State of New Mexico
Board of Pharmacy
November 8 & 9, 2004 Board Meeting
Minutes

Call To Order/Roll Call:

Woodrow Storey, Board Chairman called the meeting to order at approximately 9:05 a.m. and a quorum was determined to be present.

Members Present:

Tom Ortega, R.Ph.
Rudy Nolasco, R.Ph.
Brenda Padilla, R.Ph.
Woodrow Storey, R.Ph.
Howard Shaver
Danny Cross, R.Ph.
Amy Buesing, R.Ph.

Members Absent:

Buffie Saavedra

Staff Present:

Bill Harvey, R.Ph., Acting Executive Director/State Drug Inspector
Bill Weast, R.Ph., State Drug Inspector
Mike Lyons, R.Ph., State Drug Inspector
Larry Loring, R.Ph., State Drug Inspector
Janelle Sanchez, Administrative Secretary
Cynthia McCormick, Administrator
Sarah Trujillo, Licensing Manager
Rocio Cruz-Tapia, Licensing Clerk

Approval of the Agenda:

The Chairman stated that a new agenda has been passed out to all members and asked if there were any changes or additions to the current agenda. Mr. Harvey stated that he would like to add cases #2004-105 and 2004-032 to case presentations, CE requests from Anita Berry.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Nolasco to approve the agenda with the additions. The Board voted unanimously to pass the motion.

Approval of the September and October 2004 Board meeting minutes:

Ms. Buesing stated that in the September minutes, on page 13, line 32 an "ed" needs to be added to implement. On page 10, line 38, "and at this time" needs to be deleted.

Ms. Buesing stated that in the October minutes, the minutes and the format are looking great, but maybe when a big topic such as the wholesaler discussion comes up, a little more detail could be added.

Motion:

A motion was made by Mr. Shaver, seconded by Mr. Cross to approve the October and September 2004 Board meeting minutes with the changes mentioned. The Board voted unanimously to pass the motion.

Executive Director's Report:

Mr. Harvey presented an application received from Collin Bayliss. He stated that Mr. Bayliss has requested that the Board grant him a license at 2 previous meetings, and was instructed to go through the NABP process and then apply to the Board. He has spent some time in prison, and that's why the Board is looking so closely at this application. Ms. Frank stated that the Board may want to send this through the complaint process that way the Board may give Mr. Bayliss a hearing if needed.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to issue an NCA to Mr. Bayliss to deny the application, and if he wishes to have a hearing, the Board will use a hearing officer. The Board voted unanimously to pass the motion.

Mr. Harvey presented a request from Mr. Soon regarding approval of his emergency contraceptive course. After brief discussion, the Board decided to hold off on this issue until the appropriate committee reviews the documents.

Mr. Harvey stated that he would like to discuss the examination committee. He stated that there are 3 individuals on this committee currently, although they have not been activated yet. Danae Break, Pharm. D., AnnaMarie Garcie, R.Ph. and Rod Clark, R.Ph. a former member of the impaired pharmacist committee are the volunteers. Mr. Storey stated that he would prefer if staff referred individuals to the committee instead of the Board referring individuals.

Motion:

A motion was made by Mr. Nolasco, seconded by Mr. Cross to allow staff to refer individuals to the examining committee. The Board voted unanimously to approve the motion.

Mr. Harvey presented correspondence received from NABP regarding the updated NABPLEX blueprint and the new passing standard.

Mr. Harvey presented correspondence received from NABP regarding the new TOEFL examination, which now includes a speaking component.

Mr. Harvey presented correspondence received from Rio Arriba County RAPN regarding the program focusing on substance abuse in that area.

Mr. Harvey presented correspondence received from the Federation of State Medical Boards of the United States regarding an education workshop and scholarships offered for Board members. Mr. Cross and Mr. Nolasco stated that they would be interested in attending.

Mr. Harvey presented correspondence received from NABP regarding the transcript of the Dateline NBC Internet Drug Buy Segment. Mr. Storey stated that he would like Mr. Harvey to have RLD send out a press release regarding this issue.

Mr. Harvey presented correspondence received from NABP regarding the Ari Heller issue.

Mr. Storey stated that after speaking with Mr. Tinker, the presentation given to the Board by Frederick Soon was the Associations presentation, and he would like the Board to refer Mr. Soon to the Association for approval.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Shaver to refer Mr. Soon to the New Mexico Pharmaceutical Association for approval of the training program presented to the Board. The Board voted unanimously to pass the motion.

Mr. Harvey stated that there is an item that the staff would like to add to the 2005 legislative agenda. Mr. Weast stated that tampering issues have become very prevalent lately. He stated that he would like to add language to the Controlled Substances Act to make tampering a 3rd or 4th degree felony.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to add the issue of tampering to the legislative agenda. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Ortega, seconded by Mr. Nolasco to go into executive session to discuss the matters of Harry Pitcher and Joel Butler. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Padilla to go back into open session and all that was discussed were the issues of Harry Pitcher and Joel Butler. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Ms. Padilla, seconded by Mr. Ortega to send an order to Harry Pitcher specifying that he voluntarily surrendered his license to the Board. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to ratify the Board order for Joel Butler with the change to the fine for $10.00 per violation to support the criminal case ahead of him. The Board voted unanimously to pass the motion.

Ms. Frank stated that she did not have time to bring the Board a written opinion on Mr. Cross' question regarding whether the signature on a prescription could be stamped but could provide an oral comment at this time. In the past the Board has never interpreted prescription to mean anything other than an actual signature. At this time it would be stretching it to consider it otherwise, however, with a valid regulation the Board could interpret it to include a rubber stamp. The Federal regulations imply that an actual signature be used. Mr. Storey asked if Ms. Frank had a chance to look at Pharmacies on Native American property. She stated that there is an expert in her office that is going to look at this issue.

Mr. Harvey presented the disposal of inventory to the Board for signature.

Mr. Harvey stated that a chain pharmacy here in New Mexico has made a policy that they will not call the Board of Pharmacy when there is a forgery presented to them. Their current policy is to return the prescription to the individual and not fill it. Mr. Cross stated that he would like a letter to be sent to this pharmacy to let them know that the Board of Pharmacy does not approve of this policy, and that he would like them to appear before the Board to discuss this issue further.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to invite the pharmacy to attend the next Board meeting to explain the policy regarding not reporting forgeries to the Board. The Board voted unanimously to pass the motion.

Mr. Harvey presented a request from Anita Joe Berry for the Board to accept a course that she attended that was not ACPE accredited.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to deny the request of Anita Joe Berry. The Board voted unanimously to pass the motion.

Steve Mulryan - Variance Request:

Mr. Mulryan appeared before the Board to request that the Board grant a variance to Express Scripts regarding the 4 to 1 ratio for technicians and pharmacists. According to Mr. Mulryan: there will be pharmacists in the facility on weekends unnecessarily just to support the 4 to 1 ratio. The variance request would be for a 10 to 1 ratio. Mr. Cross stated that he would not support a variance that goes against everything the regulation was written for. Further brief discussion was held regarding this issue. Agreeing with Mr. Cross, no action was taken by the Board.

Recess for lunch:

Reconvene:

Default Orders:

Mr. Harvey presented the default orders for Ian Purley case #2003-134, David Montes case # 2003-128, Linda Marquez case # 2004-026 and Nicole Romero case # 2004-013. He stated that the NCA's and Notices were received by these individuals and they never responded.

Motion:

A motion was made by Mr. Shaver, seconded by Mr. Cross to accept the Default Orders for David Montes, Ian Purley, Nicole Romero and Linda Marquez. The Board voted unanimously to pass the motion.

Settlement Agreements:

Amy Reaume, Pharmacy Technician - Case # 2003-119:

Ms. Chavez presented to the Board a signed settlement agreement for the Board to review and discuss. She briefly described the alleged allegations in this matter. Ms. Chavez also briefly outlined the terms of the settlement agreement.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to accept the settlement in the matter of Amy Reaume as presented to the Board. The Board voted unanimously to pass the motion. Mr. Ortega abstained from the vote.

