend that the Board consider the merits of providing specific guidance to prescribers and pharmacists on how generic substitution instructions are communicated in electronically transmitted prescriptions. Based on the Texas example, proposed 49 Pa. Code § 27.201(b) could be amended to inserting a new subsection (2) as follows and renumbering accordingly:

> (b) Except for Schedule II controlled substances which must conform to § 27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription, from a prescriber or a designated agent which has been sent directly to a pharmacy of the patient's choice if the following requirements are met:
>
> (1) The prescription must contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the Electronic Transactions Act (73 P. S. §§ 2260.101--2260.5101).
>
> (2) The authorized prescriber or authorized prescriber's agent has noted "brand necessary' or 'brand medically necessary" to prohibit substitution.
>
> ~~(2)~~ (3) The prescription must include the following information: . . .

3. The Proposed Regulations Would Prohibit Prescribers' Use of EDI Networks to Deliver Electronically Transmitted Prescriptions to the Pharmacy of the Patient's Choice.

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[9] In prescriptions formatted according to the SCRIPT standard, drug product selection instructions are transmitted as numeric values: "Ø" for substitution permitted and "1" for substitution not allowed by prescriber. See SCRIPT Standard Format Implementation Guide, Version 4, Release 3 (October 2003). For recordkeeping purposes, the receiving pharmacy's computer system converts the numeric value to the appropriate and required language for prohibiting substitution in the state where the pharmacy is located.

[10] 22 Tex. Admin. Code § 291.33(c)(3)(C)(i)(I).

[11] 22 Tex. Admin. Code § 291.33(c)(3)(C)(iii)(I).

Proposed 49 Pa. Code § 27.201(a) would require electronically transmitted prescriptions to be delivered "directly from an authorized licensed prescriber or an authorized agent to the pharmacy of the patient's choice" without having been "altered, accessed, viewed, screened or manipulated by an intervening entity or person."

WebMD would respectfully submit that the adoption of the proposed restrictions would have the unintended consequence of prohibiting the use of EDI networks to route prescriptions between prescribers and pharmacies; i.e., the proposed regulation would prohibit the same transmission infrastructure that is currently used daily throughout the U.S. to transmit millions upon millions of secure electronic health care transactions between physicians, hospitals, pharmacies and payors.

To perform their basic function, EDI networks must have access to an electronically transmitted prescription. The network must have access to the prescriber's identity to verify that he or she is authorized to transmit via the network. The network must also have access to the identity, electronic "address" or facsimile number of the pharmacy to which the electronic prescription has been issued in order to route it correctly.

Many EDI networks also provide a value added service benefiting both the prescriber and the pharmacy that requires access to the electronic prescription. For electronic prescriptions formatted in the SCRIPT standard, private network switches scan each prescription to ensure that information required by law has been entered into the appropriate data field specified by the SCRIPT standard. The network does not actually "read" the prescription; it merely confirms that the required data fields are populated. If data is missing in a required field, the network automatically rejects the prescription and notifies the prescriber. If all required data is provided, the prescription is routed to the pharmacy to which it was addressed. This functionality is designed to minimize "call-backs" by ensuring to the extent possible that pharmacies receive "complete" electronic prescriptions.

In order to deliver an electronic prescription that has been encrypted and formatted according to the SCRIPT standard to a pharmacy's facsimile machine, the EDI network must also have access to the prescription in order to decrypt[12] the content and convert it to a format that can be received via a point-to-point transmission over telephone lines and printed at the pharmacy's facsimile machine. Most important, the content of the electronic prescription is not altered by such an intervention: the electronic prescription that reaches the pharmacy contains the exact same information it contained when the prescriber transmitted it.

Finally, the security and confidentiality of prescription information transmitted via an EDI network are protected under the federal privacy[13] and security[14] rules established pursuant to HIPAA (the Health Insurance Portability and Accountability Act of 1996). Without the express written authorization of the patient, protected health information cannot be used by covered entities (health care providers, health plans and health care clearinghouses) or their business associates (to include EDI networks) for any other purpose other than treatment, payment and health care operations.

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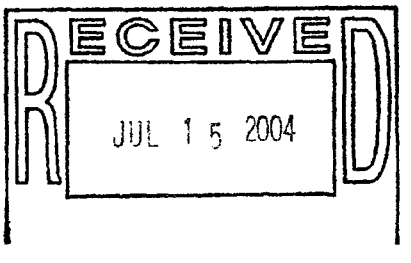
[12] In general, while pharmacy facsimile machines can convert data in digital form into print, they do not have decryption capability.

