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Arkansas State Board of Pharmacy

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2003.15 – Emergency Compounding Regulation Change

The Arkansas State Board of Pharmacy approved the following amendments to Board Regulation 07-02: Compounding as an emergency regulation change at the June 2003 Board Meeting.

07-02-0001 (5) All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized shall be tested to ensure they are (A) sterile, (B) do not contain excessive bacterial endotoxins, and (C) are of labeled potency before they are dispensed or administered.

(A) Sterility Testing (Bacterial and Fungal) – The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. Written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth must be available.

(B) Bacterial Endotoxin (Pyrogen) Testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(C) Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label.

(D) The USP Membrane Filtration Method and the USP Direct Transfer Method are the membrane filtration and direct transfer methods described in Chapter 71, United States Pharmacopeia ("USP"), 2001 Edition. The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition. Should there be any amendment or change in any of the above methods or test by USP subsequent to the effective date of this paragraph, said change or amendment to USP shall be effective under this regulation after the expiration of thirty (30) days from the effective date of said change or amendment, unless within said time period, the Executive Director objects to said change or amendment. In that case, the Executive Director shall publish the reasons for objection and afford all interested parties an opportunity to present commentary; said notice and commentary shall be pursuant to A.C.A. § 25-15-204, as amended, and the resulting decision by the Board shall be reflected by an amendment to this regulation.

07-02-0002 (m) (5) Compounding for office stock for veterinarians is prohibited, except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available.

The Board will hold a public hearing at the October 2003 Board Meeting before considering permanent promulgation of these amendments. We will be accepting written public comments until the conclusion of the public hearing at the meeting. Other regulation changes to be considered at the October Board Meeting include prohibiting the compounding of drug products that are commercially available, criminal background checks, and student health clinic permits. Please contact the Board office at 501/682-0190 if you have any questions about this or other regulation changes.

2003.16 – License Verification

If you have questions about a health care provider's license or ability to prescribe, please contact the board responsible for his or her license. The Board of Pharmacy can only provide reliable information about pharmacists, pharmacy interns, and pharmacy technicians. We have listed some numbers below that may be helpful to you:

Arkansas Medical Board	501/296-1802
Arkansas State Board of Nursing	501/686-2700
Arkansas State Board of Dental Examiners	501/682-2085
Arkansas State Board of Optometry	501/268-4351
Arkansas Board of Podiatric Medicine	501/664-3668
Arkansas State Board of Veterinary Examiners	501/224-2836

2003.17 – Emergency Pharmacy Services

Board Regulation 04-00-0006 states that, "Any pharmacy providing prescription drugs to one or more patients in a nursing

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home or other institution shall provide emergency prescription services for those patients and shall provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours." If a pharmacy is providing services to a nursing home, it is required that a pharmacist is available 24 hours a day. We have received complaints from nursing homes that a provider pharmacy has been unavailable after hours. Please contact the nursing homes that you service to make sure they have the correct information for obtaining after hours assistance.

2003.18 – List 1 Chemical Legislative Changes

Pursuant to ACT 867 of 2003, wholesalers and distributors may not store List 1 Chemicals (pseudoephedrine, ephedrine, or phenylpropanolamine alone or in a mixture) in bulk containers (non-safe harbor packaging) for distribution within or outside the state. The only exceptions to this law are distributors that sell to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian who dispenses or administers these products consistent with his or her respective professional practice act. ACT 867 of 2003 went into effect on July 16, 2003.

Pursuant to ACT 277 of 2003, retail distributors may sell products containing ephedrine, pseudophedrine, or phenylpropanolamine to any person under the age of eighteen (18) years, if the person is purchasing a pediatric product intended for a child. ACT 277 of 2003 went into effect on July 16, 2003.

2003.19 – Construction Requirement Reminder

Any construction requirements as required by Regulation 07-02-0001 – Standards for Compounding and Dispensing Sterile Products (ie, separate controlled limited access area and certification of Class 10,000) must be complied with by January 2004.

2003.20 – New Reciprocating Pharmacists

The following is a list of pharmacists who were approved to receive an Arkansas Pharmacist license by reciprocity by the Arkansas State Board of Pharmacy at its June meeting:

William Bailey	Curt Bicknell
Eric Borell	Charles Bruner
Diana Campbell	Suzanne Carter
David Cornwell	Phillip D'Amato
Dale Dolan	Helen Early
Nedra Ellis	Angela Enloe
Stacy Flynn	Amanda Gahagan
Robert Gardner	Rebecca Gilkey
Shane Goulas	Charles Greenhouse
Susan Halfen	Charles Jones
Phayboun Kattaviravong	Haili Kreifels
John LaFreniere	Kenneth Long
Monica Mathis	Linda McDougal
Loren McKay	Nathan Mouton
Nimesh Patel	Shannon Pruett
Alma Quintero	Jacob Raitt
Marc Rosenthal	Mischelle Smoot
Lloyd Warner	Sheri Zapp
Michael Zeglinski	

The Arkansas State Board of Pharmacy would like to welcome all of these pharmacists to Arkansas.

Arkansas Pharmacy Support Helpline – 870/636-0923

Special Notice About This Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter*'s contents. Please contact the Board office at 501/682-0190 if you have questions about any of the articles in this *Newsletter*.

The *Arkansas State Board of Pharmacy News* is published by the Arkansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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