David Jones, R.Ph. - Case # 2004-007:

Ms. Chavez presented to the Board a signed settlement agreement for the Board to review and discuss. She briefly described the alleged allegations in this matter. Ms. Chavez also briefly outlined the terms of the settlement agreement.

Motion:

A motion was made by Ms. Buesing, seconded by Mr. Nolasco to accept the settlement agreement in the matter of David Jones, R.Ph. as presented. The Board voted unanimously to pass the motion. Mr. Ortega abstained from the vote.

Executive Director's Report Cont'd:

Case Presentations:

Motion:

A motion was made by Mr. Ortega, seconded by Ms. Buesing to go into executive session to discuss case reports. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Nolasco, seconded by Mr. Ortega to go back into open session and all that was discussed was case presentations. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to close case # 2004-032 and to send a letter to the complainant stated the process for the investigation in the office. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to issue an NCA in case # 2004-105 and to refer the individual to the examining committee for review. The Board voted unanimously to pass the motion.

Application Approval:

Clinic Applications:

Mr. Cross stated that there are 11 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Shaver to approve all 11 applications for clinics as presented. The Board voted unanimously to pass the motion.

Home Care Applications:

Mr. Cross stated that there are 2 applications in this category and both are in order.

Motion:

A motion was made by Mr. Cross, seconded by Nolasco to approve both applications in this category as presented. The Board voted unanimously to pass the motion. Ms. Buesing abstained from the vote.

Custodial Home Applications:

Mr. Cross stated that there are 17 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Shaver to approve all 17 applications in this category as presented. The Board voted unanimously to pass the motion. Mr. Cross abstained from voting on #3 and #4.

EMS Applications:

Mr. Cross stated that there are 2 applications in this category and both are in order.

Motion:

A motion was made by Mr. Cross, seconded by Ms. Padilla to approve both applications in this category as presented. The Board voted unanimously to pass the motion.

Pharmacy Applications:

Mr. Cross stated that there are 4 applications in this category and all are in order.

Motion:

A motion was made by Mr. Shaver, seconded by Ms. Buesing to approve all 4 applications in this category as presented. The Board voted unanimously to pass the motion. Mr. Cross abstained from voting on #1.

Hospital Pharmacy Applications:

Mr. Cross stated that there is one application in this category and it is in order.

Motion:

A motion was made by Mr. Cross, seconded by Buesing to approve the one application in this category as presented. The Board voted unanimously to pass the motion.

Non Resident Pharmacies:

Mr. Cross stated that there are 14 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to approve all 14 applications in this category as presented. The Board voted unanimously to approve the motion.

Mr. Storey stated that the he would like to see non resident pharmacies and the requirements on our application put on the agenda for the next Board meeting.

Wholesaler/Broker Applications:

Mr. Cross stated that there are 5 applications in this category and all are in order.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to approve all 5 applications in this category as presented. The Board voted unanimously to pass the motion.

Pharmacist Clinician Applications:

Mr. Cross stated that there are 3 applications. The committees suggestion is to approve 1 & 2 and 3 pending receipt of documents.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to approve all 3 applications for pharmacist clinician and the 3rd application pending receipt of documentation. The Board voted unanimously to pass the motion.

Mr. Storey stated that a copy of the application list will be attached to the minutes.

Ms. Padilla stated that she is not being informed correctly or timely of the meetings of the pharmacist clinician committee and the meetings that she has attended she was one of only 2 people.

Executive Session:

Motion:

A motion was made by Mr. Cross, seconded by Ms. Buesing to go into executive session to discuss personnel issues. The Board voted unanimously to pass the motion.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Shaver to go back into open session and all that was discussed was personnel issues. The Board voted unanimously to pass the motion.

Wholesale License Discussion:

Mr. Harvey presented a large stack of petitions to the Board. Mr. Cross asked how the Board would like to decide which companies may receive a different fee than the $5000.00. Mr. Harvey stated that he has criteria for deciding, but he would like the Board to decide the pricing schedule. He stated that the Board may adopt by policy the pricing schedule recommended by Pamela Herndon. Mr. Harvey stated that the Board may want to wait on deciding until Patty Jennings appears before the Board in the morning.

RECESS:

RECONVENE:

Mr. Storey was absent for Tuesday's portion of the meeting. Ms. Buesing acted as Chairman.

Patty Jennings - NMMIP:

Ms. Jennings appeared before the Board to discuss different options with the Board regarding the Wholesaler fee and the petitions for a reduced fee. Ms. Jennings stated that 0.005 % of volume would be, in her mind, the fairest way to go with this issue. She also stated that every wholesaler who left the state because of the fees should be contacted and informed of the new process and the appeal mechanism that has been put into place. Further brief discussion was held, Mr. Cross stated that the percentage of volume would be the best way for the Board to go with this issue, and if Mr. Harvey has any problems with a company or if a company is not happy with Mr. Harvey's decision, they can then appear before the Board.

Regulation Hearings:

The Chairman opened the hearings for 16.19.21 NMAC, 16.19.4.16 NMAC and 16.19.6.11 NMAC at approximately 9:26 a.m.

The Chairman placed into evidence written comments from NACDS, WalMart, Consumer Health Products Association, Proctor and Gamble and also the Notice to the Public.

Mr. Cross read the proposed changes to 16.19.21 NMAC aloud to the Board. Those proposed changes are as follows:

16.19.21.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, **[**~~1650 University Blvd, NE - Ste. 400B~~**]**, Albuquerque, NM **[**~~87102, (505) 841-9102~~**]**.
[02-14-1889...02-15-96; 16.19.21.1 NMAC - Rn, 16 NMAC 19.21.1, 03-30-02]

16.19.21.8 PERSONS REQUIRED TO REGISTER:
A. The Board shall license an applicant to manufacture, possess, transfer or transport drug precursors unless it determines that the issuance of that license would be inconsistent with the public interest. In determining the public interest, the Board may consider the following factors:
(1) maintenance of effective controls against diversion of drug precursors into other than legitimate medical, scientific or industrial channels;
(2) compliance with applicable state and local law;
(3) any conviction of the applicant under federal or state laws relating to any controlled substance or drug precursor;
(4) past experience in the manufacturer, possession, transfer or transportation of drug precursors and the existence in the applicant's establishment of effective controls against diversion;
(5) furnishing by the applicant of false or fraudulent material in any application filed under the Drug Precursor Act or the Controlled Substances Act;
(6) suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense controlled substances or drug precursors as authorized by federal law; and
(7) any other factors relevant to and consistent with the public health and safety.
B. Licensing under this section does not entitle a licensee to manufacture, possess, transfer or transport drug precursors other than those allowed in the license.
C. Entities currently licensed by the Board shall be exempt from this registration, but not exempt from the regulation.
[03-07-80...08-27-90; 16.19.21.8 NMAC - Rn, 16 NMAC 19.21.8, 03-30-02; A, 12-31-2004]

16.19.21.9 REGISTRATION AND EXPIRATION DATE:
A. Any person who is required to be registered **under this part** and who is not registered may apply for registration at any time.
B. The license for persons required to register **under this part** shall be renewed [~~annually~~] **bi-ennially** before the last day of December [~~of each year~~].
[03-07-80...08-27-90; 16.19.21.9 NMAC - Rn, 16 NMAC 19.21.9, 03-30-02; A, 12-31-2004]

16.19.21.10 REGISTRATION FEE: The registration fee or annual renewal fee required by the Drug Precursor Act shall be**:** [~~$500.00~~]
A. for a wholesaler, manufacturer, or distributor shall be $250.00 per year
B. for a retail distributor with fewer than 10 employees shall be $25.00 per year;
C. for a retail distributor with 10 or more employees shall be $50.00 per year.
[03-07-80...08-27-90; 16.19.21.10 NMAC - Rn, 16 NMAC 19.21.10, 03-30-02; A, 08-30-04; A, 12-31-2004]

