

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of )  
    **PHAR-MOR PHARMACY #212** )  
    License No. 436 )  
    Robert W. McCurdy, )  
    Vice President of )  
    Pharmacy Operations, )  
                          ) Respondent. )

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IOWA PHARMACY EXAMINERS

Re: Pharmacist License of )  
    **GARY L. LEVINE** )  
    License No. 16727 )  
                          ) Respondent. )

CLOSING ARGUMENT

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ARGUMENT

This case is an unfortunate example of a licensee who has failed to appreciate the significance of a Board disciplinary order previously entered against it, and of a pharmacy which has failed repeatedly, and in significant ways, to comply with the laws governing the practice of pharmacy in Iowa.

The first Statement of Charges was filed against Phar-Mor Pharmacy in this matter on March 22, 1993. In that Complaint and Statement of Charges, it was alleged that pharmacists at the Phar-Mor Pharmacy complained that they felt overwhelmed by the volume of work that they were being required to perform. It was further alleged that other pharmacists had left because of the volume of work that was required, that there was no pharmacist in charge, and that the pharmacy had failed to notify the Board as required of any changes in staff pharmacists. In addition, the charges alleged that a dispensing error had occurred on February 8, 1993, in which Phar-Mor mistakenly dispensed a muscle relaxant

to an elderly patient, who took this medication for over one month and experienced some difficulties before he discovered the error. Finally, the charges alleged that due to the staff shortages, it was impossible for Phar-Mor Pharmacy to comply with the rules governing the practice of pharmacy in the State of Iowa concerning record keeping, prospective drug use review, and patient counselling.

Following a formal hearing, the Board entered an order on May 14, 1993. In that order the Board found that the February 8th dispensing error occurred, and that another dispensing error had occurred on April 12, 1993, in which the wrong strength of eye drops was dispensed. The Board concluded that Phar-Mor Pharmacy was seriously understaffed, that the adverse working conditions at the pharmacy resulted in staff pharmacists being unable to comply with the law governing the practice of pharmacy in Iowa, and that these adverse conditions caused dispensing errors.

In its final order the Board imposed a \$25,000 fine on Phar-Mor Pharmacy. The Board further required that Phar-Mor Pharmacy submit monthly reports advising the Board whether its pharmacists were maintaining and reviewing patient records and providing patient counseling. In addition, Phar-Mor Pharmacy was to provide the Board in those monthly reports with the weekly work schedule of staff members, with the total daily number of new and refilled prescriptions, with a report as to whether the pharmacist staffing hours fell below 175 hours in a one week

period, and with a report of any malpractice actions or dispensing errors within thirty days of occurrence.

Because of Phar-Mor Pharmacy's failure to comply with the provisions of the May 14th order, the Board filed a second Statement of Charges against Phar-Mor Pharmacy on October 20, 1993. In addition the Board filed a Complaint and Statement of Charges against Gary Levine, the pharmacist in charge at Phar-Mor Pharmacy since April 27, 1993. The evidence introduced at this hearing clearly establishes that all of the violations alleged in that second Statement of Charges occurred, and that in fact additional and equally serious problems have occurred since the time that second Statement of Charges was filed.

#### A. Staffing

First, while Phar-Mor Pharmacy did submit monthly reports during the entire time period of their probation, several of those monthly reports did not meet the requirements of the Board's Order, and all of the reports indicated that staffing continues to be a serious problem at the pharmacy. In the May report, Phar-Mor Pharmacy reported that pharmacist hours exceeded 175 hours in two out of four weekly periods. However, in June there was only one week in which pharmacist hours equalled or exceeded 175 hours. In July, August, September, and October there was not a single week in which pharmacist hours came even close to meeting the 175 hour threshold that was suggested in the Board's May order. In fact, from the period of July through October, the number of hours worked ranged anywhere from 118 to

144 pharmacist hours a week, establishing that Phar-Mor Pharmacy was simply not making a good faith effort to comply with the obvious intent of the Board's order.

It is clear from the Board's Order that the 175 hour language does not impose an absolute staffing requirement. Indeed, at hearing, Phar-Mor Pharmacy made clear it interpreted this language as advisory only. Gary Levine even testified he believed 175 pharmacist hours per week was excessive, and obviously scheduled accordingly. While 175 pharmacist hours was clearly not mandatory, the Board's concern about the staffing at Phar-Mor Pharmacy was evident from the May 14th Order. Phar-Mor Pharmacy's staffing decisions since the May 14th Order indicate a flagrant disregard for the obvious intent of the Board's Order. Indeed, the number of pharmacist hours declined during the probationary period, despite the fact that the number of dispensing errors reported to the Board during that same period drastically increased from the time before the first hearing.

A review of the evidence submitted at the hearing makes clear that, despite the suggestion of Mr. Levine or any other staff pharmacist to the contrary, there is simply not sufficient time for the pharmacists at Phar-Mar Pharmacy to meet all the requirements of Iowa law for dispensing prescription medications. Indeed, Robert McCurdy from Phar-Mor Pharmacy testified contrary to Mr. Levine that, in his opinion, the pharmacist staffing was not sufficient and that steps needed to be taken to insure that greater number of pharmacist hours were being worked at the

pharmacy. He testified that in fact efforts had recently been undertaken to accomplish that goal.

The lack of sufficient time to comply with all the requirements for review of patient records and for patient counseling has, since the time of the original hearing, resulted in almost twenty reported dispensing errors being committed, errors which pose a serious threat to the health and safety of Phar-Mor Pharmacy patients. In addition a review of one set of graphs prepared by investigator Lindy Pearson (Exhibit 31) establishes that the dispensing errors tended to occur at times when staffing and volume of prescription problems were the most serious. A review of the dispensing errors makes clear that most of these errors could have been prevented if a proper review of the patient's records had been done and proper patient counseling provided.

In conclusion, the number of dispensing errors that have occurred at the Phar-Mor Pharmacy since the time the Board order was entered indicates that serious problems remain at the pharmacy. Whether these problems are due solely to insufficient staffing is unclear, but certainly if Phar-Mor Pharmacy were to pay greater attention to the number of hours worked by its pharmacist and to increase the number of pharmacist hours the situation would be improved.

#### B. Violation of Board Order

The Board's May 14th Order required Phar-Mor Pharmacy to report any dispensing errors within thirty (30) days of their

occurrence. The first three monthly reports submitted in May, June, and July, contained no reports of dispensing errors. The August report contained one consumer complaint, the September report set forth nine dispensing errors, and the October report described two dispensing errors. However, it should be noted that the August, September, and October reports of consumer complaints were submitted only after the Board office had contacted Phar-Mor Pharmacy in August to advise them that they were not meeting the requirement that the monthly reports contain information about dispensing errors.

At hearing, Mr. Levine admitted that he had simply neglected to notify the Board of dispensing errors in May, June, and July. This inadvertence on his part is just one more example of Mr. Levine's and Phar-Mor Pharmacy's inattention to the Board's May 14th Order. To this day, the Board still has no information as to dispensing errors that were identified by Phar-Mor for the months of May, June, and July. Indeed, the numbers of dispensing errors which have occurred (as identified by Phar-Mor Pharmacy in its August, September, and October reports; as received directly by the Board office; and as identified by the Board staff in reviewing records for the probationary period) strongly suggests that it is likely that there were indeed dispensing errors in May, June, and July.

In conclusion, Phar-Mor Pharmacy failed to comply with the Board's May 14 Order by failing to report dispensing errors or consumer complaints for the months of May, June, and July.

Appropriate sanctions are warranted.

C. Dispensing Errors

A review of the dispensing errors reported by Phar-Mor in August, September, and October establishes that serious dispensing errors continue to occur, in a number which far exceeds the number of dispensing errors reported to the Board prior to the first hearing in this matter.

In the August report, patient Jim Schlatter was confused as to whether he received the proper medications on his refill order. (Exh. 8)

In the September report there were nine dispensing errors, many of which were very serious. The first error involved an antibiotic which was prescribed to Don Griffith for sixty (60) days, but was dispensed for only thirty (30). (Exh. 9-A)

The second error concerned a prescription for 100 mg Demerol for James Chamberlain, when in fact 50 mg Demerol was dispensed. (Exh. 9-B)

The third error involved dispensing Anusol HC suppositories to Nick Dawes, when in fact Anusol HC cream had been prescribed. (Exh. 9-C)

In the fourth case, Ada Archer received a prescription for Hydroxizine 25g, when her prescription was for Hydroxyzine 50 g. (Exh. 9-D)

An additional error occurred when Mr. Levine himself dispensed Midrin, which is a headache medication, to patient Neal Meyer. In fact, the prescription was for Miradon, an

anticoagulant. (Exh. 9-E) This is an example of a very serious dispensing error that, had the patient not immediately identified the mistake, could have resulted in very serious consequences to the patient.

The sixth error involved a prescription for Capozide for Elizabeth Murray. Capozide 25/15 was prescribed, while 25/25 was dispensed. (Exh. 9-F)

An additional error occurred when a prescription for an eye drop for Keith Hausman was in fact filled with an ear drop. (Exh. 9-G) Again, this is a situation in which there could have been serious consequences for the patient had the error not been identified by him.

In addition, Methylphenidate 10 mg was prescribed for Keen Harvey, but 20 mg Methylphenidate was dispensed. (Exh. 9-H)

Finally, Doxepin was prescribed to patient Bev Chapman with directions to take one at bedtime, when in fact Phar-Mor Pharmacy dispensed the medication with directions that it be taken one every six hours. (Exh. 9-I)

Additional dispensing errors were reported by Phar-Mor Pharmacy in its November report. The first error involved a Methylphenidate prescription for Brian Stark, which was dispensed with his mother's name on the prescription. (Exh. 10-A) A similar error occurred concerning a prescription for Joshua Maxwell, which was again dispensed under his mother's name. (Exh. 10-B)

In addition to the dispensing errors reported by Phar-Mor

Pharmacy in its monthly reports, there were additional consumer complaints made to the Board office during the probationary period. In May, the Board received a complaint from patient Gary Voss, who was dispensed two medications. The first medication was to have been for Tylenol, the second for Naprosyn. In fact, the patient received the same medication in both bottles. (Exh. 11)

Again in May, Virginia Powers complained to the Board that she had been regularly receiving only 95 capsules of Midrin instead of the 100 capsules which she had been prescribed. In addition to this complaint, she also stated that she received no counseling for any of the prescriptions that she had filled at Phar-Mor. (Exh. 12-A, 12-B) As Board investigator Dennis Dobesh testified, the patient's complaint concerning the number of pills received may or may not have been accurate. However, he further testified he went to her home with another investigator and interviewed her the same day that she had picked up her prescriptions. At that time, she advised him that she had not been counseled when she picked up her medications.

While one of the two medications Ms. Powers purchased that day had been a medication that she had previously received, i.e., the Fiorecet, she had not previously purchased Lasix from Phar-Mor Pharmacy. Therefore, even assuming she had previously been properly counseled for the Fiorecet, the counseling requirement was violated when Phar-Mor Pharmacy failed to counsel her concerning her Lasix prescription.

In addition, Ms. Powers also complained that she received a receipt for the drug Calan. However, this was a drug that she had not ordered and did not receive from Phar-Mor Pharmacy. The fact that she erroneously received this receipt is, at best, another example of Phar-Mor Pharmacy's carelessness in dispensing medications, and resulted in a billing error that, if not identified, could have had adverse consequences for the patient.

In June, the Board received a complaint concerning yet another dispensing error. (Exh. 13) Kenny Keltner complained that he had received a prescription for ear drops from his doctor, and when he received the medication from Phar-Mor Pharmacy, the label directed him to apply the medication to his toes. In addition, Mr. Keltner was concerned that his label had been placed over another label. There was some confusion in the testimony of the witnesses as to whether the improper directions were contained on the top label or the label underneath. However, Ken Blythe, the pharmacist who filled the prescription, admitted in both his testimony before the Board and in his statement at Exhibit 13 that the label for Mr. Keltner contained the erroneous directions.

