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September 2008 "Part 2 Medication Errors Prevention Update" 707-000-08-009-H05-P

Part 2
"Medication Errors Prevention Update"

<u>Licensed in FL or NY?</u> This lesson, along with next month's, fulfills the mandatory "Medication Errors" requirement.

<u>FL Pharmacists.</u> The combination of this lesson & next month's must be turned in for you to receive credit for CE Broker.

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This is Part 2 of the biannual lesson on "Medication Errors." It's been divided into two portions. In this lesson we discuss: handling an error; patient safety; patient responsibility; drug use review; and regulatory responses. This lesson provides 1.5 hours (0.15 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-08-009-H05-P. Pharmacists completing this lesson by September 30,2011 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. List requirements for a safe healthcare system
2. Describe factors that contribute to pharmacy errors
3. Discuss techniques that can reduce errors
4. Describe media perceptions of pharmacy errors
5. Consider a case study in regulatory response
6. Discuss handling an error

Handling a Medication Error

No matter how good a pharmacy system is, and no matter how conscientious, skilled and caring a pharmacist may be, errors will continue to occur. Errors can be minimized, but they cannot be eliminated. Pharmacists must manage errors after they have occurred, to assure the patient is being protected from the consequences of an error that cannot be undone, and to assure that licensing boards understand that the pharmacist who errs has done the right thing after having discovered the error.

The most important thing to do when an error has occurred is to listen to the patient. This is always a pharmacist's responsibility. It should not be delegated to a technician or to non-pharmacist management. When a patient appears at the pharmacy department and says "I think you may have made a mistake with my prescription," technicians and clerical support staff should be trained to always turn the matter over to the pharmacist. This will not occur at a convenient time, of course. It will inevitably happen on a busy day and during the rush time when patients are impatient and doctors are most arrogant. But the patient who is concerned about a potential error must take priority. There should be a private place to take the patient for a consultation at such times. Other patients do not need to overhear this discussion. It is best for the patient and for the pharmacist that an audience not gather to observe or participate in the discussion.

As the pharmacist listens to the patient, it is important to provide supportive feedback, but to not agree to anything the patient says that is open to question. Apologies are always in order, but they must be used in a safe way. When a patient says, "you people are just too busy, this is why you make so many mistakes," the pharmacist should say "I am very sorry you feel that way and I will do everything I can to find out what has happened." Agreeing with the patient is an admission of liability and it may not be true that the pharmacy was too busy or that a mistake has been made. It is permissible to make objective observations, but not to editorialize on them. For example, a pharmacist may say "your prescription was for Drug X, and your vial contains Drug Y," without speculating as to how the wrong drug got into the vial. Leave for later the determination of what happened and how it happened.

Patients who believe they may have been the victims of pharmacy error want to be listened to sympathetically; they want an apology; they want the best explanation they can get of what happened and of the consequences to them of the error (if there even has been an error); and they want reassurance that the cause of any error will be studied and changes will be made to reduce the likelihood of such an error in the future. It is impossible to promise that the error will never happen again, and patients should not expect to receive this promise. But the promise that the error will be incorporated into an organized continuous quality improvement program is a realistic promise that patients should be given.

Patient Safety

Principles of patient safety can be learned from a review of a few legal cases that have been brought against pharmacists and pharmacies. The point is not to criticize, but to learn so that prevention in the future can occur.

By far the most common pharmacy medication error is the dispensing of a drug other than the drug ordered by the prescriber. There are many reasons why the wrong drug might be dispensed, most of them having to do with a failure of communication in some way. Written communication and verbal communication may be ambiguous, and when they are, the wrong drug may be dispensed. The use of drug names that look and sound alike is a contributing factor to wrong drug errors in pharmacies. Consider the following case study from a lawsuit reported in Arkansas in 2003.

After working for thirty years in Dallas, Texas, a patient and his wife retired to DeQueen, Arkansas. While in Dallas, the patient had undergone bypass surgery. As of his last check-up in 1996, his cardiologist indicated that he had a life expectancy of five to ten years. When the couple moved to Arkansas, the patient switched to a new family practitioner.