16.19.21.14 FACILITY INSPECTION: The Board of Pharmacy may direct the drug inspector to inspect the facilities prior to approval of any **registration** application **filed under this part of any wholesaler, manufacturer, or distributor**, for security provisions and other applicable standards as required by the Drug Precursor Act **or regulations passed by the Board. A fee of $150.00 must be submitted before such inspection of any wholesaler, manufacturer, or distributor**.
[03-07-80...08-27-90; 16.19.21.14 NMAC - Rn, 16 NMAC 19.21.14, 03-30-02; A, 08-30-04; A, 12-31-2004]

16.19.21.19 INVENTORY RECORDS: [~~A.~~] All registrants are required to keep procurement records **in a readily retrievable manner for 3 years**.
[~~B. All registrants must keep a perpetual inventory. The amount of drug precursor must equal the amount on the inventory at the end of each work day.]~~
[03-07-80...08-27-90; 16.19.21.19 NMAC -0 Rn, 16 NMAC 19.21.19, 03-30-02; A, 12-31-2004]

16.19.21.23 DISTRIBUTION RECORDS:
A. All **wholesaler, manufacturer, or distributor** registrants shall include the following **in distribution** records **for drug precursors under this part**[~~where applicable~~]:
~~[A]~~**1.** purchaser's name, address and **tele**phone number, and **drug** precursor [~~license~~] **registration** number **or other license number issued by the Board in lieu of a drug precursor registration number**;
[~~B~~]**2.** quantity purchased;
[~~C~~]**3.** date supplied;
[~~D~~]**4.** **[**~~purchaser's identity must be verified by valid drivers license or other appropriate identification and the type of identification recorded in distribution records]~~ **suppliers name, address, telephone number, and drug precursor**

registration number of the supplier;

[~~E~~]**5.** **[**~~number of purchaser's precursor license must be included on distribution record~~] **distribution records must be retained for three (3) years**.

B. All retail distributor registrants, pharmacies, hospitals and clinics shall adhere to the following record keeping and distribution requirements concerning pseudoephedrine or pseudoephedrine containing products regulated by the Board:

1. that a retail distributor registrant, pharmacies, hospitals and clinics shall transfer (sell) no more than 2 blister packages not to exceed 6 grams of pseudoephedrine to any one individual in a single transaction and may not knowingly or intentionally transfer cumulative total exceeding 2 blister packages or 6 grams of pseudoephedrine during any seven day period to that one individual;

2. that a retail distributor registrant, pharmacies, hospitals and clinics must place all products regulated by the Board in direct sight of an employee of the facility and no more than 20 feet from a checkout or other security measures as approved by the Board;

3. that the retail distributor registrant, pharmacies, hospitals and clinics owner or manager must develop a written or electronic training program, to be read and signed (written or electronic) by all employees involved in the sale of regulated products that makes the employee aware of all statutes and regulations concerning the sale of regulated products;

4. that the retail distributor registrant, pharmacies, hospitals and clinics will retain all invoices of purchases of regulated products in a readily retrievable manner for a period of three (3) years;

5. that the retail distributor registrant, pharmacies, hospitals and clinics will purchase regulated products only from wholesalers, manufacturers, or distributors registered to distribute drug precursors or otherwise licensed with the Board.

[03-07-80...08-27-90; 16.19.21.23 NMAC - Rn, 16 NMAC 19.21.23, 03-30-02; A, 08-30-04; A, 12-31-2004]

16.19.21.35 CONTROLLED SUBSTANCE PRECURSORS: The following substances are designated as immediate precursors used in the manufacture of controlled substances:

A. phenyl acetone
B. ephedrine
C. phenyl-2-propanone
D. norephedrine
E. ethyl-1-methyl butyl diethyl malonate
F. allyl-1-methyl butyl diethyl malonate
G. hydroxyindole
H. 3,4,5-trimethoxybenzyl cyanide
I. 3,4,5-trimethoxybenzyl alcohol
J. 3,4,5-trimethoxyphenylacetonitraile
K. 3,4,5-trimethoxybenzoic acid amide
L. 4-benzyloxyindole
M. 4-chloro indole
N. indole
O. tryntophol
P. 3-indole glyoxylic acid
Q. 3-indole glyoxylic acid ethyl ester
R. lysergic acid
S. lysergic acid amide
T. ergotamine tartrate
U. 1-phenyl cyclohexylamine
V. 1-piperidinocyclohexanecarbonitrile
W. pseudoephedrine **single ingredient solid oral dosage form and any combination solid oral dosage form containing pseudoephedrine excluding liquid products including liquid gel products for oral administration, inhalation, injection, any product intended for pediatric use, and any solid oral dosage form for which the manufacturer of said product presents scientific evidence to the Board verifying that the product cannot be converted into a controlled substance**
X. methylamine
Y. methylformamide
Z. phenylacetic acid
AA. anhydrous ammonia;

(1) a person shall not possess any amount of anhydrous ammonia;

(2) a person must store anhydrous ammonia in a container approved for the transport of anhydrous ammonia

(~~2~~**3**) the provisions of this section do not apply to a:

(i) person who is actively operating land used for agricultural purposes;

(ii) retail distributor;
(iii) wholesaler;
(iv) manufacturer;
(v) warehouseman;
(vi) common carrier; or
(vii) person engaged in the regular course of conducting a lawful business.

BB. red phosphorous

CC. iodine matrix**, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine matrix in a single transaction**

DD. crystal iodine**, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine crystals in a single transaction**

[03-07-80…08-27-90; 16.19.21.35 NMAC - Rn, 16 NMAC 19.21.35, 03-30-02; A, 12-01-03; A, 08-30-04; A, 12-31-2004]

The Board went through the changes one line at a time. Lengthy discussion was held regarding the proposed changes.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Ortega to approve the amendments to 16.19.21 NMAC as amended by the Board and as follows:

16.19.21.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, **[**~~1650 University Blvd, NE - Ste. 400B~~**]**, Albuquerque, NM **[**~~87102, (505) 841-9102~~**]**.
[02-14-1889...02-15-96; 16.19.21.1 NMAC - Rn, 16 NMAC 19.21.1, 03-30-02; A, 01-15-2005]

16.19.21.8 PERSONS REQUIRED TO REGISTER:

A. The board shall license an applicant to manufacture, possess, transfer or transport drug precursors unless it determines that the issuance of that license would be inconsistent with the public interest. In determining the public interest, the board may consider the following factors:

(1) maintenance of effective controls against diversion of drug precursors into other than legitimate medical, scientific or industrial channels;

(2) compliance with applicable state and local law;

(3) any conviction of the applicant under federal or state laws relating to any controlled substance or drug precursor;

(4) past experience in the manufacturer, possession, transfer or transportation of drug precursors and the existence in the applicant's establishment of effective controls against diversion;

(5) furnishing by the applicant of false or fraudulent material in any application filed under the Drug Precursor Act or the Controlled Substances Act;

(6) suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense controlled substances or drug precursors as authorized by federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

B. Licensing under this section does not entitle a licensee to manufacture, possess, transfer or transport drug precursors other than those allowed in the license.

C. Entities currently licensed by the board shall be exempt from this registration, but not exempt from the regulation.

[03-07-80...08-27-90; 16.19.21.8 NMAC - Rn, 16 NMAC 19.21.8, 03-30-02; A, 01-15-2005]

16.19.21.9 REGISTRATION AND EXPIRATION DATE:

A. Any person who is required to be registered **under this part** and who is not registered may apply for registration at any time.

B. The license for persons required to register **under this part** shall be renewed [~~annually~~] **bi-ennially** before the last day of December [~~of each year~~].