Again in July the Board received a complaint from Mrs. John Gilchrist. (Exh. 14) She stated that when she picked up a prescription for her daughter at Phar-Mor Pharmacy, she noticed upon returning home that she also had in her sack a bottle of Seldane for another patient. When she called Phar-Mor Pharmacy, she was directed to simply throw the medication away. Despite

Mr. Levine's testimony that in his opinion this was not a dispensing error, it was, as a patient was given a medication that was not hers.

In August the Board received a complaint from Diane Sexton concerning an incident her husband had experienced at Phar-Mor Pharmacy. (Exh. 15) When he went to Phar-Mor to obtain a prescription, he had to wait for 35 minutes until he was ultimately notified the medication was not available.

In October the Board received a complaint from patient Marsha Stark, who had three (3) prescriptions filled at Phar-Mor Pharmacy in October, one for herself and two for her son Brian. (exh. 17, 17-A, 17-B, 17-C, 17-D) Her prescription was filled correctly, but her son's Methylphenidate prescriptions were filled under her name. In addition, Ms. Stark complained that she had not received any patient counseling concerning any of these prescriptions.

Early in November, the Board received two additional complaints from members of the public concerning prescriptions dispensed by Phar-Mor Pharmacy. The first involved a prescription for Albert Briley for Tylenol with Codeine #4. (Exh. 27) Phar-Mor Pharmacy dispensed Tylenol with Codeine #3. Mr. Briley was a cancer patient, and had the patient not noticed the error, he would not have received the pain relief he needed.

Finally, the Board received a complaint from Rhonda Chalus. (Exh. 28) She complained that when she asked to speak to a pharmacist about the conversion rate on some vitamins that she

was purchasing, she spoke to a gentleman who argued with her about the conversion rate. In addition, according to Board investigator Lindy Pearson, Ms. Chalus' description of the supposed pharmacist that she spoke to did not match the description of any of the pharmacists who are employed at Phar-Mor at this time. In addition, Ms. Chalus also complained about her purchase of a box of 1000 empty gelatin capsules. When she got home she counted those capsules and noticed that she had received only 800.

In addition to the errors reported by Phar-Mor Pharmacy and the complaints received directly by the Board office, Board investigator Lindy Pearson found evidence of two misfilled prescriptions. The first involved a prescription for Percodan which was filled with Oxycodone/APAP. (Exh. 22) The second misfilled prescription found by Ms. Pearson was written for Demerol 100mg and was filled with Demerol 50mg. (Exh. 23)

The dispensing errors identified above continued unabated since the time of the original hearing, despite the fact the Board even cautioned Phar-Mor Pharmacy regarding this problem. On August 25, 1993, the Board office contacted Mr. Levine at Phar-Mor Pharmacy to notify him that because the Board had at that time received five (5) consumer complaints, all but one of which had involved dispensing errors, the Board was very concerned about Phar-Mor's compliance with both the Board order and Iowa law governing the practice of pharmacy. (Exh. 16) Phar-Mor Pharmacy was advised at that time that a receipt of

another consumer complaint involving lack of patient counseling or a serious dispensing error could result in formal charges. Yet after that warning, a significant number of dispensing errors occurred again.

In conclusion, following the first hearing the Board found Phar-Mor Pharmacy guilty of two separate dispensing errors. On the basis of those dispensing errors and the staffing problems that existed at that time, the Board imposed the maximum fine of \$25,000, and placed Phar-Mor Pharmacy on probation for a significant period with a number of terms of probation. Since the time that order was entered, the Board has received notice of at least twenty (20) dispensing errors that have occurred at Phar-Mor Pharmacy. Some of these were reported to the Board pursuant to Phar-Mor's monthly reports, some of these were received by the Board directly from the consumer, and others were identified by Board investigators in the course of their investigation. The escalating number of dispensing errors since the time of the last hearing, in conjunction with the severe consequences that could have resulted to the patients in many of these cases, indicate that the problems at Phar-Mor Pharmacy continue unabated. Further sanctions must be imposed to ensure that Phar-Mor Pharmacy's dispensing practices are dramatically improved.

#### D. Additional Violations

In addition to the staffing problems which were evident from Phar-Mor Pharmacy's monthly reports, and the numerous dispensing

errors which continued unabated during the probationary term, Board investigators also uncovered numerous violations of pharmacy laws in their on-going investigation. In October, Board investigator Denny Dobesh visited Phar-Mor Pharmacy to discuss the complaint by patient Marsha Stark. At that time he conducted a brief inspection of other prescription records and found two prescriptions for Schedule II drugs for which the doctor's signature had not been obtained. In addition, he found nineteen (19) prescriptions for Schedule II drugs which lacked patient addresses on the original written prescription, in violation of Iowa law. (Exhibit 17, 17-E, 17-F, 17-G)

At the time of his October investigation, Mr. Dobesh also obtained copies of Phar-Mor Pharmacy Schedule II inventory records for the months of August and September. A review of those records (Exhibit 17-H and 17-I) establish that Phar-Mor Pharmacy was not keeping a perpetual Schedule II inventory but was instead keeping a monthly count. At the end of the month, if shortages or overages appeared, Phar-Mor Pharmacy simply began its next month's count using the physical count for the previous month, and made no effort to determine the reason for the shortages or overages. In addition, at no time did Phar-Mor Pharmacy ever contact the Board office to notify the Board of the discrepancies, as required by law.

A review of the August Schedule II inventory indicates the pharmacy was short 40 tablets of Percodan and 83 tablets of Methylphenidate SR 20mg. There were 54 extra tablets of

Methylphenidate 20mg, and there were discrepancies in the 10mg Ritalin and Methylphenidate. The September Schedule II inventory indicates that there were 72 missing tablets of Oxycodone missing, 44 missing tablets of Methylphenidate 10mg, and 60 missing tablets of 20mg Ritalin. In addition, Dexedrine 10mg was 20 tablets short.

A review of the Dexedrine 10mg is especially significant. At the beginning of the month, the open inventory was listed as 120 tablets. There were no purchases and there were no prescriptions. The balance should have been 120 at the end of the month, but in fact the physical count was 100, indicating a 20 tablet shortage. While Phar-Mor Pharmacy and Mr. Levine stated throughout the hearing that there was absolutely no diversion problem within the pharmacy, the evidence raises a serious question to the contrary. The Schedule II inventories for August and September indicate that the missing medications were all amphetamine drugs, and with regard to the Dexedrine there was simply no explanation for the 20 tablets that were missing. No computer error, no dispensing error, or record keeping error could account for this loss.

In addition to Dennis Dobesh's investigation, Board investigator Lindy Pearson also conducted a review of Phar-Mor Pharmacy records. (Exh. 18) Her review establishes again that Phar-Mor Pharmacy is continuing to repeatedly violate numerous laws governing the practice of pharmacy in Iowa. Ms. Pearson found that first there were over 100 Schedule II prescriptions

for which there were no patient addresses on the written prescription. (Exh. 19) In addition, there were 10 prescriptions which were missing, and for which Ms. Pearson found no original prescriptions or documentation. (Exh. 20) Further, there were five prescriptions indicating an "on hold" status. (Exh. 21) There was no indication in Phar-Mor's records as to the resolution of these prescriptions. Finally, Ms. Pearson found evidence of two misfilled prescriptions. The first involved a prescription for Percodan which was filled with Oxycodone/APAP. (Exh. 22) The second misfilled prescription found by Ms. Pearson was written for Demerol 100mg and was filled with Demerol 50mg. (Exh. 23)

Because of the fact that Phar-Mor Pharmacy was on probation, and because it had been some time since the last general pharmacy inspection, the Board office made the determination to conduct a general pharmacy inspection of Phar-Mar Pharmacy on October 26, 1993. This inspection was conducted by Lindy Pearson and Gary Ebeling, Board investigators. Again numerous discrepancies in Phar-Mor Pharmacy's record-keeping practices and additional violations of Iowa pharmacy law were noted in the course of this inspection. (Exhs. 24, 24-A)

First, Mr. Ebeling testified that no license was posted for one relief pharmacist. In addition, Mr. Ebeling noted that Phar-Mor Pharmacy had numerous outdated drugs that were mixed in with its regular inventory. Mr. Ebeling testified that on the basis of his history of investigating pharmacies throughout the state

for many years, the number of outdated drugs at Phar-Mor Pharmacy was unusually large. In addition to the outdated drugs, two bottles of Amoxicillin were found in the refrigerator with no expiration date and an unmarked vial was also found.

Further, Phar-Mor Pharmacy had no current law manual on its premises. The law manual at the pharmacy was a January 1992 manual rather than the December 1992 manual. Mr. Ebeling noted in his testimony that the manual found at the Phar-Mor Pharmacy did not contain the patient counseling requirements that became effective on January 1, 1993. Current pharmacy and CSA licenses were not in complete view, nor were pharmacist licenses and renewal certificates.

Further, Mr. Ebeling noted Phar-Mor Pharmacy dispensed generic medication without authorization of the subscriber, as required by law. He also noted in the pharmacy inspection report that new prescriptions were not properly entered on the computer. On nine (9) occasions, the date of entry of the prescription was the date that it was dispensed, as opposed to the date it was written. This erroneous practice resulted in prescriptions being improperly extended beyond the legal date; in one case, the extension was 11 months. Also, on a random check the pharmacy investigators noted that phone numbers and gender were missing on new prescriptions, and that numerous prescriptions contained no patient addresses, no physician DEA number, and no physician address. Finally, the inspection report noted that controlled substance prescriptions dispensed by Phar-Mor Pharmacy did not

contain the auxiliary label required by federal law on all controlled substances. This requirement, as testified by Mr. Ebeling, has been in effect for several years.

Following the general pharmacy inspection, Ms. Pearson prepared a Schedule II inventory for Phar-Mor Pharmacy beginning May 2, 1993, and ending October 27, 1993. Consistent with the findings of Mr. Dobesh concerning the August and September Schedule II inventories, Ms. Pearson found that there were serious discrepancies with regard to Ritalin, Methylphenidate, and Dexedrine. In addition, significant shortages of Percodan and Oxycodone were noted. Ms. Pearson testified that there were even discrepancies of Duragesic Patches and B and O Suppositories, shortages which she testified were very unusual, given that they are relatively large items and small numbers are stocked in the pharmacy.

Mr. Levine testified that the discrepancies in the Schedule II inventory resulted primarily from inability of staff to make adjustments to the records when prescriptions were filled but placed back in stock, or from other record-keeping discrepancies. He testified that he kept Schedule II inventories from month to month solely for his oversight purposes, not for "perfection." He testified that there was no diversion that he knew of, but that if there was he would have known about it. The State questions how Mr. Levine could have identified any diversion of Schedule II drugs when his inventory, which was presumably established for the purpose of monitoring Schedule II drugs, was

ignored. In sum, Mr. Levine demonstrated an overly casual attitude regarding Schedule II drugs in his pharmacy. As the pharmacist in charge of the Phar-Mor Pharmacy, this attitude is unacceptable.

In sum, numerous violations of Iowa pharmacy laws continue to occur at Phar-Mor Pharmacy. Those violations occurred while the pharmacy was under probation to the Board, and demonstrate the attitude that Phar-Mor Pharmacy has had up to this point in time toward the laws governing pharmacy practice.

#### CONCLUSION

Both Mr. Levine and Robert McCurdy testified that after receiving the second charges against Phar-Mor Pharmacy and the new charges against Mr. Levine, Phar-Mor Pharmacy has taken numerous steps to address the concerns identified in those charges. Additional staff has been hired, a perpetual Schedule II inventory has been established, a consultant has been hired to advise the pharmacy regarding its compliance with Iowa pharmacy law, and Mr. McCurdy has testified that he will be personally involved in ensuring compliance with the Board's order and the general laws governing pharmacy practice in Iowa. While these are positive developments, it is unfortunate that it has taken two contested case hearings and considerable time and expense on the part of the Board staff, Attorney General's Office, and the Board members themselves to reach this point. Given Phar-Mor Pharmacy's inattention to the Board's first order in this matter, its assurances that the problems will now be resolved, however

sincere, cannot be relied on absolutely. The Board must impose appropriate sanctions to assure that Phar-Mor will not only be punished for its continued inattention to Iowa pharmacy law, but also to ensure that incentives to comply with Iowa law remain in effect in order to protect the health and safety of the public.