Because the patient was overweight, the family practitioner prescribed Zaroxolyn to help reduce fluid retention due to the patient's diagnosis of congestive heart failure. On May 15, 1997 the
patient took his Zaroxolyn prescription to a pharmacy to have it filled. The pharmacist on duty misfilled the prescription with Ziac rather than Zaroxolyn.

Shortly after May 15, 1997, the patient suffered from substantial weight gain due to water retention. He was eventually hospitalized in DeQueen on July 15, 1997, under the care of his family practitioner. Over the course of several days, doctors were able to reduce his fluid retention and, hence, his excess weight. He was discharged from the hospital on July 20, 1997. At that time, the family practitioner was unaware of the pharmacist's mistake in filling the earlier prescription for

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Zaroxolyn, so he directed the patient to return home and double his dose of Zaroxolyn.

The patient complied with his doctor's instructions; however, because of the misfilled prescription, he proceeded to double his intake of Ziac instead of Zaroxolyn. Once again, the patient experienced a significant gain in weight due to fluid retention. This time, he was hospitalized in Texarkana on July 28, 1997. Upon admission to the hospital, the patient was diagnosed with a kidney illness. During this hospitalization, doctors treated him for the kidney condition and his weight gain due to fluid retention. When the patient was dismissed from the hospital, he was directed to again increase his Zaroxolyn intake.

On August 28, 1997, only two doses remained of the May 15 prescription, so the patient returned to the pharmacy for a refill. The pharmacist who had originally misfilled the prescription examined the two remaining doses and discovered that he had mistakenly filled the prescription with Ziac. Upon discovering the error, he advised the patient that he would contact the patient's doctors. In fact, the pharmacist never did contact any of the patient's doctors, although he did make a call to a doctor's office.

The patient returned home with the properly filled prescription of Zaroxolyn, but without any tapering dose of Ziac. One week later, on September 4, 1997, the patient died of a myocardial infarction. The patient's spouse filed a lawsuit against the pharmacy. A jury awarded the family a total of $1.275 million. This award was upheld on appeal.

Several important lessons emerge from this case report:

- Drugs starting with the same letter are often confused with each other, especially those starting with a distinctive letter such as "V" or "Z" or "X."
- Look alike drugs should not be placed on the shelf together, because they are easily confused with each other.
- Patients who receive a new prescription should be told the name of the drug and the purpose—any indication from the patient that this is unexpected or inconsistent with the doctor's information should be followed up immediately.
- Upon discovering an error, the patient's doctor should always be contacted.

WRONG PATIENT ERRORS

Simply because a prescription has been accurately processed does not mean that the correct patient will eventually receive the prescription. Pharmacies are busy places and certain times of day are very confusing. Patients have similar names or the same name. They may end up receiving medication intended for a different patient. Consider the following case report from Arkansas in 2004.

A patient presented a prescription for Cephalexin and Claritin D 24 Hour at a Siloam Springs pharmacy on November 19, 1998. Instead of receiving his correct medication, the patient was mistakenly given a bag containing medication meant for another patient who had the same last name. The medications he received were triamterene/hydrochlorothiazide and Synthroid. The patient took these medications for approximately two days, allegedly ingesting six triamterene/hydrochlorothiazide doses and two Synthroid doses. The mistake was discovered by the patient's wife after his condition did not improve.

A lawsuit was filed against the pharmacy alleging that the error resulted in post-traumatic stress disorder for the patient. The jury awarded the patient and his wife a total of $840,000. This award was affirmed on appeal. The important lessons from this case include:

- Proper instruction of support staff in the need to identify patients accurately when medications are retrieved in "will-call."
- The process of identifying patients not just by name but also by telephone number and address as well. This assures that pharmacy records are up to date, and that patients with the same name are not confused with each other.
- Reaffirmation that the "show and tell" system used for new prescriptions gives the patient an opportunity to explain that she or he is apparently not the patient for whom medications have been retrieved.

PATIENT RESPONSIBILITY

Although pharmacists have primary responsibility to assure that patients receive the correct medications, patients share the responsibility to look out for their own best interests. One reason dosage units have different colors and shapes is so they will not be confused. A patient who receives a medication that does not look the same as one that has been prescribed for several years should speak up. Patients who do not understand something they have been told should say so. Patients who wish to be provided information about medications should accept an offer of counseling when it is made. The following case report from California in 2002 describes one circumstance in which a patient did not meet his responsibility to protect himself from adverse drug effects.