[03-07-80...08-27-90; 16.19.21.9 NMAC - Rn, 16 NMAC 19.21.9, 03-30-02; A, 01-15-2005]

16.19.21.10 REGISTRATION FEE: The registration fee or annual renewal fee required by the Drug Precursor Act shall be[~~$500.00~~]**:**

A. for a wholesaler, manufacturer, or distributor shall be $250.00 per year

B. for a retail distributor with fewer than 10 employees shall be $25.00 per year;

C. for a retail distributor with 10 or more employees shall be $50.00 per year.

[03-07-80...08-27-90; 16.19.21.10 NMAC - Rn, 16 NMAC 19.21.10, 03-30-02; A, 08-30-04; A, 01-15-2005]

16.19.21.14 FACILITY INSPECTION: The board of pharmacy may direct the drug inspector to inspect the facilities prior to approval of any **registration** application **filed under this part of any wholesaler, manufacturer, or distributor**, for security provisions and other applicable standards as required by the Drug Precursor Act **or regulations passed by the board. A fee of $150.00 must be submitted before such inspection of any wholesaler, manufacturer, or distributor**.

[03-07-80...08-27-90; 16.19.21.14 NMAC - Rn, 16 NMAC 19.21.14, 03-30-02; A, 08-30-04; A, 01-15-2005]

16.19.21.19 INVENTORY RECORDS: [~~A.~~] All registrants are required to keep procurement records **in a readily retrievable manner for 3 years**.

[~~B. All registrants must keep a perpetual inventory. The amount of drug precursor must equal the amount on the inventory at the end of each work day.~~]

[03-07-80...08-27-90; 16.19.21.19 NMAC -0 Rn, 16 NMAC 19.21.19, 03-30-02; A, 01-15-2005]

16.19.21.23 DISTRIBUTION RECORDS:

A. All **wholesaler, manufacturer, or distributor** registrants shall include the following **in distribution** records **for drug precursors under this part**[~~where applicable~~]:

[~~A~~]**1.** purchaser's name, address and **tele**phone number, and **drug** precursor [~~license~~] **registration** number **or other license number issued by the board in lieu of a drug precursor registration number**;

[~~B~~]**2.** quantity purchased;

[~~C~~]**3.** date supplied;

[~~D~~]**4.** **[**~~purchaser's identity must be verified by valid drivers license or other appropriate identification and the type of identification recorded in distribution records~~] **suppliers name, address, telephone number, and drug precursor registration number of the supplier**;

[~~E~~]**5.** **[**~~number of purchaser's precursor license must be included on distribution record~~] **distribution records must be retained for three (3) years**.

B. All retail distributor registrants, pharmacies, hospitals and clinics shall adhere to the following record keeping and distribution requirements concerning pseudoephedrine or pseudoephedrine containing products regulated by the board:

(1) that a retail distributor registrant, pharmacies, hospitals and clinics shall transfer (sell) no more than 2 blister packages not to exceed 6 grams of pseudoephedrine to any one individual in a single transaction and may not knowingly or intentionally transfer cumulative total exceeding 2 blister packages or 6 grams of pseudoephedrine during any seven day period to that one individual;

(2) that a retail distributor registrant, pharmacies, hospitals and clinics must place all products regulated by the board in direct sight of an employee of the facility and no more than 20 feet from a checkout or other security measures as approved by the board;

(3) that the retail distributor registrant, pharmacies, hospitals and clinics owner or manager must develop a written or electronic training program, to be read and signed (written or electronic) by all employees involved in the sale of regulated products that makes the employee aware of all statutes and regulations concerning the sale of regulated products;

(4) that the retail distributor registrant, pharmacies, hospitals and clinics will retain

all invoices of purchases of regulated products in a readily retrievable manner for a period of three (3) years;

5. that the retail distributor registrant, pharmacies, hospitals and clinics will purchase regulated products only from wholesalers, manufacturers, or distributors registered to distribute drug precursors or otherwise licensed with the board.

[03-07-80...08-27-90; 16.19.21.23 NMAC - Rn, 16 NMAC 19.21.23, 03-30-02; A, 08-30-04; A, 01-15-2005]

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B. ephedrine
C. phenyl-2-propanone
D. norephedrine
E. ethyl-1-methyl butyl diethyl malonate
F. allyl-1-methyl butyl diethyl malonate
G. hydroxyindole
H. 3,4,5-trimethoxybenzyl cyanide
I. 3,4,5-trimethoxybenzyl alcohol
J. 3,4,5-trimethoxyphenylacetonitraile
K. 3,4,5-trimethoxybenzoic acid amide
L. 4-benzyloxyindole
M. 4-chloro indole
N. indole
O. tryntophol
P. 3-indole glyoxylic acid
Q. 3-indole glyoxylic acid ethyl ester
R. lysergic acid
S. lysergic acid amide
T. ergotamine tartrate
U. 1-phenyl cyclohexylamine
V. 1-piperidinocyclohexanecarbonitrile
W. pseudoephedrine **single ingredient solid oral dosage form and any combination solid oral dosage form containing pseudoephedrine excluding liquid products including liquid gel products for oral administration, inhalation, injection, any product intended for pediatric use, and any solid oral dosage form for which the manufacturer of said product presents scientific evidence to the board verifying that the product cannot be converted into a controlled substance**
X. methylamine
Y. methylformamide
Z. phenylacetic acid
AA. anhydrous ammonia;

(1) a person shall not possess any amount of anhydrous ammonia;

(2) a person must store anhydrous ammonia in a container approved for the transport of anhydrous ammonia

[(~~2)~~](**3**) the provisions of this section do not apply to a:

(i) person who is actively operating land used for agricultural purposes;
(ii) retail distributor;
(iii) wholesaler;
(iv) manufacturer;
(v) warehouseman;
(vi) common carrier; or

(vii) person engaged in the regular course of conducting a lawful business;

BB. red phosphorous;

CC. iodine matrix**, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine matrix in a single transaction;**

DD. crystal iodine**, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine crystals in a single transaction.**

[03-07-80…08-27-90; 16.19.21.35 NMAC - Rn, 16 NMAC 19.21.35, 03-30-02; A, 12-01-03; A, 08-30-04; A, 01-15-2005]

The Board voted unanimously to pass the motion.

Mr. Cross read the proposed changes to 16.19.4.16 NMAC and 16.19.6.11 NMAC. The proposed changes are as follows:

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional judgment and shall therefore only be performed by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) initial identification, evaluation and interpretation of the prescription order and any necessary clarification prior to dispensing;

(3) professional consultation with a patient or his agent regarding a prescription;

(4) evaluation of available clinical data in patient medication record system.

(5) oral communication to the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription**.**[~~; and~~]

[~~(7) Preparation of prescription drug orders for cancer chemotherapy solutions.~~]

B. ONLY A PHARMACIST SHALL PERFORM THE FOLLOWING DUTIES:

(1) final check on all aspects of the completed prescription **including sterile products and cytotoxic preparations** , and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(2) evaluation of pharmaceuticals for formulary selection within the facility;

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications;

(4) ensure that supportive personnel have been properly trained for the duties they may perform.

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories). This does not apply to substitution of generic equivalents.

(6) any other duty required of a pharmacist by any federal or state law.

C. PATIENT RECORDS:

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacists comments relevant to the individuals drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional judgment concerning both the offer to counsel and the content of counseling.

D. PROSPECTIVE DRUG REVIEW:

(1) A pharmacist or pharmacist intern shall review the patient record for:

(a) clinical abuse/misuse;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

(e) incorrect drug dosage;

(f) incorrect duration of drug treatment;

(g) drug-allergy interactions;

(h) appropriate medication indication.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

E. COUNSELING:

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling which may include, in their professional judgment, one or more of the following:

(a) the name and description of the drug;

(b) the dosage form, dosage, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescriptions refill information;

(i) action to be taken in the event of a missed dose;

(j) the need to check with the pharmacist or practitioner before taking other medication; and

(k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by the mail, the pharmacist shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (1) of his or her right to request counseling; and (2) a toll-free telephone number in which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record. For pharmacies delivering more than 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week. The facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

F. [REPEALED]

G. REGULATORY ASSESSMENT: Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three (3) years from the date of the last entry in the profile record.