The repeated and flagrant violations of the laws governing the practice of pharmacy in Iowa by Phar-Mor Pharmacy, at a time when their license to practice pharmacy is on probation from the Board, is appalling and cannot be ignored. Attention to the large and small details of the laws governing the profession is the essence of the practice of pharmacy, and is the obligation of every pharmacy and pharmacist in the State of Iowa. Phar-Mor Pharmacy must be sanctioned for its continued failure to abide by those laws, and for its failure to comply with an order of the Board which previously sought to resolve many of these issues. Mr. Levine should also be sanctioned for allowing these violations to continue during the time he was the pharmacist in charge at Phar-Mor Pharmacy. The State requests that the Board impose those sanctions it deems appropriate to accomplish this end. With regard to Phar-Mor Pharmacy, in addition to an extension of the probationary period and a continuation of the existing terms of probation, the State requests that the Board give consideration to other sanctions, such as imposition of the maximum statutory fine; requiring monitoring of Phar-Mor Pharmacy by a consultant at Phar-Mor Pharmacy expense, with an associated reporting requirement; imposition of mandatory pharmacist

staffing based on prescription volume; and a suspension period, if the Board believes such a period is warranted. With regard to Mr. Levine, the State requests the Board impose those sanctions that are appropriate and consistent with prior decisions of a similar nature.

Respectfully submitted,

BONNIE J. CAMPBELL  
IOWA ATTORNEY GENERAL



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THERESA O'CONNELL WEEG  
Assistant Attorney General  
2nd Floor Hoover Bldg.  
Des Moines, Iowa 50319

copy to:

Jim Gritzner  
1900 Hub Tower  
Des Moines, Iowa 50309

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the

1 day of December 1993  
R. Dale

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of <b>PHAR-MOR PHARMACY #212</b> License No. 436 Robert W. McCurdy, Vice President of Pharmacy Operations, Respondent	} } } } } } }	<b>COMPLAINT AND STATEMENT OF CHARGES AND NOTICE OF HEARING</b>
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**COMES NOW**, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 22nd day of March, 1993, and files this Complaint and Statement of Charges against Phar-Mor Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Alan M. Shepley, Chairperson; Marian L. Roberts, Vice Chairperson; Donna J. Flower; Phyllis A. Miller; Phyllis A. Olson; Ronald B. Reiff; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 10101 "B" University Avenue, Clive, Iowa 50325, and holds license number 436.

3. General pharmacy license number 436, issued in the name of Phar-Mor Pharmacy #212, with John P. Romano as pharmacist in charge, was renewed on November 24, 1992, and is current until December 31, 1993.

4. On March 22, 1993, the Board received and reviewed information which alleges the following:

a. Respondent's pharmacist in charge, two staff pharmacists, and several non-pharmacist pharmacy assistants have recently resigned their positions with Phar-Mor Pharmacy, allegedly as a result of adverse working conditions. Since losing these employees, Respondent has been unable to provide adequate staffing for the prescription department.

b. In a written statement received by the Board on March 22, 1993, pharmacist "J.L." alleges that she was employed by Respondent for a short time. She states, in part, that Respondent's prescription volume is too

high for three pharmacists to handle; that due to the working conditions it is impossible for any pharmacist to fully comply with Iowa pharmacy law and Board rules; that corporate pharmacy management has been aware of the problem but has failed to take effective action; and that urgent action is needed to correct the situation.

c. In a written statement received by the Board on March 22, 1993, pharmacist "D.S." alleges that he is currently employed by Respondent. He states, in part, that he has been overwhelmed by the prescription volume which has been as high as 700 prescriptions a day; that due to inadequate staffing, the pharmacists are unable to comply with Iowa pharmacy law and Board rules; that the high volume of prescriptions and the staffing shortage are contributing to dispensing errors; that he intends to resign his position with Respondent in the near future; and that urgent action is required to protect the public health.

d. Respondent currently has no pharmacist in charge of Phar-Mor Pharmacy # 212.

e. Respondent failed to notify the Board of the change of staff pharmacists which has occurred at Phar-Mor Pharmacy #212.

f. A complaint was received at the Board office on March 22, 1993, from "P.D." who alleged that a prescription for her father, "P.B." was incorrectly refilled by Phar-Mor Pharmacy #212 on or about February 8, 1993. "P.B." was to have received #60 Lopid 600mg tablets. Instead, he received a mixture of Lopid 600mg tablets and Methocarbamol tablets. Lopid is an antihyperlipidemic agent. Methocarbamol is a skeletal muscle relaxant which may cause drowsiness and blurred vision. "P.B.," who is an elderly man with heart and eye problems, did not discover the dispensing error until March 19, 1993, after he had taken most of the tablets. He had previously expressed concern to his daughter over experiencing unexplained drowsiness while driving his car. "P.D." questioned whether Phar-Mor Pharmacy #212 was adequately staffed to prevent the occurrence of dispensing errors.

g. It is alleged by Pharmacy Board Investigators Dennis D. Dobesh and Holger A. Christensen that due to Respondent's staffing shortages, it is impossible for pharmacists at Phar-Mor Pharmacy #212 to comply with board rules pertaining to patient records, prospective drug use review, and patient counseling.

5. Respondent is guilty of violating Iowa Code section 155A.15(2)(c) by virtue of the allegations in paragraph 4.

Iowa Code section 155A.15 provides, in part, the following:

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

6. Respondent is guilty of violations of 657 Iowa Administrative Code sections 3.4, 3.4(7), 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraph 4.

657 Iowa Administrative Code section 3.4 provides, in part, the following:

All areas where prescription drugs are dispensed will require a general pharmacy license, a hospital pharmacy license, or a nonresident pharmacy license... Applicants for general...pharmacy license shall comply with board rules regarding general...pharmacy licenses...

657 Iowa Administrative Code section 3.4(7) provides, in part, the following:

Change of pharmacists. When a change of pharmacist occurs, other than the pharmacist in charge or a relief pharmacist who works on an occasional, irregular, or infrequent basis, the names and license numbers shall be sent to the board office. The pharmacy shall maintain a log of all licensed pharmacists who have worked at that pharmacy and who are not regularly employed at that pharmacy. Such log shall be available for inspection and copying by the board or its representative.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a

location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other

drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

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. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, 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. Prescription refill information;
- i. Action to be taken in the event of a missed

dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

b. A statement of the patient's right to request consultation; and

c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs.

....  
8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....  
u. Violating any of the grounds for revocation

or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The Iowa Board of Pharmacy Examiners finds that paragraph 5 and 6 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

**WHEREFORE**, the undersigned charges that Respondent Phar-Mor Pharmacy # 212 has violated Iowa Code section 155A.15(2)(c) and 657 Iowa Administrative Code sections 3.4, 3.4(7), 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(j), and 9.1(4)(u).

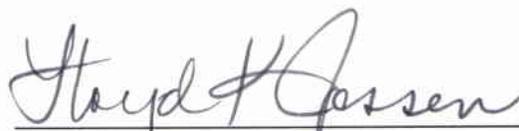
**IT IS HEREBY ORDERED**, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that Robert W. McCurdy appear on behalf of Phar-Mor Pharmacy before the Iowa Board of Pharmacy Examiners on Wednesday, April 28, 1993, at 1:00 p.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend, revoke, or not renew the license to operate a pharmacy issued to Phar-Mor Pharmacy # 436 on November 24, 1992, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision may be rendered. The failure of Respondent to appear could result in the permanent suspension or revocation of its license.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for the public interest in these proceedings. Information regarding the hearing may be obtained from Lynette A. F. Donner, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-8760). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen  
Executive Secretary/Director

BEFORE THE IOWA BOARD OF PHARMACY EXAMINERS

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RE: Pharmacy License of )  
PHAR-MOR PHARMACY #212 ) DIA NO. 93PHB-7  
License No. 436 )  
Robert W. McCurdy, )  
Vice President of )  
Pharmacy Operations, ) FINDINGS OF FACT  
Respondent ) CONCLUSIONS OF LAW,  
DECISION AND ORDER

---

TO: PHAR-MOR PHARMACY #212

A Complaint and Statement of Charges and Notice of Hearing was filed by Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners (Board) on March 22, 1993. The Complaint alleged that the Respondent had violated a number of pharmacy-related statutes and rules. The Complaint and Statement of Charges included the Notice of Hearing, which set the hearing for April 28, 1993, at 1:00 p.m. The hearing was held on that date in the Grimes Office Building, Conference Room 3 North, Des Moines, Iowa. The following members of the Board were present: Alan M. Shepley, Chairperson; Marian L. Roberts, Vice-Chairperson; Phyllis A. Olson; Phyllis Miller; and Arlan Van Norman. Lynnette Donner, Assistant Attorney General, appeared on behalf of the state. The Respondent appeared through its counsel, Joseph R. West. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided. All of the testimony was recorded by a certified court reporter. The hearing was closed to the public at the Respondent's request pursuant to Iowa Code section 272C.6(1). After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f) to deliberate and instructed the Administrative Law Judge to prepare their Findings of Fact, Conclusions of Law, Decision and Order.

THE RECORD

The record includes the Complaint and Statement of Charges and Notice of Hearing, the testimony of the witnesses, and the following exhibits:

- Exhibit A: Letter received March 22, 1993 (Sidhu to Board)
- Exhibit B: Letter received March 22, 1993 (Lasnek to Board)
- Exhibit C: Statement of Schroder dated March 24, 1993
- Exhibit D: Notification of pharmacist staffing change, received April 12, 1993, and attached weekly work schedule

- Exhibit E: Complaint Report dated March 22, 1993, and attachments
- Exhibit F: Complaint Report dated April 12, 1993, and attachments
- Exhibit G: Complaint dated April 21, 1993
- Exhibit H: Complaint Report March 18, 1993, and attached Log
- Exhibit I: Computer Printout

#### FINDINGS OF FACT

1. Respondent is licensed to operate a pharmacy at 10101 "B" University Avenue, Clive, Iowa 50325, and holds license number 436. General pharmacy license number 436, issued in the name of Phar-Mor Pharmacy #212, with John P. Romano as pharmacist in charge, was renewed on November 24, 1992, and is current until December 31, 1993. (official file)

2. Phar-Mor Pharmacy #212 was opened in late 1989 and grew steadily. In the first 12 to 14 months of operation, the average number of prescriptions grew to 2,000 per week. The pharmacy was staffed with two full-time pharmacists, John Romano and Greg Evans, and one full-time and two or three part-time pharmacy technicians. In February 1991, a third full-time pharmacist, Shelly Larson, and additional support staff were added. The three pharmacists were experienced and apparently capable of handling a high volume of prescriptions. (testimony of Dan Smith, Holger Christensen)

3. In July 1992, massive corporate fraud and embezzlement was discovered at Phar-Mor, which led to the indictment of several key officers of the corporation. Phar-Mor filed for bankruptcy in August 1992. These events caused many of Phar-Mor's best employees to leave its employ and made recruiting efforts difficult. (testimony of Robert McCurdy)

4. Partially in response to new federal regulations requiring counseling of Title XIX pharmacy patients (OBRA), Phar-Mor introduced a new computer software system (PDX) in some of its stores in late 1992. Since the Iowa regulations applied OBRA type requirements to all patients, Phar-Mor decided to make conversion of its Iowa stores to the new computer system a priority. The new system was slower than the old system and difficult for some employees to learn. (testimony of Robert McCurdy)

5. In early 1993 the Respondent lost all three of its experienced pharmacists. Gregory Evans resigned on January 29, 1993. Shelly Larson resigned on February 18, 1993. John Romano resigned on

March 11, 1993. The Respondent did not notify the Board of these resignations. (testimony of Holger Christensen; Exhibit D)

6. The Respondent hired two new pharmacists on February 9, 1993, and February 17, 1993. On March 10, 1993, Dalbir Sidhu was transferred from the Waterloo store to assume the duties of pharmacist in charge at #212. Sidhu, who was not experienced in high volume, felt overwhelmed by the prescription volume, the lack of experienced staffing, and other adverse working conditions at store #212. (testimony of Dan Smith, Holger Christensen; Exhibits A, D)