[13] Codified at 45 C.F.R. Parts 160 and 164.

[14] Codified at 45 C.F.R. Part 142.



Accordingly, to ensure that authorized prescribers continue to have access to a secure and efficient communication infrastructure, WebMD would respectfully recommend that proposed 49 Pa. Code §27.201(a) be further amended to read as follows:

> (a) For the purposes of this section, an electronically transmitted prescription means the communication of original prescriptions or refill authorizations ~~to the pharmacist~~ by electronic means, to include computer-to-computer, computer-to-facsimile machine ~~of data base exchange~~ or e-mail transmissions (which does not include prescription orders transmitted by telephone or facsimile machine) ~~of original prescriptions or refill authorizations,~~ which have been sent directly from an authorized licensed prescriber or an authorized agent to the pharmacy of the patient's choice and whose content contains the exact same information it contained when the authorized prescriber transmitted it ~~which have not been altered, accessed, viewed, screened or manipulated by an intervening entity or person unless authorized by law~~.

***Summary***

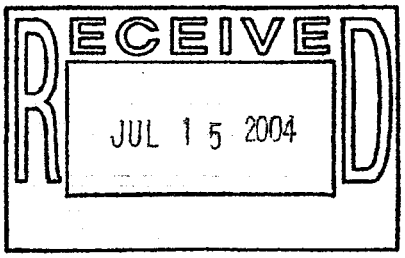
WebMD appreciates the opportunity to provide comments and recommendations concerning the Board's proposed regulations to govern electronically transmitted prescriptions. WebMD believes that the recommendations discussed above will help to facilitate the adoption and deployment of electronic prescribing systems in Pennsylvania.

If you have any questions about WebMD's recommendations, please do not hesitate to call me.

Very truly yours,

Robert D. Marotta
Senior Vice President and Regulatory Counsel

cc: WebMD Corporation



Original: 2405

(8)

NeighborCare™

2004 JUL 22 AM 9:14

July 16, 2004

Melanie Zimmerman
State Board of Pharmacy
P.O. Box 2649
Harrisburg, PA 17105-2649

Re: Proposed Rule Making [49 PA CODE CH. 27] Technology and Automation [34Pa.B. 3146]

Dear Ms. Zimmerman:

NeighborCare, Inc. (NeighborCare) appreciates the opportunity to comment in response to the proposal by the Pennsylvania State Board of Pharmacy ("the Board") to amend Chapter 27 of the Pennsylvania Code to allow for greater incorporation of technology into the practice of pharmacy. NeighborCare commends and supports the Board's efforts and offers the following comments.

**NeighborCare's Background**

NeighborCare is a billion-dollar provider of pharmacy services with locations in 28 states.[1] We work with over a quarter of a million individual patients each day. In Pennsylvania we have approximately 400 employees and provide services to approximately 35,000 of Pennsylvania's citizens. We are based in Baltimore, Maryland, and are the nation's third largest provider of institutional pharmacy services to long term care facilities, assisted living communities and assorted group settings.

Unlike hospitals, most long-term care facilities do not have on-site pharmacists to dispense prescription drugs, but depend instead on institutional pharmacies to provide the necessary pharmacy products and services and to play a key role monitoring patient medications and providing consultant pharmacy services. Institutional pharmacies

[1] California, Colorado, Connecticut, Florida, Illinois, Indiana, Iowa, Kentucky, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island , South Carolina, Texas, Virginia, Washington, West Virginia, and Wisconsin

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Tel 610.992.0856 Fax 610.962.5471

purchase prescription and nonprescription medical supplies from wholesale distributors and manufacturers, and repackage and distribute these products to residents in long-term care facilities, residential and independent living communities and other institutional health care settings.

Our core institutional pharmacy functions are complemented by retail pharmacy and home care networks supporting community healthcare and also by NeighborCare At Home, a community-based home infusion and home medical division. The Company's pharmacy operations consist of 64 institutional pharmacies (five are jointly-owned), 33 community-based professional retail pharmacies (two are jointly-owned) and 20 on-site pharmacies which are located in patients' facilities and serve only patients of that facility. In addition, NeighborCare operates 16 home infusion, respiratory and medical equipment distribution centers (four are jointly-owned). NeighborCare's success has stemmed from our core philosophy of providing the highest quality healthcare services in a clinically appropriate manner and in the most efficient and cost effective way in the marketplace.

