Original: 2197

IRRC

From: Miller, Sarah E.
Sent: Friday, January 04, 2002 8:27 AM
To: IRRC
Subject: FW: State Board of Pharmacy Final-Form Regulation #16A-549; Reference Libraries; Facsimile Machines

IRRC 01-03-02.doc

-----Original Message-----
From: Greene, Richard [mailto:RGreene@excelleRx.com]
Sent: Thursday, January 03, 2002 4:57 PM
To: Miller, Sarah E.
Subject: RE: State Board of Pharmacy Final-Form Regulation #16A-549; Reference Libraries; Facsimile Machines

Dear Sarah,

Thank you for contacting me regarding the proposed regulations. Attached is a copy of my recommendations for the commission to review. Unfortunately I will be unable to attend the meeting. I will however be at home recovering from surgery. Please feel free to call me at home to discuss these suggestions in detail at 215-657-3222 or my cell phone at 215-450-9014.

<<IRRC 01-03-02.doc>>
Sincerely,

Richard B. Greene, R.Ph.
Director of Regulatory Affairs
Hospice Pharmacia
(a division of excelleRx Inc.)
530 Walnut Street, Suite 550
Philadelphia, PA 19106
Tel: 877-882-7822 x0509
Tel (direct): 215-282-0509
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Email: rgreene@excellerx.com

-----Original Message-----
From: Miller, Sarah E. [mailto:SarahM@IRRC.STATE.PA.US]
Sent: Thursday, December 27, 2001 11:24 AM
To: rgreene@excellerx.com
Subject: FW: State Board of Pharmacy Final-Form Regulation #16A-549; Reference Libraries; Facsimile Machines

> The Independent Regulatory Review Commission (IRRC) is currently
> reviewing this final-form regulation from the State Board of Pharmacy.
> Since you commented on this regulation at the proposed stage the
> final-form might be of interest to you. It is scheduled for action on
> IRRC's January 10, 2002, public meeting. If you have any questions or
> concerns please contact me.
>
> Sarah Miller
> Regulatory Analyst
> IRRC
> 717-783-6835

Richard B. Greene
Hospice Pharmacia
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January 3, 2002

Independent Regulatory Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Final Form Regulations, 16A-549

Dear Independent Regulatory Commission,

I have been actively involved with the proposed changes to: Title 49: Professional and Vocational Standards, Part 11 Department of State, Subpart A: Professional and Occupational Affairs, Chapter 27: State Board of Pharmacy. After careful review, I would like to offer the following suggestions.

Supplies Comments:

A better approach addressing the library requirements would be to require materials that fulfill the requirements, rather than listing specific materials. This would avoid requiring materials not applicable in the current or future settings. A list of examples of suggested appropriate materials would assist in the pharmacy to satisfy this requirement.

§ 27.14 Supplies

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(c) A pharmacy shall maintain at least the following equipment and supplies:

*****

(14) Each pharmacy practice shall maintain in its library at least one (1) reference book (printed or electronic) from either of the last (2) editions that address each category listed below:

(1) drug monographs;
(2) patient counseling;
(3) pharmacology and therapeutics;
(4) pharmaceutical technology;
(5) product availability and identification;
(6) drug interactions (e.g., drug-drug, drug-food, drug-lab tests);

(7) health related periodicals;
(8) toxicology, poisoning and antidote information;
(9) stability and compatibility information;
(10) laboratory tests and/or microbiology; and;
(11) current Pennsylvania Pharmacy Laws issued by the Pennsylvania Board of Pharmacy and updates.

A single reference may fulfill the requirements of more than one (1) category.

An adequate reference library, which meets the following standards:

(i) Enables a pharmacy to prepare and dispense prescriptions properly, consistent with its scope of practice.

(ii) Includes reference sources appropriate to the type of pharmacy practice at that particular location. A pharmacy shall include in the pharmacy's library current material regarding the technical, clinical, and professional aspects with emphasis in the area in which the pharmacy specializes.

(iii) Enables the pharmacist to compound medications in a safe and effective manner consistent with the accepted standards of pharmacy practice.

(iv) Lists the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy;

(v) Lists the therapeutic usage and dosages

An example of references can be but not limited to the following:

(i) The United States Pharmacopeia, The National Formulary
(ii) Physician Desk Reference
(iii) Drug Facts and Comparisons
(iv) Remington's Pharmaceutical Sciences
(v) The United States Dispensatory
(vi) Physicians' Generix
(vii) USPDI (United States Pharmacopeia Dispensing Information)
(viii) American Drug Index
(ix) Goodman and Gilman's Pharmacological Basis of Therapeutics
(x) AHFS Drug Information
(xi) Radiological Health Handbook
(xii) The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals
(xiii) Martindale: The Extra Pharmacopeia

§ 27.20 Facsimile machines

(a) Schedule II Controlled Substances

(1) A pharmacist may fill a prescription for a Schedule II Controlled Substance, which was received on a facsimile machine if the original prescription signed by the medical practitioner is presented to the

pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained as the original pharmacy record.

(2) There are three exceptions to the requirement that the pharmacist review the original prescription received on a facsimile machine before dispensing a Schedule II Controlled Substance. A pharmacist may fill a prescription for a Schedule II Controlled Substance, which was received on a facsimile machine and may use the facsimile as the original pharmacy record in the following situations.

(i) A prescription for a Schedule II Controlled Substance to be prepared for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion in the patient's home or hospice.

(ii) A prescription for a Schedule II Controlled Substance for a resident of a long term care facility.

(iii) A prescription for a Schedule II Controlled Substance prescribed for a patient enrolled in a hospice program.

Please Note:

Section 27.20 (a) (2) (iii) The word **narcotic** should be removed

The use of the term narcotic may not always apply to all Schedule II substances. This is the reason the Drug Enforcement Agency has removed the term NARCOTIC from their language.

Thank you, again for allowing me the opportunity to offer these comments.

Sincerely,

Hospice Pharmacia
(a division of excelleRx, Inc.)

Richard B. Greene, R.Ph.
Director of Regulatory Affairs