7. On March 18, 1993, Holger Christensen, a staff investigator for the Board, visited store #212 because he had heard about staff resignations. Christensen found the pharmacy to be very understaffed, and the pharmacist in charge to be overwhelmed. Christensen realized that the pharmacists could not possibly be complying with Iowa pharmacy statutes and rules. (testimony of Holger Christensen; Exhibit H)

8. The pharmacist in charge and one of the staff pharmacists filed letters of complaint with the Board on March 22, 1993. They complained that the pharmacy was severely understaffed for the volume of prescriptions, that the staff could not comply with OBRA or Iowa law, and that dispensing errors were being made. The pharmacist-in-charge and both new staff pharmacists all resigned. (Exhibits A, B, D)

9. On March 22, 1993, a Complaint Report was filed with the Board regarding a dispensing error by the Respondent on February 8, 1993. An elderly man had had a prescription for Lopid #60 filled at store #212. The man was actually given 95 tablets, some of which were Lopid and some were Methocarbamol. This mistake was not discovered until the man had been taking the tablets for more than a month. (testimony of Holger Christensen; Exhibit E)

10. On March 24, 1993, a pharmacy technician employed by store #212 filed a statement with the Board, in which she complained of understaffing and dispensing errors being made. (testimony of Holger Christensen; Exhibit C)

11. On April 11, 1993, Respondent hired two new full-time pharmacists. In addition, the Respondent has three part-time pharmacists. A corporate manager has been on site to supervise and recruit new employees. The Respondent is actively trying to recruit another full-time pharmacist and has raised the number of pharmacist hours per week. The prescription volume is approximately 2,400 prescriptions a week. (testimony of Dan Smith, Holger Christensen, Denny Dobish; Exhibits D, H)

12. On April 12, 1993, the Board received another complaint of a dispensing error by the Respondent. A woman received the wrong strength of eye drops. (testimony of Holger Christensen; Exhibit F)

13. On April 12, 1993, the Respondent notified the Board of its staff changes which occurred between January 29, 1993 and April 11, 1993. (Exhibit D)

14. The Board has expended significant resources to monitor Pharmor's pharmacy operation between March 22, 1993, and April 28, 1993. Board investigators have made daily visits to the pharmacy to observe staffing and to monitor compliance with Iowa laws and Board regulations. (testimony of Holger Christensen, Denny Dobish)

#### CONCLUSIONS OF LAW

1. Iowa Code section 155A.15(2)(c)(1991) provides in relevant part:

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

. . . .  
c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

2. 657 Iowa Administrative Code section 3.4 provides, in part, the following:

All areas where prescription drugs are dispensed will require a general pharmacy license, a hospital pharmacy license, or a nonresident pharmacy license . . . Applicants for general . . . pharmacy license shall comply with board rules regarding general . . . pharmacy licenses . . .

657 Iowa Administrative Code section 3.4(7) provides, in part, the following:

Change of pharmacists. When a change of pharmacist occurs, other than the pharmacist in charge or a relief pharmacist who works on an occasional, irregular, or infrequent basis, the names and license numbers shall be sent to the board office. The pharmacy shall maintain a

log of all licensed pharmacists who have worked at that pharmacy and who are not regularly employed at that pharmacy. Such log shall be available for inspection and copying by the board or its representative.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber and

f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

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. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, 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. Prescription refill information;
- i. Action to be taken in the event of a missed dose.
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

- b. A statement of the patient's right to request consultation; and

- c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs. . . .

8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the

board determines that the licensee or registrant is guilty of the following acts or offenses: . . .

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy . . .

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

3. The preponderance of the evidence established that the Respondent violated Iowa Code Section 155A.15(2)(c)(1991) and 657 IAC 3.4 and 3.4(7) when changes in pharmacist staffing were not promptly sent to the Board. The changes in staff were not reported until after a Complaint and Statement of Charges was filed.

4. The preponderance of the evidence established that the Respondent violated Iowa Code Section 155A.15(2)(c)(1991) and 657 IAC 3.4, 6.1, 8.5(4), 8.18, 8.19, 8.20, and 9.1(4)(a), when it allowed severe understaffing of the pharmacy and adverse working conditions which resulted in the inability of staff pharmacists to comply with the mandates of rules 8.18, 8.19 and 8.20, and caused dispensing errors.

#### DECISION AND ORDER

IT IS HEREBY ORDERED, that pharmacy license number 436, issued to PHAR-MOR PHARMACY #212, is suspended for a period of ninety (90) days. However, the suspension is stayed and Respondent is placed on probation for a period of three years upon the following terms and conditions:

1. Within thirty (30) days of the date of this Order, Respondent shall pay a civil penalty of \$25,000.00 by delivering a check made payable to the Treasurer of Iowa to the Executive Secretary of the Board. The check shall be deposited into the general fund.

2. The Respondent must submit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules. The reports shall include:

a. The weekly work schedule for all pharmacy staff (pharmacists and supportive personnel), and the total number of hours worked by each registered pharmacist and each pharmacy assistant each day.

- b. The total number of new and refilled prescriptions filled each day.

The monthly reports shall be submitted during the first year of probation and thereafter, as directed by the Board.

3. The Respondent must immediately notify the Board if the level of staffing falls below 175 pharmacist hours per week.

4. The Respondent shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.

5. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

6. No pharmacist employed by the Respondent and practicing at the Clive location (store #212) shall supervise any registered intern or perform any of the duties of a preceptor.

7. Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. If a petition to revoke probation is filed against the pharmacy during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

8. Upon successful completion of probation, the pharmacy license will be fully restored.

Finally, it is ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 9.27, that the pharmacy shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary of the Board shall bill the pharmacy for any transcript costs associated with this disciplinary hearing. The pharmacy shall remit for these expenses within thirty (30) days of receipt of the bill.

DIA No. 93PHB-7

Page 10

Dated this 14th day of May, 1993.



\_\_\_\_\_  
Marian Roberts, Chairperson  
Iowa Board of Pharmacy Examiners



\_\_\_\_\_  
Margaret LaMarche  
Administrative Law Judge

ML/jmm

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of	)	MODIFICATION OF
PHAR-MOR PHARMACY #212	)	DECISION
License No. 436	)	AND
Respondent	)	ORDER

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COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 20th day of May, 1993, and declares that:

1. On May 14, 1993, the Board issued a Decision and Order (DIA No. 93 PHB-7) which included, in part, the following provisions:

The Respondent must immediately notify the Board if the level of staffing falls below 175 pharmacist hours per week.

No pharmacist employed by the Respondent and practicing at the Clive location (store #212) shall supervise any registered intern or perform any of the duties of a preceptor.

2. The provisions of the Decision and Order (DIA No. 93 PHB-7) for Phar-Mor Pharmacy #212, as stated above, are now hereby modified to provide as follows:

The Respondent must notify the Board weekly when the level of staffing falls below 175 pharmacist hours per week.

Beginning June 14, 1993, no pharmacist employed by Respondent and practicing at the Clive location (Store #212) shall supervise any registered intern or perform any of the duties of a preceptor. Respondent shall, between May 14, 1993, and June 14, 1993, transition the responsibilities previously held by registered interns to other qualified employees.

Dated this 20th day of May 1993.

IOWA BOARD OF PHARMACY EXAMINERS

  
Lloyd K. Jessen

Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of	}	
PHAR-MOR PHARMACY #212	}	PETITION TO
License No. 436	}	REVOKE
Gary L. Levine,	}	PROBATION
Pharmacist in charge,	}	AND
Respondent	}	NOTICE OF HEARING

---

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 20th day of October, 1993, and files this Petition to Revoke Probation and Notice of Hearing against Phar-Mor Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 10101 "B" University Avenue, Clive, Iowa 50325, and holds license number 436.

3. General pharmacy license number 436, issued in the name of Phar-Mor Pharmacy #212, with Gary L. Levine as pharmacist in charge, was issued on April 27, 1993, and is current until December 31, 1993.

4. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on March 22, 1993. An administrative hearing was held on April 28, 1993, in Des Moines, Iowa.

5. On May 14, 1993, the Board issued its "Findings of Fact, Conclusions of Law, Decision and Order." The Board's Order suspended Respondent's license to operate a pharmacy for 90 days. The suspension was stayed, however, and Respondent's license was placed on probation for a period of three years, beginning May 14, 1993, and ending May 13, 1996.

6. The Board's Order also provided, in part, that during the probationary period the Respondent must:

(2) ...[S]ubmit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and

providing patient counseling as required by Board rules...

....

(4) The Respondent shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.

(5) The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

....

(7) Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. If a petition to revoke probation is filed against the pharmacy during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

7. On September 14, 1993; October 12, 1993; and October 20, 1993, the Board received and reviewed information which alleges the following:

a. Since the beginning of Respondent's probation, the Board has received six complaints against the Respondent directly from consumers. The dates of occurrence of the complaints are as follows: May 7, 1993; May 11, 1993; June 14, 1993; July 2, 1993; July 6, 1993; and October 17, 1993. Five of the six complaints involved one or more dispensing errors.

b. During the months of May, June, and July 1993, Respondent failed to comply with subparagraph 4 of the Board's Order by failing to report to the Board any dispensing errors brought to Respondent's attention by consumers within thirty (30) days of such occurrence.

c. Pharmacists employed by Respondent committed nine additional dispensing errors which occurred on the following dates: August 18, 1993; September 2, 1993 (2 errors); September 3, 1993; September 7, 1993; September 8, 1993; September 9, 1993; September 17, 1993; and October 4, 1993. Respondent notified the Board of these incidents (consumer complaints) on October 7, 1993. All nine incidents involved one or more dispensing errors.

d. All fourteen dispensing errors reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Respondent.

e. An inspection of Respondent's controlled substance records on October 19, 1993, by Board Investigator Dennis D. Dobesh revealed the following:

(1) No patient addresses were recorded on 19 schedule II controlled substance prescriptions filled between August 5, 1993, and September 20, 1993.

(2) Prescription number N2200778 for patient "E.B." for #60 Ritalin 5mg, a Schedule II controlled substance, was dispensed on September 25, 1993, without a written prescription of a practitioner. No written prescription had been obtained as of October 19, 1993.

(3) Prescription number N2200816 for patient "J.C." for #30 Demerol 100mg, a Schedule II controlled substance, was dispensed on October 8, 1993, without a written prescription of a practitioner. No written prescription had been obtained as of October 19, 1993.

(4) Respondent's Schedule II Inventory Record for August 1993 reveals the following significant shortages of Schedule II controlled substances:

40 tablets of Percodan  
150 tablets of Ritalin 10mg  
83 tablets of Methylphenidate-SR 20mg

(5) Respondent's Schedule II Inventory Record for September 1993 reveals the following significant shortages of Schedule II controlled substances:

72 tablets of Oxycodone/APAP  
44 tablets of Methylphenidate 10mg  
60 tablets of Ritalin 20mg  
20 capsules of Dexedrine 10mg

f. Respondent has failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy. Respondent has failed to keep and maintain records as required by the controlled substances Act. Respondent has failed to establish effective controls against diversion of prescription drugs.

g. The staffing and procedures of Respondent's prescription department are inadequate to protect the public health and safety.

8. Respondent is guilty of violating subparagraphs 2, 4, and 5 of the Board's Order by virtue of the information contained in paragraph 7 of this Petition to Revoke Probation.

9. In addition, Respondent is guilty of violating Iowa Code sections 155A.15(2)(c), 155A.15(2)(h), 155A.15(2)(i), 124.308(1), 124.402(1)(a), 124.402(1)(c), and 272C.3(2)(a) by virtue of the allegations in paragraph 7 of this Petition to Revoke Probation.

1993 Iowa Code section 155A.13 provides, in part, the following:

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath:...

e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

1993 Iowa Code section 155A.15 provides, in part, the following:

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

....  
h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

i. Failed to establish effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by this chapter and other Iowa or federal laws or rules.