[08-27-90; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 03-30-02; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12-15-02; A, 12-01-2003; A, 02-01-04; A, 01-15-2005]

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

A. The pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of drugs and parenteral products appropriate to the scope of pharmaceutical services provided. The following items shall be in the pharmacy:

(1) An updated reference source, appropriate to each practice site, either electronic or paper version;

(2) One copy of the most recently published New Mexico Pharmacy Laws, Rules and Regulations and available revisions, either electronic or paper version

B. PARENTERAL PHARMACEUTICALS

(1) Purpose: To ensure that the citizens of New Mexico receive routine safe and competent delivery of parenteral products and nutritional support throughout the state. To establish guidelines for licensure and inspection of such facilities by the State Board of Pharmacy.

(2) Definitions

(a) "Parenteral Products Pharmacy" is a retail pharmacy which prepares and distributes prescriptions for sterile products intended for parenteral administration to patients either at home or in or out of an institution licensed by the State.

(b) "Parenteral Product" means any preparation administered by injection through one or more layers of skin tissue.

(c) "Sterile" means a preparation that has undergone a valid sterilization process and is devoid of all living microorganisms, packaged in such a way to ensure the retention of this characteristic.

(d) "Preparation" means a sterile product which has been subjected to manipulation by a pharmacist under aseptic conditions to render the product suitable for administration.

(e) "Aseptic Conditions" means a cabinet or facility capable of obtaining Class 100 clean air as defined by the federal standards 209E and which is certified by a testing agency at least every six months.

(f) "Aseptic Technique" means proper manipulation of articles within a Class 100 clean air room or station to maintain sterility.

(g) "Disinfectant" means a chemical compound used to kill and or control microbial growth within a Class 100 area or its surroundings and is approved for such use by the Environmental Protection Agency.

(h) "Antimicrobial Soap" means soap containing an active ingredient that is active both in vitro and vivo against skin microorganisms.

(i) "Surgical Hand Scrub" means an antimicrobial containing preparation which significantly decreases the number of microorganisms on intact skin.

(j) "SOP" means standard operating procedures. These are written standards for performance for tasks and operations within a facility.

(k) "Quality Control" means procedures performed on preparations to assess their sterility and/or freedom from other contamination.

(l) "Quality Assurance" means the procedures involved to maintain standards of goods and services.

(m) "Class 100 Environment" means having less than 100 particles 0.5 microns or larger per cubic foot.

(n) "Class 100,000 Environment" means having less than 100,000 particles 0.5 microns or larger per cubic foot.

(o) "Critical Area" means any area in the controlled area where products or containers are exposed to the environment.

(p) "Process Validation" means documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

(q) "Positive Pressure Controlled Area" means the clean room is to have a positive pressure differential relative to the adjacent pharmacy.

(r) "Barrier Isolator" is an enclosed containment device which provides a controlled Class 100 environment. The device has four components; the stainless steel shell, HEPA filtration of entering and exiting air flows, glove ports for people interaction and an air lock for moving products into and out of the controlled environment.

(s) "Plan of Care" the pharmacist in collaboration with the patient or caregiver and other health care providers, is responsible for developing an appropriate and individualized care plan for each patient to include the following:

(i) a description of actual or potential drug therapy problems and their proposed solutions;

(ii) a description of desired outcomes of drug therapy provided;

(iii) a proposal for patient education and counseling; and

(iv) a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and non compliance) and the frequency with which monitoring is to occur.

(t) USP/NF section 797 titled "Pharmacy Compounding - Sterile Products"
(u) "Cytotoxic drugs" shall be defined in the most current AHFS (chapter 10)

(3) Pharmacist-in-Charge: In order to obtain a license, all parenteral product pharmacies must designate a pharmacist in charge of operations who is:

(a) licensed to practice pharmacy in the State of New Mexico;

(b) responsible for the development, implementation and continuing review of written SOP's **consistent with USP/NF standards** which are used by the operation in their daily operation;

(c) pharmacist on staff who is available for twenty-four hour seven-day-a-week services;

(d) responsible for establishing a system to assure that the products prepared by the establishment are administered by licensed personnel or properly trained and instructed patients.

(4) Physical Requirements

(a) The parenteral products pharmacy must have sufficient floor space to assure that the products are properly prepared and stored to prevent contamination or deterioration prior to administration to the patient and meet the following:

(i) be separated physically from other pharmacy activities and enclosed on all sides except for doors and/or windows for the passage of materials;

(ii) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet; the stand alone parenteral product pharmacy must have a minimum of 240 square feet;

(iii) addition of a parenteral area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure;

(iv) a new parenteral pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

(b) Equipment and Materials. The parenteral products pharmacy has sufficient equipment and physical facilities to safely compound and store such products and includes the following:

(i) either a Class 100 clean air work station or a room which meets Class 100 conditions;

(ii) refrigeration capacity for proper storage or prepared parenterals at [~~5 C~~] **2C to 8C**after preparation and until prescriptions are picked up by or delivered to the patient or their agent;

(iii) if bulk reconstitution of antibiotics is performed the facility has a freezer capable of freezing and storing the product at -20 C for periods not to exceed the manufacturer's recommendations;

(c) References. Parenteral products pharmacies maintain in their library at least one current edition reference book from each category listed below in addition to other required references:

(i) Drug Monograph Reference, i.e., USP-DI, AHFS: Drug Information Service, Martindale's Extra Pharmacopoeia, or other suitable reference;

(ii) Stability and Incompatibility Reference; i.e., Trissell's Handbook of Parenteral Medications, King/Cutter IV Incompatibilities, or other suitable reference;

(iii) Reference on Pharmaceutical Technology and Compounding; i.e., Remington's Pharmaceutical Sciences, Block's Disinfection Sterilization and Preservation, or other suitable reference;

(iv) Periodicals, i.e., American Journal of Hospital Pharmacy, ASHP's Clinical Pharmacy, American Journal of Parenteral and Enteral Nutrition, or other suitable periodical.

(5) Documentation Requirements for Parenteral Product Pharmacies: Written policies and procedures must be available for inspection and review by authorized agents of the Board of Pharmacy. Written policies and procedures must be submitted to the State Board of Pharmacy prior to the issuance of any license. These records must include but are not limited to:

(a) cleaning, disinfection, evaluation and maintenance of the preparation area;

(b) regular recertification of the clean air unit or units by independent testing agencies;

(c) surveillance of parenteral solutions for microbiological contamination;

(d) surveillance of parenteral solutions for particulate contamination;

(e) personnel qualifications, training and performance guidelines;

(f) facility and equipment guidelines and standards;

(g) SOP's for dispensing all solutions and medications;

(h) SOP's for disposal of physical, chemical and infectious waste;

(i) quality control guidelines and standards;

(j) quality assurance guidelines and standards;

(k) SOP's for determination of stability, incompatibilities or drug interactions.

(6) Record keeping and Patient Profile; The parenteral products pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:

(a) Prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;

(b) Patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;

(c) [~~Patient contact is documented. Patients are contacted at least every 3 days and any problems that cannot be solved by the patients agent or pharmacist (or which result in changes in the patient's behavior) are transmitted to the physician in charge for response and documentation;~~] **Patients are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;**

(d) Documentation that the patient or their agent has received training in the safe administration of their medication.