The patient received two prescriptions, one for trazodone and one for Zoloft. On May 15, 1998 the patient dropped these prescriptions off at his pharmacy. The next day, when he picked up the medications, a pharmacy clerk noted that

the patient had already been using Zoloft, but he asked whether the patient would like to speak with the pharmacist about trazodone. The patient testified that the conversation occurred this way:

"And so when I came up to the cashier, she took the prescription and looked on the screen, and she said, 'Oh, you have already been taking the Zoloft.' And she asked me if I wanted to speak to the pharmacist about the sleep aid. And I kind of joked with her and said you know, 'Oh I don't need to talk to him about a sleeping pill,' you know, and that was the end of our conversation."

The patient also testified that he had declined counseling from the pharmacist "because I thought of the sleep aid as a not very powerful drug. I mean, you could get sleep aids at 7-Eleven." And when asked at deposition, "Did you have any questions about the trazodone?" the patient responded: "No."

The patient also signed a form entitled "Patient Counseling/Eligibility Form" when he picked up his medications. Above his signature was checked a box next to the statement: "I do not wish to be counseled by the pharmacist and I do not have any questions."

At the time the patient picked up his medication, the pharmacy maintained a computer system with patient profiles from which it could be determined whether the patient was receiving a new prescription. With newly prescribed drugs, the pharmacy provided a written handout that, among other things, warned of the side effects of taking the drug. Nonetheless, transmittal of this information to the patient was not a pharmacy requirement. And the patient testified that he never received this written information.

After the patient took the drug at bedtime several days later, he awoke with an erection that did not subside. The pharmacy's written information for trazodone stated: "Males: notify your doctor immediately if you experience painful and prolonged erections." The patient was not treated for at least three days, and he sustained permanent injury.

The patient sued the pharmacy alleging that the pharmacy "negligently and carelessly compounded, prepared and otherwise dispensed" trazodone to him, that it "knew or should have known of the serious and foreseeable side effects of trazodone," and that it "negligently and carelessly failed to warn, advise or otherwise inform him of the known and knowable side effects of the drug trazodone."

The court dismissed the case against the pharmacy, ruling that the patient had waived his right to counseling under California regulations applicable to pharmacies. The court also ruled that the patient had waived any right to counseling that might exist under the law of negligence. This dismissal was affirmed on appeal. The case has several important lessons for medication error prevention:

- Be sure to offer counseling on all new prescriptions and do so in an audible and obvious way.
- Document all refusals of counseling with patient signature accompanying the documentation.
- Develop a policy of distributing warning leaflets with all new prescriptions to assure that patients have been put on notice of drug side effects, and have the policy available as proof that responsibilities are being met.

DRUG USE REVIEW

When the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) was passed, it was generally viewed as a uniform patient counseling requirement, but the section of the legislation requiring prospective drug use review (DUR) by pharmacists prior to dispensing was not given extensive attention. As it has turned out, the DUR provisions are more important than the patient counseling provisions. While patient counseling may be waived by the patient, DUR may not be. Under the DUR requirements, pharmacists must screen each new prescription to determine whether any potential problems with drug therapy exist, and these potential problems must be resolved before the medication is dispensed. The following case report from Illinois in 2004 describes how this DUR requirement was allegedly not met.

On August 4, 1993, a man went to a pharmacy and picked up a prescription for the drug Toradol, for his wife. The prescription had been telephoned in earlier that day by the wife's physician. Computer information in the pharmacy showed that the wife was allergic to aspirin and ibuprofen. Neither the husband nor the wife was aware that Toradol was an NSAID, nor had they any reason to believe that the wife would be allergic to the medication.

According to the allegations of a subsequent lawsuit, the pharmacy computer system would have displayed a warning when the husband asked for the Toradol, because of the wife's allergies to NSAIDs. They further alleged that the pharmacy computer system would not allow a prescription label to be printed after such a warning, unless the pharmacist manually overrode the system. Also, they alleged that it was pharmacy policy to prevent the pharmacist from doing an override without first talking with the prescribing physician. The lawsuit contended that one or more pharmacy employees noticed the warning and knew that Toradol would have a harmful effect on the wife, but printed the prescription label nonetheless, intending to cause her harm.