1993 Iowa Code section 124.308 provides, in part, the following:

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

1993 Iowa Code section 124.402 provides, in part, the following:

1. It is unlawful for any person:
  - a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308;
  - ....
  - c. To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter;

1993 Iowa Code section 272C.3 provides, in part, the following:

2. Each licensing board may impose one or more of the following as licensee discipline:
  - a. Revoke a license, or suspend a license... upon failure of the licensee to comply with a decision of the board imposing licensee discipline.

10. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(b), 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraph 7 of this Petition to Revoke Probation.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.  
8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist

to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

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. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, 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. Prescription refill information;
- i. Action to be taken in the event of a missed dose;
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

- b. A statement of the patient's right to request consultation; and

- c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs.

....

8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

....

i. ...violating a lawful order of the board in a disciplinary hearing...

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The Iowa Board of Pharmacy Examiners finds that paragraphs 7, 8, 9, and 10 allege grounds for which Respondent's probation may be revoked and its license to operate a pharmacy in Iowa can be disciplined.

**IN ADDITION,** the undersigned charges that Respondent Phar-Mor Pharmacy # 212 has violated Iowa Code sections 155A.15(2)(c), 155A.15(2)(h), 155A.15(2)(i), 124.308(1), 124.402(1)(a), 124.402(1)(c), and 272C.3(2)(a) and 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(b), 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u).

**IT IS HEREBY ORDERED,** pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that Gary L. Levine appear on behalf of Phar-Mor Pharmacy before the Iowa Board of Pharmacy Examiners on Tuesday, November 23, 1993, at 9:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to revoke Respondent's probation and to impose the 90-day license suspension which was stayed on May 14, 1993, and take whatever additional disciplinary action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision, including disciplinary action, may be rendered.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for representation of the public interest in these proceedings. Information regarding the hearing may be obtained from Theresa O'Connell Weeg, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-6858). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen  
Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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RE: Pharmacy License of	)	FINDINGS OF FACT,
	)	CONCLUSIONS OF LAW,
PHAR-MOR PHARMACY #212	)	DECISION AND ORDER
License No. 436	)	
Gary L. Levine,	)	
Pharmacist in charge,	)	
	)	DIA NO. 93PHB-11
Respondent	)	

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TO: PHAR-MOR PHARMACY #212

On October 20, 1993, the Executive Secretary/Director of the Iowa Board of Pharmacy Examiners (Board) filed a Petition to Revoke Probation and Notice of Hearing against Phar-Mor Pharmacy #212 (Respondent), a licensed pharmacy, alleging that the Respondent had violated the terms of its probation established in the Board's Order dated May 14, 1993.

The hearing on the Petition to Revoke Probation was held on November 23, 1993, in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Des Moines, Iowa. The following members of the Board were present: Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus and Arlan D. Van Norman. The Respondent appeared and was represented by counsel, James Gritzner. The state was represented by Theresa Weeg, Assistant Attorney General. The hearing was recorded by a certified court reporter. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided.

The parties agreed to include in this record the recording of four informal interviews of Gary Roseman, Nick Bluel, Ken Blythe, and Dennis Harker, which were conducted by the Board immediately preceding the hearing. The attorneys were present for the interviews but did not participate.

The parties were allowed to submit closing arguments in written form. On December 2, 1993, the Board convened in closed executive session, by telephone conference call, pursuant to Iowa Code section 21.5(1)(f), to deliberate its decision. The Administrative Law Judge was directed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order.

THE RECORD

The record includes the Complaint and Statement of Charges and Notice of Hearing, Respondent's Motion for Continuance, November 2, 1993 letter notifying Respondent that the continuance motion had

been denied, testimony of the witnesses, and the following exhibits:

- Exhibit 1: Complaint and Statement of Charges, Phar-Mor Pharmacy, March 22, 1993
- Exhibit 2: Order, May 14, 1993
- Exhibit 3: Petition to Revoke Probation, Phar-Mor Pharmacy, October 20, 1993
- Exhibit 4: Complaint and Statement of Charges, Gary Levine, October 20, 1993
- Exhibit 5: Phar-Mor Pharmacy, monthly report, May 30, 1993
- Exhibit 6: Phar-Mor Pharmacy, monthly report, July 3, 1993
- Exhibit 7: Phar-Mor Pharmacy, monthly report, August 2, 1993
- Exhibit 8: Phar-Mor Pharmacy, monthly report, August 31, 1993
- Exhibit 9: Phar-Mor Pharmacy, monthly report, September 29, 1993
  - 9-A. Incident report, 8/18/93 (DG)
  - 9-B. Incident report, 9/2/93 (JC)
  - 9-C. Incident report, 9/2/93 (ND)
  - 9-D. Incident report, 9/3/93 (AA)
  - 9-E. Incident report, 9/7/93 (NM)\*
  - 9-F. Incident report, 9/8/93 (EM)
  - 9-G. Incident report, 9/9/93 (KH)\*
  - 9-H. Incident report, 9/17/93 (KH)
  - 9-I. Incident report, 10/4/93 (BC)\*

\* "Date RX dispensed" is unclear from reporting form; date information is derived from other information on that form.

- Exhibit 10: Phar-Mor Pharmacy, monthly report, November 1, 1993
  - 10-A. Incident report, 10/17/93 (BS)
  - 10-B. Incident report, 10/18/93 (JM)
- Exhibit 11: Complaint report re: Incident on 5/7/93 (GV and S. Humphrey, M.D.)
- Exhibit 12: Complaint reports re: VP:

- 12-A. Complaint report re: incident on 5/11/93 (VP)
- 12-B. Complaint report re: incident on 4/21/93 (VP)
  
- Exhibit 13: Complaint report re: incident on 6/14/93 (KK)
- Exhibit 14: Complaint report re: incident on 7/6/93 (SG)
- Exhibit 15: Complaint report dated 8/9/93 re: incident (BS)
- Exhibit 16: Letter from L. Jessen to G. Levine, 8/25/93
- Exhibit 17: Investigative report of D. Dobesh, 10/19/93
  - 17-A. Letter and attachments from MS, 10/17/93
  - 17-B. Statement of N. Bluel, 10/19/93
  - 17-C. Prescription No. N2200856 for BS, 10/17/93
  - 17-D. Prescription No. N2200857 for BS, 10/17/93
  - 17-E. Prescription No. N2200778 for EB, 9/25/93
  - 17-F. Prescription No. N2200816 for JC, 10/18/93
  - 17-G. List of Schedule II prescriptions without addresses
  - 17-H. Phar-Mor Schedule II inventory record for August 1993
  - 17-I. Phar-Mor Schedule II inventory record for September 1993.
  
- Exhibit 18: IBPE memo re: Phar-Mor C-II filling discrepancies, 4/21/93-10/26/93 (L. Pearson)
  
- Exhibit 19: 102 Schedule II prescriptions with no addresses (\* not included in Board exhibit folders \*)
  
- Exhibit 20: 2 Schedule II prescriptions for JC and EB with no doctor's signature
  
- Exhibit 21: 5 "on-hold" prescriptions (GO 4/27/93 and 6/30/93, TM 8/25/93, LP 9/27/93, and A 9/28/93)
  
- Exhibit 22: Prescription for GM, 6/11/93
  
- Exhibit 23: Prescription for JC, 9/2/93
  
- Exhibit 24: IBPE General Pharmacy Inspection Report for Phar-Mor, 10/26/93
  
- Exhibit 25: Computation Table

- Exhibit 26: Phar-Mor Schedule II monthly inventories for 5/93-9/93
- Exhibit 27: Complaint report re: incident on 11/3/93 (AB)
- Exhibit 28: Complaint report re: incident on 11/11/93 (RC)
- Exhibit 29: Letter from J. Rovers to L. Jessen, 11/11/93
- Exhibit 30: Letter from L. Jessen to J. Rovers, 11/16/93
- Exhibit 31: Graphs, May to October 1993, total pharmacist hours v. new prescriptions and total prescriptions  
(\* not included in Board exhibit folders \*)
- Exhibit 32: Graphs, May to October 1993, total pharmacy staff hours v. new prescriptions  
(\* not included in Board exhibit folders \*)
- Respondent's Exhibit A: Affidavit of Randell Kavalier, D.O.
- Respondent's Exhibit B: Affidavit of John P. Clark D.O.
- Respondent's Exhibit C: Copy of prescription refill form for Ritalin and prescription for Demerol
- Respondent's Exhibit D: Factbase: Phar-Mor #212
- Respondent's Exhibit E: Future of #212, Des Moines

#### FINDINGS OF FACT

1. Phar-Mor Pharmacy #212 is licensed to operate a pharmacy at 10101 "B" University Avenue, Clive, Iowa 50325, and holds license number 436. (Board file)
2. Gary Levine is currently employed as the pharmacist in charge of Phar-Mor Pharmacy #212, 10101 "B" University Avenue, Clive, Iowa 50325. He has been the pharmacist in charge of Phar-Mor Pharmacy #212 since April 27, 1993. (testimony of Gary Levine; Board file)
3. On March 22, 1993, the Executive Secretary/Director for the Board filed Complaint and Statement of Charges against the pharmacy license of Phar-Mor Pharmacy #212 alleging that the pharmacy had violated a number of pharmacy related statutes and rules. (Exhibit 1)
4. Following a hearing, the Board issued its Findings of Fact, Conclusions of Law, Decision and Order on May 14, 1993. The Board found that the pharmacy had failed to promptly report pharmacist

staffing changes to the Board, in violation of Iowa Code section 155A.15(2)(c) (1991) and 657 IAC 3.4 and 3.4(7). In addition, the Board found that the pharmacy had allowed severe understaffing and adverse working conditions in the pharmacy, which resulted in the inability of staff pharmacists to comply with the mandates of 657 IAC 8.18, 8.19, and 8.20, and caused dispensing errors (Exhibit 2).

5. The Board ordered that pharmacy license 436, issued to Phar-Mor Pharmacy #212, be suspended for a period of ninety (90) days. However, the suspension was stayed and the pharmacy was placed on probation for a period of three years, subject to certain terms and conditions. The terms and conditions included the payment of a \$25,000.00 civil penalty and the following probationary terms, in relevant part:

. . . .

2. The Respondent must submit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules. The reports shall include:

a. The weekly work schedule for all pharmacy staff (pharmacists and supportive personnel), and the total number of hours worked by each registered pharmacist and each pharmacy assistant each day.

b. The total number of new and refilled prescriptions filled each day.

The monthly reports shall be submitted during the first year of probation and thereafter, as directed by the Board.

3. The Respondent must immediately notify the Board if (later modified to "when") the level of staffing falls below 175 pharmacist hours per week.

4. The Respondent shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.

5. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

6. No pharmacist employed by the Respondent and practicing at the Clive location (store #212) shall supervise any registered intern or perform any of the duties of a preceptor.

7. Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. If a petition to revoke probation is filed against the pharmacy during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final. (Exhibit 2)
6. On October 20, 1993, the Board filed a Petition to revoke Probation against the pharmacy license of Phar-Mor #212 and a Compliant and Statement of Charges against the pharmacist license of Gary Levine. (Exhibits 3, 4)
7. In the monthly reports filed by Gary Levine and Phar-Mor from May through October, 1993, there were only three weeks where pharmacist staffing was 175 hours or more. While the probation terms did not mandate 175 pharmacist hours each week, there is no doubt that 175 hours was the suggested staffing goal. Often, the pharmacist hours were significantly less than 175 hours. (testimony of Lindy Pearson; Exhibits 5 - 10)
8. The monthly reports filed by Gary Levine and Phar-Mor in May, June, and July listed no dispensing errors. On August 25, 1993, the Board's Executive Director sent a letter of warning to Gary Levine as pharmacist in charge of Phar-Mor. The letter informed Phar-Mor that the Board had received five consumer complaints since April 28, 1993, four of which involved dispensing errors at Phar-Mor. None of these dispensing errors were reported to the Board by Phar-Mor. Phar-Mor was reminded that it was required to report errors brought to its attention by consumers within thirty days of their occurrence. The letter further stated,  
  
Due to the number of dispensing errors which have occurred in a brief period of time, the committee is very concerned that the staffing and procedures of the prescription department are inadequate to protect the public health and safety. Furthermore, they regard these incidents as a violation of the terms and conditions of probation as set forth in the Board's Decision and Order.  
  