C. STERILE PHARMACEUTICAL PREPARATION

(1) Pharmacies compounding sterile pharmaceuticals shall prepare products in an appropriate aseptic environment which meets Class 100 requirements. Devices used to maintain a Class 100 environment will:

(a) be certified in the course of normal operation by an independent contractor according to Federal Standard 209E et seq. for operational efficiency at least every 6 months and when moved. Certification records will be maintained for 3 years;

(b) have pre-filters which are inspected periodically and inspection/replacement date documented according to written policy; and

(c) have a positive pressure controlled area that is certified as at least a Class 100,000 which is functionally separate from other areas of the pharmacy and which minimizes the opportunity for particulate and microbial contamination. This area shall:

(i) have a controlled aseptic environment or contain a device which maintains an aseptic environment;

(ii) be clean, lighted, and at an average of 80-150 foot candles;

(iii) be a minimum of 100 sq. ft to support sterile compounding activities;

(iv) be used only for the compounding of sterile pharmaceuticals using appropriate aseptic technique including gowning and gloving;

(v) be designed to avoid outside traffic and airflow;

(vi) be ventilated in a manner which does not interfere with aseptic environment control conditions;

(vii) have non-porous, washable floor coverings, hard cleanable walls and ceilings (which may include acoustical ceiling tiles coated with an acrylic paint) to enable regular disinfection;

(contain only compounding medication and supplies and not be used for bulk storage.

(viii) a self contained, Class 100 barrier isolator not located in the clean room is acceptable. The barrier isolator may only be located in an area which is maintained under sanitary conditions and traveled only by persons engaged in sterile product preparation. Such barrier isolators must be certified by an independent certification contractor according to Class 100 conditions, as defined by Federal Standard 209E et seq. prior to use and at six-month intervals. Certification records will be maintained for 3 years.

(d) Store medications and supplies on shelves above the floor.

(e) Develop and implement a disposal process for packaging materials, used supplies, containers, syringes, and needles. This process shall be performed to enhance sanitation and avoid accumulation in the controlled area.

(f) Prohibit particle generating activities in the controlled area:

(i) removal of medications or supplies from cardboard boxes shall not be done in the controlled area;

(ii) cardboard boxes or other packaging/ shipping material which generate an unacceptable amount of particles shall not be permitted. The removal of immediate packaging designed to retain sterility or stability will be allowed.

(g) Cytotoxic drugs shall:

~~(i)~~ **[**~~be prepared only by a licensed pharmacist~~**]**;

~~(ii)~~**(i)** be prepared in a vertical flow biological safety cabinet, micro-biological isolation chamber or equivalent containment device;

~~(iii)~~**(ii)** be prepared in a cabinet thoroughly cleaned prior to use for preparation of other products; said cleaning will be documented;

~~(iv)~~**(iii)** be prepared in a cabinet located in a controlled area as described in 11.C.(1).(c);

~~(v)~~**)iv)** be disposed of according to written policies and procedures maintained at the facility.

(h) Maintain a library of specialty references appropriate for the scope of services provided. Reference material may be hard copy or computerized.

(2) Requirements for training.

(a) **Prior to** ~~All pharmacists~~ compounding sterile pharmaceuticals, or ~~pharmacists~~ supervising pharmacy ~~technicians~~ **personnel** compounding sterile pharmaceuticals**, all pharmacists** shall ~~effective December 31, 2002,~~ have completed a minimum of 20 contact hours ~~(after January 1, 1999 and before manipulating sterile products)~~ of didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the Policy and Procedures or training manual. Such training shall be evidenced by completion of a recognized course in an accredited college of pharmacy or an ACPE approved course which shall include instruction and hands-on experience in the following areas:

(i) aseptic technique;
(ii) critical area contamination factors;
(iii) environmental monitoring;
(iv) facilities;
(v) equipment and supplies;
(vi) sterile pharmaceutical calculations and terminology;
(vii) sterile pharmaceutical compounding documentation;
(viii) quality assurance procedures;
(ix) proper gowning and gloving technique;
(x) the handling of cytotoxic and hazardous drugs; and
(xi) general conduct in the controlled area.

(b) All pharmacist interns ~~who~~ **prior to** compound**ing** sterile pharmaceuticals shall ~~effective December 31, 2002 (after January 1, 1999 and before manipulating sterile products)~~ have completed a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or

(ii) completion of a course sponsored by an ACPE approved provider.

(c) All pharmacy technicians who compound sterile pharmaceuticals shall have a high school or equivalent education and ~~effective December 31, 2002~~ be a Pharmacy Certified Technician, and complete a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which provides 40 hours of instruction and experience in the areas listed in paragraph 1; or

(ii) completion of a course sponsored by an ACPE approved provider which provides 40 hours of instructions and experience in the areas listed in paragraph 1.

(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs and all pharmacy interns or technicians compounding sterile chemotherapy drugs shall, effective December 31, 2007, have completed a Board approved training program in chemotherapy drug preparation. Effective January 1, 2008, all pharmacists, interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.

~~(d)~~**(e)** Documentation of Training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:

(i) Name of person receiving the training or completing the testing or process validation;

(ii) Date(s) of the training, testing, or process validation;

(iii) General description of the topics covered in the training or testing or of the process validated;

(iv) Name of person supervising the training, testing, or process validation;

(v) Signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

~~(e)~~**(f)** No product intended for patient uses shall be compounded by an individual until the process validation test indicates that the individual can competently perform aseptic procedures.

~~(f)~~**(g)** On an annual basis the pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation to supplement initial training. A written record of such training will be maintained for 3 years.

(3) Patient or Caregiver Training for Home Sterile Products:

(a) The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC;

(b) The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy;

(c) There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

(i) routine performance of Prospective Drug Use Review and patient monitoring functions by a pharmacist;

(ii) patient monitoring plans that include written outcome measures and systems for routine patient assessment;

(iii) documentation of patient training; and

(4) Quality Assurance/compounding and preparation of sterile pharmaceuticals.

(a) There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:

(i) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;

(ii) if bulk compounding of parenteral solutions is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine. The test must include appropriate tests for particulate matter and pyrogens;

(iii) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. A plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken. A periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(iv) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and , if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.

(b) There shall be a mechanism for tracking and retrieving products which have been recalled.

(c) Automated compounding devices shall:

(i) have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;

(ii) be observed every thirty days by the operator during the mixing process to ensure the device is working properly;

(iii) have data entry verified by a pharmacist prior to compounding; and

(iv) have accuracy of delivery of the end product verified according to written policies and procedures.

(d) If batch preparation of sterile products is being performed, a worksheet (log) must be maintained for each batch. This worksheet shall consist of formula, components, compounding directions or procedures, a sample label and evaluation and testing requirements, if applicable, and shall be used to document the following:

(i) all solutions and ingredients and their corresponding amounts, concentrations and volumes;

(ii) component manufacturer and lot number;

(iii) lot or control number assigned to batch;

(iv) date of preparation;

(v) expiration date of batch prepared products;

(vi) identity of personnel in preparation and pharmacist responsible for final check;

(vii) comparison of actual yield to anticipated yield, when appropriate.

(5) Application of Regulation; Pharmacies licensed by the board prior to adoption of this regulation shall comply with the controlled area standards defined in section 11.C.(1).(c). by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy, or relocate the pharmacy after the effective date of this regulation, Section 11(2)A.3. shall apply. All other portions of this regulation apply on the effective date.

[16.19.6.11 NMAC - Rp 16 NMAC 19.6.11, 03-30-02]

Brief discussion was held regarding the proposed changes.

Motion:

A motion was made by Mr. Cross, seconded by Mr. Nolasco to approve the proposed changes as amended by the Board and as follows:

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional judgment and shall therefore only be performed by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) initial identification, evaluation and interpretation of the prescription order and any necessary clarification prior to dispensing;

(3) professional consultation with a patient or his agent regarding a prescription;

(4) evaluation of available clinical data in patient medication record system.

(5) oral communication to the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription**.**[~~; and~~]

[~~(7) Preparation of prescription drug orders for cancer chemotherapy solutions.]~~

B. ONLY A PHARMACIST SHALL PERFORM THE FOLLOWING DUTIES:

(1) final check on all aspects of the completed prescription **<u>including sterile products and cytotoxic preparations</u>** , and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(2) evaluation of pharmaceuticals for formulary selection within the facility;

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications;

(4) ensure that supportive personnel have been properly trained for the duties they may perform.

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories). This does not apply to substitution of generic equivalents.

(6) any other duty required of a pharmacist by any federal or state law.