After taking the Toradol, the wife suffered severe, long-term medical problems as a result of her allergic reaction to the drug. The lawsuit alleged that these problems resulted from the negligence of the pharmacy personnel, and that the pharmacy personnel had acted in a willful and wanton manner, intending to harm the wife. Thus far, the legal right to maintain this lawsuit has been upheld by the courts. While it is not yet known whether the patient or the pharmacy will ultimate-

ly prevail, the case does teach important lessons.

- Only pharmacists should accept responsibility for DUR overrides; support personnel must be taught to refer overrides to a pharmacist.
- Any time a DUR alert indicates a potential for harm to a patient, the prescriber should be contacted to assure that the prescription is safe for the patient.
- All DUR consults should be clearly documented in a record that can be located later, to provide assurance to those reviewing pharmacy actions that the actions were appropriate.

REGULATORY RESPONSES TO PHARMACY ERROR

Through their boards of pharmacy, pharmacists have been given regulatory authority to solve the problem of medication errors, by adopting regulatory practices that protect the public health. As self-regulating professionals, pharmacists have struggled with the development of an appropriate solution to the difficult problem of pharmacy error. Punishment of pharmacists is ineffective, because pharmacists do not make mistakes intentionally, and punishment does not deter unintentional actions. Reporting systems do not reliably produce solutions, because practice sites vary considerably, and centrally located reporting system administrators have difficulty knowing which solutions to error will actually work at a distant practice site.

Educational programs likewise cannot provide a high level of assurance that changes will be made effectively, because the necessary step between education and implementation is not always present. Most regulators believe that a multi-faceted approach is the most effective. A case study from Nevada provides a useful example of such a multi-faceted approach.

A CASE STUDY IN REGULATORY RESPONSE

BEFORE THE NEVADA STATE BOARD OF PHARMACY, NEVADA STATE BOARD OF PHARMACY, Petitioner,
FINDINGS OF FACT, v. CONCLUSIONS OF LAW AND ORDER.
PAMELA S. GOFF, RPh, Certificate of Registration No: 15083, Case Number 06-069A-RPH-S.
NAZANIN REZVAN, RPh, Certificate of Registration No: 16715, Case Number 06-069B-RPH-S.
JACKSON YU, RPh, Certificate of Registration No: 15169, Case Number 06-069C-RPH-S.
ASIA I. CORNELIUS, PT, Certificate of Registration No: PT04626, Case Number 06-069-PT-S.
SUMMERLIN HOSPITAL MEDICAL CENTER PHARMACY, Certificate of Registration No: IA02194, Case Number 06-069-IA-S. Respondents. _____/

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on July 25, 2007, in Las Vegas, Nevada. The Board was represented by Louis Ling, General Counsel to the Board. Respondent Pamela Goff was represented by Robert Graham and Rob Graham & Associates; Respondent Nazanin Rezvan was represented by John Bailey and Bailey and Merrill; Respondent Jackson Yu was represented by Mr. Bailey and by Wendy Cozal; Respondent Asia Cornelius was represented by Mr. Bailey; and Respondent Summerlin Hospital Medical Center Pharmacy (Summerlin Pharmacy) was represented by Michael Prangle and Kenneth Webster and Hall, Prangle & Schoonveld, LLC. Based on the presentations of the parties and the public records in the possession and control of the Board, the Board issued the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. At hearing, Board Staff presented the testimony of Pamela Goff, Nazanin Rezvan, Asia Cornelius, Jackson Yu, Gretta Woodington, and Kathleen Shinn. The parties stipulated to the entry of five exhibits, four proffered by Board Staff and one proffered by Summerlin. Based on the testimony and evidence presented to the Board, the presentations of the parties, and the public records in the possession and control of the Board, the Board finds the following to be the facts in this matter.

2. On October 19, 2006, Alyssa Shinn was born to Mr. and Mrs. Shinn at Summerlin Hospital. Alyssa Shinn was born prematurely, weighing slightly over one pound at birth, and was placed in the Neonatal Intensive Care Unit (NICU) at Summerlin Hospital. Alyssa Shinn was under the care and treatment of Dr. Zenteno.