NeighborCare's history goes back almost half a century when our founders first began building businesses on the premise that the patient be at the center of the care process. NeighborCare actually grew out of a series of strategic acquisitions and mergers that included Drug Lane Pharmacy Services, Accredited Surgical Company, Woodhaven Pharmacy, Scotchwood Pharmacy Services, Vitalink Pharmacy Services and NeighborCare Pharmacies. These mergers brought together some of the most innovative and creative pioneers of the pharmaceutical industry. At the end of 2003 with the successful spin off of Genesis ElderCare and NeighborCare's new status as a stand alone, NeighborCare became a publicly traded company. Today, many of these same early founders remain active and contributing members of NeighborCare.

Based on market analysis and the aging American population, we estimate the demand for pharmacy services in long-term care and assisted living facilities will double by 2010. We are currently in the process of redefining our business process to evolve to meet this need. This will be accomplished by improving our operating efficiency through the introduction of innovative technology and automation. These efforts are expected to improve NeighborCare's productivity, as well as our patients' access to pharmaceuticals.

**Amendments to Chapter 27**

On June 18, 2004 the Board issued a Proposed Rulemaking action to amend §§ 27.1 and 27.14 and to add §§ 22.201-27.204, which will allow for greater efficiencies to be achieved by pharmacies through technology. The stated purpose of the rulemaking action is to set standards for the use of computer-based information and communications systems that are prevalent in the fields of medicine and pharmacy. The proposed rulemaking provides for the use of centralized prescription processing and automated medication systems. Additionally, it allows pharmacies to accept an electronically transmitted prescription, maintain the prescription electronically, and maintain other required records electronically. The Board's Proposed Rulemaking action conforms to

the trend established in many other state pharmacy boards as well as the National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules.

**NeighborCare's Comments**

NeighborCare lauds the goals of the Board in attempting to provide standards for the use of technology that will allow pharmacists to spend more time serving patients and engaging in the clinical aspects of the practice of pharmacy. NeighborCare believes the electronic transmission of prescriptions, paperless record retention and central processing represent the next generation of pharmacy management. The Board has chosen to address and create standards for some of the most cost and resource-efficient vehicles for delivering superior and better quality pharmacy services.

NeighborCare particularly supports the Boards proposed rulemaking with regard to central processing systems. Central processing systems allow a pharmacy to configure its software and workflow to meet its business needs. Such systems will allow pharmacies to meet the growing pharmaceutical dispensing demands at a time when the number of pharmacist available is shrinking. Pharmacies with multiple locations gain flexibility to streamline workflow and information across the full resources of the chain, rather than store-by-store. This fundamental shift allows for managing and distributing workflow through a centralized location and data processing system.

Growing demands and fiscal constraints are driving innovative health reform solutions and changes in pharmacy practice. Central processing, utilizing these processes, allows pharmacies to take advantage of the speed, accuracy and efficiency of proven automated solutions, while maintaining and enhancing the critical pharmacist-patient relationship. The patient benefits from implementation of these technologies. The local community pharmacist has more time to spend with their patients. Prescriptions are processed using the highest level of quality assurance, and medication incidents are reduced. As proposed, central processing will increase quality assurance. There are a greater number of checks implemented throughout the system, and the enhanced audit trail that is possible with individual pharmacist responsibility for each step in the dispensing process.

By way of recommending that § 27.203 be as clear as possible, NeighborCare's understanding of the responsibilities noted in § 27.203 is that dispensing responsibility is specific and separate to each pharmacy for actions occurring at each licensed pharmacy. For example pharmacy A, the "central processing center" would be responsible for the accuracy and drug utilization review for a prescription label approved by the center. Likewise pharmacy B, the "filling or dispensing pharmacy" would be responsible for the accuracy of the drug dispensed, inventory management and distribution of the drug product.

NeighborCare and others in the industry will benefit from the regulatory guidance provided by the Proposed Rulemaking. NeighborCare is working to increase the efficiency of our operations in Pennsylvania through innovative technology which will enhance our workflow and provide superior service to our patients. We encourage the Board to move this process along as expeditiously as possible so that NeighborCare might proceed with its technological enhancements plans.

We appreciate the Board's consideration of our comments.