The pharmacy was warned that continued failure to report dispensing errors or another complaint regarding lack of counseling or a serious dispensing error would result in formal charges. (testimony of Denny Dobesh; Exhibits 5 - 8, 16)
9. Gary Levine admitted that he failed to report dispensing errors to the Board in May, June, and July. As pharmacist in charge, it was his duty to make records of all errors and report them to the Board. The Board still does not know what errors may have occurred during these months, with the exceptions of those

directly reported by consumers to the Board. Of these consumer complaints, two stand out as the most serious:

a. On May 7, 1993, customer GV took two prescriptions to Phar-Mor to be filled, one was for Tylenol #3, a pain medication, the other was for Naprosyn, a muscle relaxant. The pharmacist erroneously gave the customer Tylenol #3 in both bottles. This incident occurred before the Board's order of May 14, 1993 was issued. Nevertheless, it should have been reported in June. Levine admitted that he knew about this error and should have reported it.

b. On June 14, 1993, customer KK received a prescription for ear drops with erroneous instructions to apply to the toes. Levine admitted that this error should have been reported. (testimony of Holger Christensen; Exhibits 11 - 15).

10. After receiving the Board's letter of warning in August, Gary Levine did begin reporting consumer complaints and dispensing errors. One complaint was reported in August, nine dispensing errors were reported in September, and two were reported in October. In addition, two complaints were received in November, which have not yet been investigated by the Board. The errors included wrong drugs, wrong strength, and incorrect labeling (wrong patient name, erroneous directions). At the times these errors occurred, pharmacist staffing was generally significantly below the 175 hours per week suggested by the Board. Phar-Mor has fired one full-time pharmacist who was responsible for many of the dispensing errors and has removed a part-time pharmacist from its schedule. (testimony of Denny Dobesh, Lindy Pearson, Gary Levine; Exhibits 8 - 10, 31-32)

11. During a general pharmacy inspection, Board investigators found evidence of two more misfilled prescriptions that had not been previously reported. (testimony of Lindy Pearson; Exhibits 22, 23)

12. Phar-Mor Pharmacy #212 has numerous deficiencies in its handling of Schedule II controlled substances and inventories. Over 100 prescriptions for Schedule II controlled substances did not contain written addresses of the patient. Schedule II controlled drugs were dispensed on two occasions for which the pharmacy could not produce a written prescription signed by the physician. The pharmacy produced affidavits from the physicians at the hearing which stated they had authorized or executed prescriptions to the patients and a copy of one prescription. However, the pharmacy failed to demonstrate that the written prescription was ever presented to the pharmacy. (testimony of Denny Dobesh, Lindy Pearson; Exhibits 17, 17-E, 17-F, 17-G, 19, 20; Exhibits A, B)

13. The actual physical count of Schedule II controlled substances from May 2, 1993, to October 27, 1993, at Phar-Mor #212 demonstrates numerous shortages and overages of Schedule II drugs. Most of the shortages involved stimulants. Gary Levine could not adequately document or explain these discrepancies. It is not possible to conclude whether these discrepancies are due to paper errors or diversion. In October, the pharmacy instituted a perpetual inventory system for Schedule II controlled substances. (testimony of Denny Dobesh, Lindy Pearson, Gary Levine; Exhibit 25)

14. Phar-Mor Pharmacy #212 was inspected in October 1993. The inspection report cited numerous deficiencies. The Board agrees with Phar-Mor that only six of the drugs on the shelves were outdated. The Board is concerned about the following deficiencies:

a. New prescriptions are improperly entered on the computer with the date dispensed as the date of entry, rather than the date written. In one case, this caused the prescription to be extended eleven months beyond its expiration date.

b. The pharmacy failed to have a current law manual.

c. Genders and phone numbers were missing on patient records.

(testimony of Gary Ebeling; Exhibit 24)

15. None of the pharmacists employed at Phar-Mor and interviewed by the Board could recall having read the pharmacy's Policy and Procedure Manual. (testimony of Gary Roseman, Nick Bluel, Ken Blythe, Dennis Harker)

16. Robert McCurdy, Vice President of Pharmacy Operations for Phar-Mor, testified that Phar-Mor is willing to do whatever is necessary to resolve the problems at store #212, regardless of cost. The pharmacy operating hours have been reduced by five hours. McCurdy testified that he has re-emphasized the pharmaceutical care regulations to the pharmacists at store #212 because he was not satisfied that they were being performed consistently. Phar-Mor has hired John Rovers, an Assistant Clinical Professor of Pharmacy at Drake University, as a consultant to provide on-site supervision at Phar-Mor #212. Rovers reports directly to McCurdy. (testimony of Robert McCurdy)

17. Robert McCurdy concedes that Gary Levine lacks a sense of management and testified that Phar-Mor would help Levine develop to become a better manager. When McCurdy visited the store, he was not convinced that the right number of pharmacy employees were scheduled for the right time. McCurdy has become more proactive in scheduling at store #212. In the opinion of McCurdy, 168 pharmacist hours should be ample to staff the pharmacy for seventy-five

(75) hours of operation and the filling of approximately 2,400 prescriptions. (testimony of Robert McCurdy)

18. John Rovers has been on site at Phar-Mor #212 all but two days since November 1, 1993, observing the operations of the pharmacy and auditing record keeping. He reviews the perpetual inventory daily. Specifically, Rovers is monitoring staff compliance with drug utilization review, prospective drug review, and patient counseling. (testimony of John Rovers)

#### CONCLUSIONS OF LAW

1. Iowa Code section 155A.12 (1993) provides in relevant part:

. . . The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.

5. Violated any provision of the controlled substances Act or rules relating to the Act.

2. Iowa Code section 155A.13 (1993) provides in relevant part:

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath: . . .

e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

3. Iowa Code section 155A.15 (1993) provides in relevant part;

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

i. Failed to establish effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by this chapter and other Iowa or federal laws or rules.

4. Iowa Code section 124.308 (1993) provides in relevant part:

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

5. Iowa Code section 124.402 (1993) provides in relevant part:

1. It is unlawful for any person:

a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308;

c. To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter;

6. Iowa Code section 272C.3 (1993) provides in relevant part:

2. Each licensing board may impose one or more of the following as licensee discipline:

a. Revoke a license, or suspend a license . . . upon failure of the licensee to comply with a decision of the board imposing licensee discipline.

7. 657 Iowa Administrative Code 6.1 provides:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

8. 657 Iowa Administrative Code 8.5(4) provides:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice

which if engaged in by a pharmacist would be unethical conduct.

9. 657 IAC 8.18 provides in relevant part:

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;

4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

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. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

10. 657 Iowa Administrative Code section 8.20 provides in relevant part:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, 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. Prescription refill information;
- i. Action to be taken in the event of a missed dose.
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the

statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

b. A statement of the patient's right to request consultation; and

c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs. . . .

8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

11. 657 Iowa Administrative Code section 9.1(4) provides in relevant part:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses: . . .

i. . . . violating a lawful order of the board in a disciplinary hearing . . .

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy . . .

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

12. The preponderance of the evidence established that Phar-Mor Pharmacy #212 has failed to comply with subparagraph 4 of the Board's Order by failing to report to the Board several dispensing errors brought to its attention by consumers within thirty (30) days of such occurrence. Phar-Mor Pharmacy #212 has violated Iowa Code section 272C.3(1993) and 657 IAC 9.1(4)(i).

13. The preponderance of the evidence established that Phar-Mor Pharmacy #212 violated 657 IAC 8.18, 8.19 and 8.20. Most of the numerous errors reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had

been provided by the pharmacists employed by Phar-Mor #212. The inadequate number of pharmacist hours at times of high prescription volume when errors occurred also supports the conclusion that prospective drug use review and patient counseling was inadequate or omitted. In addition the patient record systems were inadequate because some lacked patient genders, phone numbers, and dates of birth.

14. The preponderance of the evidence established that Phar-Mor Pharmacy #212 violated Iowa Code sections 155A.15(c)(h) and (i), 124.308 and 124.402 (1993) and 657 IAC 9.1(4)(j) when it failed to record patient addresses on Schedule II controlled substance prescriptions, when it dispensed Schedule II controlled substances without a written prescription of the practitioner, and when it failed to provide sufficient safeguards and effective controls against diversion of prescription drugs. The physical count of Schedule II controlled drugs at the pharmacy establishes significant shortages which have not been accounted for by the pharmacy.

15. The preponderance of the evidence has established that Phar-Mor Pharmacy #212 has failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy, in violation of paragraph 5 of the Board's Order and Iowa Code section 272C.3 (1993) and 657 IAC 9.1(4)(i).

#### DECISION AND ORDER

IT IS HEREBY ORDERED, that pharmacy license number 436, issued to Phar-Mor Pharmacy #212, is suspended for a period of 90 days. However, the suspension is stayed and Phar-Mor Pharmacy #212 is placed on probation for a period of five years, commencing with the effective date of this Order, upon the following terms and conditions:

1. Within thirty (30) days of the date of this Order, Phar-Mor Pharmacy #212 shall pay a civil penalty of \$25,000.00 by delivering a check made payable to the Treasurer of Iowa to the Executive Secretary of the Board. The check shall be deposited into the general fund.

2. Phar-Mor Pharmacy #212 must submit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules. The reports shall include:

- a. The weekly work schedule for all pharmacy staff (pharmacists and supportive personnel), and the total

number of hours worked by each registered pharmacist and each pharmacy assistant each day.

b. The total number of new and refilled prescriptions filled each day.

The monthly reports shall be submitted during the first year of probation and thereafter, as directed by the Board.

3. Phar-Mor Pharmacy #212 is required to maintain an average staffing ratio of seven (7) pharmacist hours (R.Ph. licensed in Iowa) per every 100 prescriptions filled, to be calculated on a weekly basis. If the pharmacy discovers that it has failed to meet this mandatory minimum staffing ratio for a particular week, it must report this information to the Board no later than 9:00 a.m. on the following Monday and take immediate action to prevent such future occurrences. The Board, in its discretion, may take further disciplinary action for any violation of this minimum staffing requirement. This minimum staffing ratio may be reviewed by the Board after the first year of probation is successfully completed.

4. Phar-Mor Pharmacy #212 shall submit its Policies and Procedures Manual to the Board, for its approval, before January 5, 1994. The manual must specifically address issues of patient records, dispensing accuracy, incident report procedures, prospective drug review, patient counseling, and procedures for Schedule II controlled substance prescriptions.

a. Phar-Mor Pharmacy #212 shall require all pharmacists and supportive personnel to read the Policies and Procedures Manual and to sign written statements certifying that they have read it. Copies of these written statements shall be included in the monthly reports for the month in which they are obtained;

b. Phar-Mor Pharmacy #212 shall require all pharmacists to read the current law manual and to sign written statements certifying that they have read it. Copies of these written statements shall be included in the monthly reports for the month in which they are obtained;

c. Phar-Mor Pharmacy #212 shall require all pharmacy employees to wear badges that bear, at a minimum, their first name and title;

d. Within 15 days of receipt of this Order, Respondent shall notify all current pharmacy employees of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by the Board's Order. Respondent shall cause all current pharmacy employees to

report to the Board in writing acknowledging that the employees have read the Board's Order.

e. Prior to employing a new pharmacist, Respondent shall fully inform the pharmacist of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by the Board's Order. Respondent shall cause any new pharmacy employee, including a temporary, part-time or full-time pharmacy employee, to report to the Board in writing acknowledging that the employee has read the Board's Order.

5. Phar-Mor Pharmacy #212 shall maintain a monthly physical inventory and a perpetual inventory record of all Schedule II controlled substances and shall report and justify any discrepancies within fifteen days, as required by law. In addition, a copy of any such report shall be sent to Robert W. McCurdy, Vice President of Pharmacy Operations.

6. The current and all future pharmacists-in-charge of Phar-Mor Pharmacy #212 are required to attend a formal course in management training, to be pre-approved by the Board.