3. As part of Alyssa Shinn's care, Dr. Zenteno had ordered that Alyssa Shinn receive total parenteral nutrition (TPN), and those TPN orders were compounded by Summerlin Pharmacy. Per Summerlin Pharmacy's policies and procedures, compounded orders such as TPN orders were to be received by the Summerlin Pharmacy by 5:00 p.m. each night.

4. On November 8, 2006, Dr. Zenteno created a written order for TPN for Alyssa Shinn. The written order showed that Dr. Zenteno created the order at 4:30 p.m., but the order was not scanned into the computer system and received by the pharmacy until after 5:00 p.m. One of the components included in the TPN order for Alyssa Shinn was zinc, written by Dr. Zenteno for the concentration of 330 mcg/100 ml.

5. At 7:44 p.m., Ms. Goff processed the TPN order for Alyssa Shinn into the pharmacy's computer system. Because Dr. Zenteno's order for the zinc was written in quantity per volume rather than in quantity per patient weight, and because Summerlin Pharmacy's automated TPN compounding device (known as a BAXA device) was set up for orders to be placed in quantity per weight, Ms. Goff calculated the total volume for the bag that would contain the finished TPN, and then performed a calculation to convert Dr. Zenteno's zinc order as appropriate for the total volume of the bag. Ms. Goff performed this first calculation correctly, but because there had been concerns raised by the nursing staff regarding the quantity per volume calculations appearing on TPN labels, Ms. Goff recalculated the zinc order to convert it from mcgs/deciliters to mcgs/kilograms. In recalculating the zinc order, Ms. Goff selected "mg" for the quantity rather than "mcg" as ordered, thus resulting in a final quantity of zinc of 330 mg per 100 ml rather than 330 mcg per 100 ml. Thus, when Ms. Goff printed the two label sets for the preparation of Alyssa Shinn's TPN order per Summerlin Hospital's policies and procedures, the labels contained an incorrect dose of zinc that was one thousand times more than ordered.

6. After creating the two label sets, Ms. Goff presented the label sets to Ms. Rezvan for Ms. Rezvan's double-checking of the accuracy of the data entered by Ms. Goff that was contained on the label sets. Such double-checking is required by Summerlin Pharmacy's policy and procedure for TPNs. Ms. Rezvan received Alyssa Shinn's TPN order, but, in violation of Summerlin Pharmacy's policy, did not place her initial on the label sets. Ms. Rezvan failed to catch the error Ms. Goff had committed regarding Alyssa Shinn's TPN order. At hearing, Ms. Rezvan explained that she simply did not notice the "mg" instead of the "mcg" that should have been on the zinc component of the order. After completing her check of the order, per Summerlin Pharmacy's procedure, Ms. Rezvan forwarded the label sets to the compounding room so that the order could be filled.

7. Ms. Cornelius was the pharmaceutical technician who performed the compounding on November 8, 2006. Ms. Cornelius was asked to compound a few products November 8, 2006 because the usual compounding pharmaceutical technician was unavailable that night.

8. Ms. Cornelius' testimony and the testimony of the pharmacists who worked with her or who supervised her showed that Ms. Cornelius was poorly trained regarding the compounding of products using the BAXA device. Several of the pharmacists who worked with Ms. Cornelius gave specific instances where Ms. Cornelius made errors in filling prescription orders. According to Ms. Cornelius, her training consisted of watching another technician use the BAXA device for about one week. Ms. Cornelius explained that prior to compounding Alyssa Shinn's TPN, she had compounded fewer than 20 other products using the BAXA device. Ms. Cornelius testified that she had not replenished a syringe on the BAXA device before the night of November 8, 2006, and she was so poorly trained and unknowledgeable that she did not sense or understand that anything was wrong with Alyssa Shinn's TPN processing even though she replenished the zinc syringe numerous times. At hearing, Ms. Cornelius' testimony created the impression that she was sincere in her ignorance, but that her ignorance was profound. The testimony also showed that Summerlin Pharmacy had been told by its staff about concerns with Ms. Cornelius' competence and ignorance, but, nonetheless, Ms. Cornelius was allowed to compound TPNs by Summerlin Pharmacy.