Sincerely,

s/s John Walker

John Walker R.Ph.
Vice President of Northeast Region

MAS/lkz
cc: John J. Arlotta, Chairman, President & Chief Executive Officer

Original: 2405

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

July 16, 2004

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5410: Technology And Automation

Dear Chairman McGinley:

Pursuant to Section 5(b.1) of the Regulatory Review Act (71 P.S. §845/5(b.1), enclosed is a copy of written comment received by the State Board of Pharmacy regarding Regulation 16A-5410.

Sincerely,

Michael J. Romano RPh

Michael J. Romano, R. Ph., Chairperson
State Board of Pharmacy

MJR/CLC:kp
Enclosure
c: Joyce McKeever, Deputy Chief Counsel
Department of State

Melanie Zimmerman, Board Administrator
State Board of Pharmacy

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WILLIAM L. (BUCK) STEVENS, R.PH.
Senior Vice President • Governmental Affairs

101 Jim Wright Freeway South, Suite 200 • Fort Worth, Texas 76108-2202
Direct (817) 367-4577 • Fax (817) 246-0131

14 July 2004

Original: 2405

The Honorable Carole Clarke
Counsel
Pennsylvania State Board of Pharmacy
124 Pine Street
Harrisburg, PA 17101

Dear MS Clarke:

I appreciate the opportunity to comment on the proposed rules for the Pennsylvania State Board of Pharmacy.

Our company provides software to some 10,000 pharmacies around the country. Many small and large chains and independents in Pennsylvania are our customers. As the need for technology solutions has grown we have moved forward to develop new technology. We are in the process of developing a state of the art central fulfillment solution in Fort Worth, Texas. We will have the best records in the industry. Our solution returns the prescription to the originating pharmacy and if the patient and/or originating pharmacy requests, we can mail the prescription to the patient directly.

For home bound patients or patients without transportation we think this feature is a tremendous help. As the federal government continues to develop the guidelines for Medicare this can allow the community pharmacist, who has the most complete patient records, to provide this service that would otherwise be directed to mail order.

As an example, the State of Texas added language as follows to their Central Fill rule...*return of the dispensed prescriptions to the requesting pharmacy for delivery to the patient or patient's agent, or at the request of the requesting pharmacy, direct delivery to the patient.* This flexibility serves the best interest of the patients and the pharmacy.

The State of Kansas added language as follows...*returning the filled order to the requesting pharmacy for delivery to the patient or patient's agent or, at the request of the requesting pharmacy, directly delivering the filled order to the patient.*

States from Oregon to Virginia and from Arizona to New Jersey have approved this "home delivery". We very much appreciate your consideration.

Sincerely,

William L. "Buck" Stevens

Original: 2405

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

July 8, 2004

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5410: Technology And Automation

Dear Chairman McGinley:

Pursuant to Section 5(b.1) of the Regulatory Review Act (71 P.S. §845/5(b.1), enclosed are copies of written comments received by the State Board of Pharmacy regarding Regulation 16A-5410.

Sincerely,

Michael J. Romano RPh

Michael J. Romano, R. Ph., Chairperson
State Board of Pharmacy

MJR/CLC:kp
Enclosure
c: Joyce McKeever, Deputy Chief Counsel
Department of State

Melanie Zimmerman, Board Administrator
State Board of Pharmacy

Original: 2405

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DIAMOND PHARMACY SERVICES

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PHONE: 724.349.1111 FAX: 724.349.2945

07/06/04

Melanie Zimmerman
State Board of Pharmacy
PO Box 2649
Harrisburg, PA 17105-2649



Ms. Zimmerman,

I am writing to support the proposed amendment to sections 27.1 and 27.14 and the addition of amendments 27.201-27.204 to the Pennsylvania Pharmacy Act. I strongly feel that these additions will allow pharmacies in Pennsylvania to compete better nationally with other companies in other states who are already using this technology. Not only will these additions make our pharmacies more efficient, but they will also permit us to gain additional contracts in other states that were previously unobtainable. In addition, these measures will increase accuracy and patient safety by allowing the pharmacist to focus more of his/her time on clinical decisions. Overall, these changes will increase patient safety, bring more business to our companies, make our companies more competitive, and bring more jobs to Pennsylvania.

Sincerely,

Mark Zilner RPh

Mark Zilner, RPh
Director of Operations
Diamond Pharmacy Services
645 Kolter Dr.
Indiana, PA 15701
800-882-6337 ext. 1003