7. The Respondent shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.

8. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

9. No pharmacist employed by the Respondent and practicing at the Clive location (store #212) shall supervise any registered intern or perform any of the duties of a preceptor.

10. Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. If a petition to revoke probation is filed against the pharmacy during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

11. Upon successful completion of probation, the pharmacy license will be fully restored.

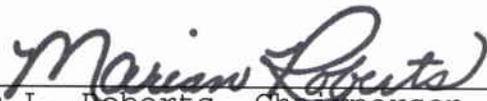
Finally, it is ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 9.27, that the pharmacy shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary of the Board shall bill the pharmacy for any

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transcript costs associated with this disciplinary hearing. The pharmacy shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 9th day of December, 1993.

  
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Marian L. Roberts, Chairperson  
Iowa Board of Pharmacy Examiners

ML/jmm

cc: Theresa Weeg  
James Gritzner

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of	)	<b>SECOND</b>
<b>PHAR-MOR PHARMACY #212</b>	)	<b>PETITION TO</b>
License No. 436	)	<b>REVOKE</b>
Gary L. Levine,	)	<b>PROBATION</b>
Pharmacist in charge,	)	<b>AND</b>
Respondent	)	<b>NOTICE OF HEARING</b>

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**COMES NOW**, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 6th day of March, 1995, and files this Second Petition to Revoke Probation and Notice of Hearing against Phar-Mor Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Jay J. Cayner; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 10101 "B" University Avenue, Clive, Iowa 50325, and holds license number 436.

3. General pharmacy license number 436, issued in the name of Phar-Mor Pharmacy #212, with Gary L. Levine as pharmacist in charge, was issued on December 19, 1994, and is current until December 31, 1995.

4. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on March 22, 1993. The Complaint alleged that the pharmacy had violated a number of pharmacy related statutes and rules. An administrative hearing was held on April 28, 1993, in Des Moines, Iowa.

5. On May 14, 1993, the Board issued its "Findings of Fact, Conclusions of Law, Decision and Order." The Board found that the pharmacy had failed to promptly report pharmacist staffing changes to the Board, in violation of Iowa Code section 155A.15(2)(c)(1991) and 657 IAC 3.4 and 3.4(7). In addition, the Board found that the pharmacy had allowed severe understaffing and adverse working conditions in the pharmacy, which resulted in the inability of staff pharmacists to comply with the mandates of 657 IAC 8.18, 8.19, and 8.20, and caused dispensing errors. The Board's Order suspended Respondent's license to operate a pharmacy for 90 days. The suspension was stayed, however, and Respondent's license was placed on probation for a period of three years, beginning May 14, 1993, and ending May 13, 1996. Respondent was also fined \$25,000.

6. A Petition to Revoke Probation and Notice of Hearing was filed against Respondent on October 20, 1993. The Petition alleged that Respondent had violated the terms of its probation as established by the Board in the disciplinary order dated May 14, 1993. It was also alleged that Respondent had violated a number of pharmacy-related statutes and rules. An administrative hearing was held on November 23, 1993, in Des Moines, Iowa.

7. On December 9, 1993, the Board issued its "Findings of Fact, Conclusions of Law, Decision and Order." The Board found Respondent guilty of the following: (1) failure to comply with the May 14, 1993, Board Order by failing to report to the Board several dispensing errors brought to its attention by consumers within 30 days of such occurrence; (2) failure to comply with Board rules pertaining to patient records, prospective drug use review, and patient counseling; (3) failure to keep complete and accurate controlled substance records; (4) failure to provide accountability for certain Schedule II controlled substances; and (5) failure to obey all federal and state laws and regulations substantially related to the practice of pharmacy. The Board's Order suspended Respondent's license to operate a pharmacy for 90 days. The suspension was again stayed, but the length of Respondent's probationary period was extended from three years to five years, beginning December 9, 1993, and ending December 8, 1998. The Board also required Respondent to maintain an average staffing ratio of seven (7) pharmacist hours (R.Ph. licensed in Iowa) per every 100 prescriptions filled. And Respondent was again fined \$25,000.

8. The Board's Findings of Fact dated December 9, 1993, included the following:

13. The actual physical count of Schedule II controlled substances from May 2, 1993, to October 27, 1993, at Phar-Mor #212 demonstrates numerous shortages and overages of Schedule II drugs. Most of the shortages involved stimulants. Gary Levine could not adequately document or explain these discrepancies...

9. The Board's Conclusions of Law dated December 9, 1993, included the following:

13. The preponderance of the evidence established that Phar-Mor Pharmacy #212 violated 657 IAC 8.18, 8.19, and 8.20. Most of the numerous errors reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Phar-Mor #212. The inadequate number of pharmacist hours at times of high prescription volume when errors occurred also supports the conclusion that prospective drug use review and patient counseling was inadequate or omitted. In addition the patient record systems were

inadequate because some lacked patient genders, phone numbers, and dates of birth.

14. The preponderance of the evidence established that Phar-Mor Pharmacy #212 violated Iowa Code section...155A.15(2)(i)...when it failed to provide sufficient safeguards and effective controls against diversion of prescription drugs.

10. The Board's Order dated December 9, 1993, provided, in part, that during the probationary period the Respondent must do the following:

2. ...[S]ubmit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules...

3. Phar-Mor Pharmacy #212 is required to maintain an average staffing ratio of seven (7) pharmacist hours (R.Ph. licensed in Iowa) per every 100 prescriptions filled, to be calculated on a weekly basis. If the pharmacy discovers that it has failed to meet this mandatory minimum staffing ratio for a particular week, it must report this information to the Board no later than 9:00 a.m. on the following Monday and take immediate action to prevent such future occurrences. The Board, in its discretion, may take further disciplinary action for any violation of this minimum staffing requirement...

4. Phar-Mor Pharmacy #212 shall submit its Policies and Procedures Manual to the Board, for its approval, before January 5, 1994. The manual must specifically address issues of patient records, dispensing accuracy, incident report procedures, prospective drug review, patient counseling, and procedures for Schedule II controlled substance prescriptions.

...

e. ...Respondent shall cause any new pharmacy employee, including a temporary, part-time, or full-time pharmacy employee, to report to the Board in writing acknowledging that the employee has read the Board's Order.

...

8. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

...

10. Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further

discipline. If a petition to revoke probation is filed against the pharmacy during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

11. On March 23, 1994, the Board issued a letter of warning to Respondent. The letter advised Respondent that "continued dispensing errors...which indicate a lack of adequate pharmacist staffing or a lack of effective patient counseling, may result in further formal disciplinary action."

12. On April 1, 1994, the Board received a written response from Robert W. McCurdy of Phar-Mor Inc., who stated that he did not believe that the dispensing errors were related to scheduling. He indicated that he believed the pharmacy had a pharmacist "quality" problem. He further indicated that pharmacist personnel would be changed.

13. On May 11, 1994, the Board required Respondent to appear at an informal conference on June 9, 1994, to discuss the dispensing errors which had occurred at Phar-Mor Pharmacy #212 since November 23, 1993. Following the informal conference, Respondent submitted a letter dated June 15, 1994, to the Board for its consideration. The letter stated that "we have reviewed the prescription operating procedures of our pharmacy and will make or have made the following changes or additions in order that dispensing accuracy be the number one priority."

14. In a letter dated June 16, 1994, the Board responded to Respondent's letter of June 15 and stated the following:

...The Board has reviewed the proposed changes which you have outlined in your letter and has agreed, at this time, to allow the probationary period of the pharmacy to continue.

....

...[I]t is also our understanding that your pharmacy will increase the pharmacist staffing of the prescription department from approximately 140-145 hours per week to 160-168 hours per week and that you are currently striving to hire an additional pharmacist to alleviate the problems associated with staffing.

The Board will continue to monitor the activities of your pharmacy very closely in order to determine if these changes will enable the pharmacy to function in a manner that protects the public health and safety.

15. A review of the weekly prescription volume and pharmacist staffing at Phar-Mor Pharmacy #212 between June 19, 1994, and January 28, 1995, indicates that dispensing errors have occurred on high prescription volume days and that pharmacist staffing has not reached a consistent level of 160-168 hours per week.

16. A series of 52 documented dispensing errors has occurred at Phar-Mor Pharmacy #212. These errors have included wrong drug (24 times); wrong strength of drug (18 times); wrong quantity of drug (2 times); incorrect drug substitution (2 times); and incorrect labeling, including wrong patient name, wrong doctor name, or wrong directions for use (6 times).

a. During 1993 a total of 22 dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) February 8, 1993 -- wrong drug
- (2) April 12, 1993 -- wrong strength
- (3) May 7, 1993 -- wrong drug
- (4) May 11, 1993 -- wrong quantity of drug
- (5) June 14, 1993 -- wrong directions for use
- (6) July 6, 1993 -- wrong drug
- (7) August 18, 1993 -- wrong quantity of drug
- (8) September 2, 1993 (**two Rx errors**) -- one wrong strength and one wrong drug
- (9) September 3, 1993 -- wrong strength
- (10) September 7, 1993 -- wrong drug
- (11) September 8, 1993 -- wrong strength
- (12) September 9, 1993 -- wrong drug
- (13) September 17, 1993 -- wrong strength
- (14) October 1, 1993 -- wrong drug
- (15) October 4, 1993 -- wrong directions for use
- (16) October 17, 1993 -- wrong patient name
- (17) October 18, 1993 -- wrong patient name
- (18) November 3, 1993 -- wrong drug
- (19) December 20, 1993 -- wrong drug
- (20) December 30, 1993 -- wrong strength
- (21) December 31, 1993 -- wrong strength

b. During 1994 a total of 28 dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) January 6, 1994 (**two Rx errors**) -- one wrong drug and one wrong doctor name
- (2) January 26, 1994 -- wrong drug
- (3) January 29, 1994 (**two Rx errors**) -- both wrong drugs
- (4) January 30, 1994 -- wrong drug
- (5) January 31, 1994 -- wrong strength
- (6) February 1, 1994 -- wrong strength
- (7) February 4, 1994 -- wrong strength
- (8) February 21, 1994 -- wrong drug
- (9) March 1, 1994 -- wrong drug
- (10) March 2, 1994 -- wrong strength
- (11) March 3, 1994 -- wrong strength
- (12) April 12, 1994 -- wrong strength
- (13) April 25, 1994 (**three Rx errors**) --

- one wrong drug, one wrong strength, and one substituted drug
- (14) May 2, 1994 -- wrong drug
  - (15) May 27, 1994 (**two Rx errors**) -- both wrong drugs
  - (16) June 1, 1994 -- wrong strength
  - (17) July 21, 1994 -- wrong directions
  - (18) August 16, 1994 -- wrong strength
  - (19) August 24, 1994 -- wrong drug
  - (20) September 2, 1994 -- wrong strength
  - (21) November 9, 1994 -- substituted drug
  - (22) November 30, 1994 -- incomplete drug
  - (23) December 2, 1994 -- wrong drug

c. During January 1995 a total of two dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) January 10, 1995 -- wrong strength
- (2) January 12, 1995 -- wrong drug

d. Most, if not all, of these 52 dispensing errors which have occurred between February 8, 1993, and January 12, 1995, could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Respondent.

e. Respondent failed to report to the Board a dispensing error which is alleged to have occurred on July 21, 1994. The consumer who reported the dispensing error to the Board has indicated, in writing, that she confronted a male pharmacist at Phar-Mor #212 on July 21, 1994, regarding the error. Respondent reported no errors or incident reports for the month of July 1994.

f. Respondent also failed to report to the Board a dispensing error which is alleged to have occurred on January 6, 1994. The consumer reported the error to the Board by telephone on January 14, 1994.

g. The Board also received another complaint directly from a different consumer on January 14, 1994. That complaint alleged that a male pharmacist at Phar-Mor #212 had failed to provide the consumer with information that she needed.

17. A review of Respondent's hardcopy prescription records from June 1, 1994, to December 27, 1994, has revealed various inconsistencies, ambiguous notations, and a lack of pertinent information on some hardcopy prescriptions.