C. PATIENT RECORDS:

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacists comments relevant to the individuals drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional judgment concerning both the offer to counsel and the content of counseling.

D. PROSPECTIVE DRUG REVIEW:

(1) A pharmacist or pharmacist intern shall review the patient record for:

(a) clinical abuse/misuse;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

(e) incorrect drug dosage;

(f) incorrect duration of drug treatment;

(g) drug-allergy interactions;

(h) appropriate medication indication.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

E. COUNSELING:

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall include appropriate elements of patient counseling which may include, in their professional judgment, one or more of the following:

(a) the name and description of the drug;

(b) the dosage form, dosage, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescriptions refill information;

(i) action to be taken in the event of a missed dose;

(j) the need to check with the pharmacist or practitioner before taking other medication; and

(k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by the mail, the pharmacist shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (1) of his or her right to request counseling; and (2) a toll-free telephone number in which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record. For pharmacies delivering more than 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week. The facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

F. [REPEALED]

G. REGULATORY ASSESSMENT: Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three (3) years from the date of the last entry in the profile record.

[08-27-90; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 03-30-02; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12-15-02; A, 12-01-2003; A, 02-01-04; A, 01-15-2005]

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

A. The pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of drugs and parenteral products appropriate to the scope of pharmaceutical services provided. The following items shall be in the pharmacy:

(1) An updated reference source, appropriate to each practice site, either electronic or paper version;

(2) One copy of the most recently published New Mexico Pharmacy Laws, Rules and Regulations and available revisions, either electronic or paper version

B. PARENTERAL PHARMACEUTICALS

(1) Purpose: To ensure that the citizens of New Mexico receive routine safe and competent delivery of parenteral products and nutritional support throughout the state. To establish guidelines for licensure and inspection of such facilities by the state board of pharmacy.

(2) Definitions

(a) "Parenteral products pharmacy" is a retail pharmacy which prepares and distributes prescriptions for sterile products intended for parenteral administration to patients either at home or in or out of an institution licensed by the state.

(b) "Parenteral product" means any preparation administered by injection through one or more layers of skin tissue.

(c) "Sterile" means a preparation that has undergone a valid sterilization process and is devoid of all living microorganisms, packaged in such a way to ensure the retention of this characteristic.

(d) "Preparation" means a sterile product which has been subjected to manipulation by a pharmacist under aseptic conditions to render the product suitable for administration.

(e) "Aseptic conditions" means a cabinet or facility capable of obtaining [~~Class 100~~]

ISO class 5 clean air as defined by the federal standards 209E and which is certified by a testing agency at least every six months.

(f) "Aseptic technique" means proper manipulation of articles within a [~~Class 100~~] **ISO class 5** clean air room or station to maintain sterility.

(g) "Disinfectant" means a chemical compound used to kill and or control microbial growth within a [~~Class 100~~] **ISO class 5** area or its surroundings and is approved for such use by the environmental protection agency.

(h) "Antimicrobial soap" means soap containing an active ingredient that is active both in vitro and vivo against skin microorganisms.

(i) "Surgical hand scrub" means an antimicrobial containing preparation which significantly decreases the number of microorganisms on intact skin.

(j) "SOP" means standard operating procedures. These are written standards for performance for tasks and operations within a facility.

(k) "Quality control" means procedures performed on preparations to assess their sterility and/or freedom from other contamination.

(l) "Quality assurance" means the procedures involved to maintain standards of goods and services.

(m) "[~~Class 100~~] **ISO class 5** Environment" means having less than 100 particles 0.5 microns or larger per cubic foot.

(n) "[~~Class 100,000~~] **ISO class 8** Environment" means having less than 100,000 particles 0.5 microns or larger per cubic foot.

(o) "Critical area" means any area in the controlled area where products or containers are exposed to the environment.

(p) "Process validation" means documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

(q) "Positive pressure controlled area" means the clean room is to have a positive pressure differential relative to the adjacent pharmacy.

(r) "Barrier isolator" is an enclosed containment device which provides a controlled [~~Class 100~~] **ISO class 5** environment. The device has four components; the stainless steel shell, HEPA filtration of entering and exiting air flows, glove ports for people interaction and an air lock for moving products into and out of the controlled environment.

(s) "Plan of care" means an individualized care plan for each patient receiving parenteral products in a home setting to include the following:

(i) a description of actual or potential drug therapy problems and their proposed solutions;

(ii) a description of desired outcomes of drug therapy provided;

(iii) a proposal for patient education and counseling; and

(iv) a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and non compliance) and the frequency with which monitoring is to occur.

(t) USP/NF standards means USP/NF Chapter 797 titled "*pharmacy compounding - sterile products*"

(u) "Cytotoxic drugs" shall be defined in the most current american hospital formulary service (AHFS)

(3) Pharmacist-in-Charge: In order to obtain a license, all parenteral product pharmacies must designate a pharmacist in charge of operations who is:

(a) licensed to practice pharmacy in the state of New Mexico;

(b) responsible for the development, implementation and continuing review of written SOP's **consistent with USP/NF standards** which are used by the operation in their daily operation;

(c) pharmacist on staff who is available for twenty-four hour seven-day-a-week services;

(d) responsible for establishing a system to assure that the products prepared by the establishment are administered by licensed personnel or properly trained and instructed patients;

(e) responsible for developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral products in a home setting.

(4) Physical Requirements

(a) The parenteral products pharmacy must have sufficient floor space to assure that the products are properly prepared and stored to prevent contamination or deterioration prior to administration to the patient and meet the following:

(i) be separated physically from other pharmacy activities and enclosed on all sides except for doors and/or windows for the passage of materials;

(ii) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet; the stand alone parenteral product pharmacy must have a minimum of 240 square feet;

(iii) addition of a parenteral area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure;

(iv) a new parenteral pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

(b) Equipment and materials. The parenteral products pharmacy has sufficient equipment and physical facilities to safely compound and store such products and includes the following:

(i) either a [~~Class 100~~] **ISO class 5** clean air work station or a room which meets [~~Class 100~~] **ISO Class 5** conditions;

(ii) refrigeration capacity for proper storage [~~or~~] **of** prepared parenterals at [~~5 C~~] **2C to 8C** after preparation and until prescriptions are [~~picked up by or delivered to~~]**received by** the patient or their agent;

(iii) if bulk reconstitution of antibiotics is performed the facility has a freezer capable of freezing and storing the product at -20C for periods not to exceed the manufacturer's recommendations;

(c) References. Parenteral products pharmacies maintain in their library at least one current edition reference book from each category listed below in addition to other required references:

(i) drug monograph reference, i.e., USP-DI, AHFS: *drug information service, martindale's extra pharmacopoeia*, or other suitable reference;

(ii) stability and incompatibility reference; i.e., *trissell's handbook of parenteral medications, king/cutter IV incompatibilities*, or other suitable reference;

(iii) reference on pharmaceutical technology and compounding; i.e., *remington's pharmaceutical sciences, block's disinfection sterilization and preservation,* or other suitable reference;

(iv) periodicals, i.e., *american journal of hospital pharmacy, ASHP's clinical pharmacy, american journal of parenteral and enteral nutrition*, or other suitable periodical.

(5) Documentation Requirements for Parenteral Product Pharmacies: Written policies and procedures must be available for inspection and review by authorized agents of the board of pharmacy. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:

(a) cleaning, disinfection, evaluation and maintenance of the preparation area;

(b) regular recertification of the clean air unit or units by independent testing agencies;

(c) surveillance of parenteral solutions for microbiological contamination;

(d) surveillance of parenteral solutions for particulate contamination;

(e) personnel qualifications, training and performance guidelines;

(f) facility and equipment guidelines and standards;
(g) SOP's for dispensing all solutions and medications;
(h) SOP's for disposal of physical, chemical and infectious waste;
(i) quality control guidelines and standards;
(j) quality assurance guidelines and standards;
(k) SOP's for determination of stability, incompatibilities or drug interactions.