18. On February 8, 1995, the Board received a complaint from "Jane Doe", a former employee of Phar-Mor #212 (Complaint No. 95010). "Jane Doe" alleged that irregularities were occurring within the prescription department of Phar-Mor #212. The irregularities included misconduct by employees of the prescription department. "Jane Doe" also alleged that the drug "Lortab" was being diverted from the pharmacy by an employee of the prescription department. "Jane Doe" further alleged that she had contacted an assistant store manager at Phar-Mor #212 to report the problems, but that no action was taken. Soon after "Jane Doe" reported the problems to a Phar-Mor company "employee complaint telephone hotline," she was discharged from her employment at Phar-Mor #212. "Jane Doe" has also alleged that Respondent failed to allow her to read the entire Board disciplinary order dated December 9, 1993, when she began working in the prescription department, as required by subparagraph (4)(e) of the Board Order.

19. Respondent has repeatedly been unable to provide accountability for all controlled substances purchased.

a. Respondent's Schedule II Inventory Record for August 1993 revealed a shortage of 273 tablets of Schedule II controlled substances, including Percodan, Ritalin 10mg, and Methylphenidate-SR 20mg.

b. Respondent's Schedule II Inventory Record for September 1993 revealed a shortage of 196 tablets of Schedule II controlled substances, including Oxycodone/APAP, Methylphenidate 10mg, Ritalin 20mg, and Dexedrine 10mg.

c. Two selective accountability audits of Respondent's Schedule III, IV, and V controlled substances were conducted by the Board in February 1995 following receipt of Complaint No. 95010 from "Jane Doe" on February 8, 1995. The audit period for ten Schedule III hydrocodone products was approximately nine months, from May 1, 1994, to February 9, 1995. The audit period for various other Schedule III, IV, and V controlled substances was nearly ten months, from May 1, 1994, to February 22, 1995. These audits revealed the following significant shortages and overages of controlled substances:

(1) A shortage of 13,277 tablets or capsules as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
1,024	Lorcet 10/650
495	Lortab 7.5/500
3,224	Hydrocodone/APAP 7.5/500
3,828	Hydrocodone/APAP 7.5/750
38	Vicodin 5
1,344	Vicodin ES 7.5/750
58	Phentermine 37.5
584	Alprazolam 1
229	Xanax 1
42	Xanax 0.5
527	Xanax 0.25
22	Lorazepam 0.5
73	Valium 10
1,733	Diazepam 10
16	Diazepam 2
40	Ativan 1

(2) A shortage of 5,415ml of oral liquids as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
5,192ml	Promethazine with Codeine Liquid
223ml	Tussionex Suspension

(3) An overage of 1,887 tablets or capsules as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
82	Lortab 2.5/500
75	Hydrocodone/APAP 5/500
29	Ionamin 15
52	Ionamin 30
29	Diethylpropion 75
653	Propoxyphene/NAP/APAP 100
53	Alprazolam 2
112	Alprazolam 0.5
133	Alprazolam 0.25
33	Valium 5
17	Valium 2
23	Diazepam 5
69	Ativan 0.5
527	Lorazepam 1

(4) An overage of 257ml of liquids as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
245ml	Codclear-DH Syrup
12ml	Testosterone Enanthate Injection 200mg

20. A review of selected patient medication profiles at Phar-Mor #212 has revealed that Phar-Mor's pharmacists have failed to conduct effective prospective drug use review (DUR) as required by Board rules. Certain patients appear to have received excessive amounts of certain controlled substances. Phar-Mor pharmacists have failed to take appropriate steps to avoid or resolve over-utilization and clinical abuse or misuse of these drugs.

21. Respondent failed to take a complete and accurate biennial inventory of all controlled substances on May 1, 1994. This failure to take a complete and accurate inventory has contributed to Respondent's inability to provide accountability for all controlled substances purchased by Phar-Mor #212.

22. Respondent failed to maintain in the pharmacy a complete set of purchase invoices for controlled substances purchased by Phar-Mor #212 since May 1, 1994. This failure to maintain invoices has also contributed to Respondent's inability to provide accountability for all controlled substances purchased by Phar-Mor #212.

23. Respondent has again failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy. Respondent has again failed to keep and maintain records as required by law and Board rules. **Respondent has again failed to establish effective controls against loss or diversion of controlled substances.**

24. The staffing and procedures of Respondent's prescription department are still inadequate to protect the public health and safety.

25. Respondent is guilty of violating the terms of its probation by violating paragraphs 2, 3, 4, and 8 of the Board's Order by virtue of the information contained in paragraphs 11 through 24 of this Petition to Revoke Probation.

26. In addition, Respondent is guilty of violating Iowa Code sections 155A.15(2)(c), 155A.15(2)(h), 155A.15(2)(i), 124.308(3), 124.402(1)(a), 124.402(1)(c), and 272C.3(2)(a) by virtue of the allegations in paragraphs 11 through 24 of this Petition to Revoke Probation.

1995 Iowa Code section 124.308 provides, in part, the following:

3. ...[A] controlled substance included in schedule III or IV, which is a prescription drug... shall not be dispensed without a written or oral prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

1995 Iowa Code section 124.402 provides, in part, the following:

1. It is unlawful for any person:
  - a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308;
  - ....
  - c. To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter;

1995 Iowa Code section 155A.13 provides, in part, the following:

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath:...
  - e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

1995 Iowa Code section 155A.15 provides, in part, the following:

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...
  - c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.
  - ....
  - h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.
  - i. Failed to establish effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by this chapter and other Iowa or federal laws or rules.

1995 Iowa Code section 272C.3 provides, in part, the following:

2. Each licensing board may impose one or more of the following as licensee discipline:

a. Revoke a license, or suspend a license... upon failure of the licensee to comply with a decision of the board imposing licensee discipline.

27. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(b), 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraphs 11 through 24 of this Petition to Revoke Probation.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device,

prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

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. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, 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. Prescription refill information;
- i. Action to be taken in the event of a missed dose;
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect call. A combination of oral counseling and alternative forms of counseling is encouraged.

8.20(3) Patient counseling, as described above, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

8.20(4) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

....

i. ...violating a lawful order of the board in a disciplinary hearing...

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The Iowa Board of Pharmacy Examiners finds that paragraphs 25, 26, and 27 allege grounds for which Respondent's probation may be revoked and its license to operate a pharmacy in Iowa can be disciplined.

**IN ADDITION,** the undersigned charges that Respondent Phar-Mor Pharmacy # 212 has violated 1995 Iowa Code sections 155A.15(2)(c), 155A.15(2)(h), 155A.15(2)(i), 124.308(3), 124.402(1)(a), 124.402(1)(c), and 272C.3(2)(a) and 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(b), 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u).

**IT IS HEREBY ORDERED,** pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that Gary L. Levine appear on behalf of Phar-Mor Pharmacy before the Iowa Board of Pharmacy Examiners on Wednesday, April 5, 1995, at 9:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to revoke Respondent's probation and to impose the 90-day license suspension which was stayed on May 14, 1993, and which was again stayed on December 9, 1993, or take whatever other disciplinary action that they deem necessary and appropriate, including permanent revocation of Respondent's license to operate a pharmacy in Iowa.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision, including disciplinary action, may be rendered.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for representation of the public interest in these proceedings. Information regarding the hearing may be obtained from Linny Emrich, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-3658). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS

A handwritten signature in black ink, appearing to read "Lloyd K. Jessen", written over a horizontal line.

Lloyd K. Jessen  
Executive Secretary/Director

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

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Re:	)	<b>ORDER</b>
Pharmacy License of	)	<b>ACCEPTING</b>
<b>PHAR-MOR PHARMACY</b>	)	<b>SURRENDER OF LICENSE</b>
License No. 436,	)	<b>TO OPERATE</b>
Clive, Iowa,	)	<b>A PHARMACY</b>
Respondent	)	

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*COMES NOW*, Phyllis A. Olson, Vice Chairperson of the Iowa Board of Pharmacy Examiners, on the 11th day of July, 1995, and declares that:

1. On March 6, 1995, the Board issued a Second Petition to Revoke Probation and Notice of Hearing to the Respondent.
2. On May 8, 1995, Respondent executed a voluntary surrender of its pharmacy license number 436 pursuant to 657 Iowa Administrative Code § 9.25. The voluntary surrender became effective on May 21, 1995. In so doing, Respondent waived its right to a formal hearing before the Iowa Board of Pharmacy Examiners.
3. On July 11, 1995, the Board reviewed Respondent's voluntary surrender of its license to operate a pharmacy and agreed to accept it.

*WHEREFORE*, it is hereby ordered that Respondent's voluntary surrender of its Iowa general pharmacy license number 436 is hereby accepted and, pursuant to 657 Iowa Administrative Code § 9.25, said surrender shall be considered a revocation of license with respect to any future request for reinstatement.

**IOWA BOARD OF PHARMACY EXAMINERS**



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Phyllis A. Olson, Vice Chairperson

V O L U N T A R Y   S U R R E N D E R   O F  
L I C E N S E   T O   O P E R A T E   A   P H A R M A C Y

Phar-Mor Pharmacy #212 of 10201 "B" University Avenue, Clive, Iowa, of its own free will and without any mental reservation and not as a result of any inducement, promise, or threat on the part of anyone, does hereby voluntarily surrender its license to operate a pharmacy in the State of Iowa, number 436, to the Iowa Board of Pharmacy Examiners. This surrender of license shall become effective upon the signature of an authorized representative of the licensee, Phar-Mor Pharmacy #212, and the issuance of an Order Accepting Surrender of License to Operate a Pharmacy by the Iowa Board of Pharmacy Examiners.

Phar-Mor Pharmacy #212, of its own free will and without any mental reservation and not as the result of any inducement, promise, or threat given or made by any representative, officer, or employee of the Iowa Board of Pharmacy Examiners, or of any other state official, does hereby further acknowledge that by voluntarily signing this surrender statement that it is knowingly and willingly giving up the exercise of the following legal rights:

- (1) Its right to a formal hearing before the Iowa Board of Pharmacy Examiners on the matter of its continued licensure pursuant to Chapter 155A, Code of Iowa 1995.
- (2) Its right to be represented by an attorney in preparation for and during such formal hearing before the Iowa Board of Pharmacy Examiners.
- (3) Its right to submit evidence and to have witnesses called on its own behalf at such formal hearing.
- (4) Its right to be represented by an attorney in this matter at this time.

Phar-Mor Pharmacy #212 does hereby acknowledge that pursuant to 657 Iowa Administrative Code section 9.25, a license to operate a pharmacy which has been voluntarily surrendered shall be considered a revocation of license with respect to a request for reinstatement, which will be handled under the terms established by 657 Iowa Administrative Code section 9.23, which provides as follows:

Any person whose license to...operate a pharmacy...has been revoked...must meet the following eligibility requirements:

1. Must have satisfied all the terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license or permit was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the board's order or the date of voluntary surrender.

3. All proceedings for reinstatement shall be initiated by the respondent who shall file with the board an application for reinstatement of the license. Such application shall be docketed in the original case in which the license was revoked, suspended, or relinquished. All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board. The board and the respondent may informally settle the issue of reinstatement. The respondent may choose to have an informal reinstatement conference before the board, as provided in rule 657-9.24(17A,147,155A,124B, 272C).
4. An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension no longer exists and that it will be in the public interest for the license or permit to be reinstated. The burden of proof to establish such facts shall be on the respondent.
5. An order for reinstatement shall be based upon a decision which incorporates findings of facts and conclusions of law and must be based upon the affirmative vote of a quorum of the board. This order shall be available to the public as provided in 657-Chapter 14.

Phar-Mor Pharmacy #212 hereby further acknowledges that it shall not engage in any of the practices or aspects thereof of the operation of a pharmacy in the State of Iowa for which such a license is required.

5-8-95

Date of Signature

*Robert M. Kuroki*

Authorized Representative  
Phar-Mor Pharmacy #212

Subscribed and sworn to before me this 8<sup>th</sup> day of May, 1995.



CHRISTINE M. MINNOW  
Notary Public - State of Ohio  
My Commission Expires October 7, 1998

*Christine M. Minnow*  
Notary Public