(6) Record keeping and Patient Profile; The parenteral products pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:

(a) Prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;

(b) Patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;

(c) [~~Patient contact is documented. Patients are contacted at least every 3 days and any problems that cannot be solved by the patients agent or pharmacist (or which result in changes in the patient's behavior) are transmitted to the physician in charge for response and documentation;~~] **Patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;**

(d) Documentation that the patient **receiving parenteral products in a home setting** or their agent has received **a written copy of their plan of care and** training in the safe administration of their medication.

C. STERILE PHARMACEUTICAL PREPARATION

(1) Pharmacies compounding sterile pharmaceuticals shall prepare products in an appropriate aseptic environment which meets [~~Class 100~~] **ISO class 5** requirements. Devices used to maintain a [~~Class 100~~] **ISO class 5** environment will:

(a) be certified in the course of normal operation by an independent contractor according to Federal Standard 209E et seq. for operational efficiency at least every 6 months and when moved. Certification records will be maintained for 3 years;

(b) have pre-filters which are inspected periodically and inspection/replacement date documented according to written policy; and

(c) have a positive pressure controlled area that is certified as at least a [~~Class 100,000~~] **ISO class 8** which is functionally separate from other areas of the pharmacy and which minimizes the opportunity for particulate and microbial contamination. This area shall:

(i) have a controlled aseptic environment or contain a device which maintains an aseptic environment;

(ii) be clean, lighted, and at an average of 80-150 foot candles;

(iii) be a minimum of 100 sq. ft to support sterile compounding activities;

(iv) be used only for the compounding of sterile pharmaceuticals using appropriate aseptic technique including gowning and gloving;

(v) be designed to avoid outside traffic and airflow;

(vi) be ventilated in a manner which does not interfere with aseptic environment control conditions;

(vii) have non-porous, washable floor coverings, hard cleanable walls and ceilings (which may include acoustical ceiling tiles coated with an acrylic paint) to enable regular disinfection;

(contain only compounding medication and supplies and not be used for bulk storage.

(viii) a self contained, [~~Class 100~~] **ISO class 5** barrier isolator not located in the clean room is acceptable. The barrier isolator may only be located in an area which is maintained under sanitary conditions and traveled only by persons engaged in sterile product preparation. Such barrier isolators must be certified by an independent certification contractor according to [~~Class 100~~] **ISO**

class 5 conditions, as defined by federal standard 209E et seq. prior to use and at six-month intervals. Certification records will be maintained for 3 years.

(d) Store medications and supplies on shelves above the floor.

(e) Develop and implement a disposal process for packaging materials, used supplies, containers, syringes, and needles. This process shall be performed to enhance sanitation and avoid accumulation in the controlled area.

(f) Prohibit particle generating activities in the controlled area:

(i) removal of medications or supplies from cardboard boxes shall not be done in the controlled area;

(ii) cardboard boxes or other packaging/ shipping material which generate an unacceptable amount of particles shall not be permitted. The removal of immediate packaging designed to retain sterility or stability will be allowed.

(g) Cytotoxic drugs shall:

~~(i)~~ **[**~~be prepared only by a licensed pharmacist~~**]**;

~~(ii)~~**(i)** be prepared in a vertical flow biological safety cabinet, micro-biological isolation chamber or equivalent containment device;

~~(iii)~~**(ii)** be prepared in a cabinet thoroughly cleaned prior to use for preparation of other products; said cleaning will be documented;

~~(iv)~~**(iii)** be prepared in a cabinet located in a controlled area as described in 11.C.(1).(c);

~~(v)~~**)iv)** be disposed of according to written policies and procedures maintained at the facility.

(h) Maintain a library of specialty references appropriate for the scope of services provided. Reference material may be hard copy or computerized.

(2) Requirements for training.

(a) All pharmacists **prior to** compounding sterile pharmaceuticals, or [~~pharmacists]~~ supervising pharmacy [~~technicians]~~ **personnel** compounding sterile pharmaceuticals**, all** shall [~~effective December 31, 2002,]~~ have completed a minimum of 20 contact hours [~~(after January 1, 1999 and before manipulating sterile products)]~~ of didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the policy and procedures or training manual. Such training shall be evidenced by completion of a recognized course in an accredited college of pharmacy or an ACPE approved course which shall include instruction and hands-on experience in the following areas:

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) facilities;

(v) equipment and supplies;

(vi) sterile pharmaceutical calculations and terminology;

(vii) sterile pharmaceutical compounding documentation;

(viii) quality assurance procedures;

(ix) proper gowning and gloving technique;

(x) the handling of cytotoxic and hazardous drugs; and

(xi) general conduct in the controlled area.

(b) All pharmacist interns [~~who]~~ **prior to [**~~compound~~]**compounding** sterile pharmaceuticals shall [~~effective December 31, 2002 (after January 1, 1999 and before manipulating sterile products)]~~ have completed a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or

(ii) completion of a course sponsored by an ACPE approved provider.

(c) All pharmacy technicians who compound sterile pharmaceuticals shall have a high school or equivalent education and [~~effective December 31, 2002~~] be a [~~Pharmacy~~] Certified **Pharmacy** Technician, and complete a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which provides 40 hours of instruction and experience in the areas listed in paragraph 1; or

(ii) completion of a course sponsored by an ACPE approved provider which provides 40 hours of instructions and experience in the areas listed in paragraph 1.

(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall, effective December 31, 2007, have completed a Board approved training program in chemotherapy drug preparation. All pharmacy interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.

[~~(d)~~]**(e)** Documentation of Training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:

(i) name of person receiving the training or completing the testing or process validation;

(ii) date(s) of the training, testing, or process validation;

(iii) general description of the topics covered in the training or testing or of the process validated;

(iv) name of person supervising the training, testing, or process validation;

(v) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

[~~(e)~~]**(f)** No product intended for patient uses shall be compounded by an individual until the process validation test indicates that the individual can competently perform aseptic procedures.

[~~(f)~~]**(g)** On an annual basis the pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation to supplement initial training. A written record of such training will be maintained for 3 years.

(3) Patient or Caregiver Training for Home Sterile Products:

(a) The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC;

(b) The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy;

(c) There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

(i) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(ii) patient monitoring plans that include written outcome measures and systems for routine patient assessment;

(iii) documentation of patient training; and

(4) Quality Assurance/compounding and preparation of sterile pharmaceuticals.

(a) There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:

(i) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;

(ii) if bulk compounding of parenteral solutions is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;

(iii) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(iv) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and , if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.

(b) There shall be a mechanism for tracking and retrieving products which have been recalled.

(c) Automated compounding devices shall:

(i) have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;

(ii) be observed every thirty days by the operator during the mixing process to ensure the device is working properly;

(iii) have data entry verified by a pharmacist prior to compounding; and

(iv) have accuracy of delivery of the end product verified according to written policies and procedures.

(d) If batch preparation of sterile products is being performed, a worksheet (log) must be maintained for each batch. This worksheet shall consist of formula, components, compounding directions or procedures, a sample label and evaluation and testing requirements, if applicable, and shall be used to document the following:

(i) all solutions and ingredients and their corresponding amounts, concentrations and volumes;

(ii) component manufacturer and lot number;

(iii) lot or control number assigned to batch;

(iv) date of preparation;

(v) expiration date of batch prepared products;

(vi) identity of personnel in preparation and pharmacist responsible for final check;

(vii) comparison of actual yield to anticipated yield, when appropriate.

(5) Application of Regulation; Pharmacies licensed by the board prior to adoption of this regulation shall comply with the controlled area standards defined in section 11.C.(1).(c). by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy, or relocate the pharmacy after the effective date of this regulation, Section 11(2)A.3. shall apply. All other portions of this regulation apply on the effective date.

[16.19.6.11 NMAC - Rp 16 NMAC 19.6.11, 03-30-02; A, 01-15-2005]

The Board voted unanimously to pass the motion.