9. When Ms. Cornelius compounded Alyssa Shinn's TPN, she was required because of the total calculated volume to use a 500 ml bag rather than the 250 ml bag that was usual for neonatal patients. Ms. Cornelius replenished the zinc supply in the BAXA device eleven times in the course of making Alyssa Shinn's TPN, accounting for 45-48 vials of zinc. Even though such a quantity of zinc was unprecedented to Ms. Cornelius, she did not speak of her knowledge or concerns regarding the zinc to any pharmacist on duty on the evening of November 8, 2006. As part of preparing Alyssa Shinn's TPN order, Ms. Cornelius manually added two ingredients beyond those that were placed in the bag by the BAXA device. Per Summerlin Pharmacy policy and procedure, when Ms. Cornelius completed the compounding of Alyssa Shinn's TPN order, she presented the bag on which one of the two label sets had been placed, the duplicate label set, and the vials and syringes for the two manually-added ingredients to Mr. Yu for his verification. At hearing, Ms. Cornelius explained that she did not tell Mr. Yu or any other pharmacist about the huge quantity of zinc she had added to Alyssa Shinn's TPN because she did not know or think there was anything wrong with what she had done.

10. Mr. Yu verified Alyssa Shinn's TPN order presented to him by Ms. Cornelius. At the time, Summerlin Pharmacy's policy and procedure required the verifying pharmacist to verify only the vials and syringes of the manually added ingredients, but did not require the verifying pharmacist to compare the completed TPN product with the order to verify whether the completed TPN product was compliant with the order. When Mr. Yu verified Alyssa Shinn's TPN order as filled by Ms. Cornelius, he performed the verification according to Summerlin Pharmacy's policy and procedure, thus performing a verification limited to verifying the vials and syringes of the manually added ingredients. Because Ms. Cornelius did not inform Mr. Yu of the unusual quantity of zinc she had used, and because the zinc was not manually added but added to

the bag by the BAXA device, and because Mr. Yu performed only the limited verification required of him by Summerlin Pharmacy, Mr. Yu did not catch that Alyssa Shinn's TPN bag contained a one thousand times overdose of zinc.

11. At hearing, Mr. Yu explained that he followed Summerlin Pharmacy's policy and procedure rigidly and that he looked only at Alyssa Shinn's identifying information at the top of the BAXA printout and at the manual additive information on the bottom of the printout and that he did not look at any of the ingredient information in the middle of the printout. Mr. Yu admitted that there were several clues that something about Alyssa Shinn's order were wrong, including the large size of the IV bag and the clear statement on the printout – had he read it – that the bag contained 481.80 mls of zinc in a bag that contained a total of 580 mls. In close questioning from several Board members, Mr. Yu revealed that his "verification" was really cursory, since he admitted that he did not seek out any information beyond the BAXA printout, which did not include Alyssa Shinn's weight, and that had he examined even the three manual additives that he did look at closely he would have seen that even they were not calculated properly. Nonetheless, throughout his testimony, Mr. Yu insisted that he bore no responsibility for the error regarding Alyssa Shinn's TPN because he had followed Summerlin Pharmacy's policy and procedure, even though his verification failed to catch the calculation errors on the few items he admits he did check, namely the manual additives.

12. After verifying Alyssa Shinn's TPN bag, Mr. Yu gave it back to Ms. Cornelius for her to manually add the manual additives. Ms. Corrnelius made the manual additions to Alyssa Shinn's TPN bag and sent it to the NICU for administration to Alyssa Shinn.

13. At approximately 3:00 a.m. on November 9, 2006, nursing staff at the NICU began administration of the TPN bag that contained the zinc overdose.

14. On November 9, 2006 at approximately 6:00 a.m., Ms. Cornelius was going off shift and Rebecca Weiss, a lead pharmaceutical technician, was coming on shift. In the course of discussing the previous evenings work, Ms. Cornelius related to Ms. Weiss the unusual preparation of Alyssa Shinn's TPN order because Ms. Cornelius had had to replenish the zinc in the BAXA machine numerous times to create the TPN bag. Ms. Weiss immediately rechecked Alyssa Shinn's order and discovered the zinc overdosing, and thereafter she took her concerns to Mr. Yu's attention. At approximately 6:15 a.m. on November 9, 2006, Mr. Yu contacted the NICU and ordered that Alyssa Shinn's TPN be immediately discontinued, which it was. Mr. Yu thereafter contacted the managing pharmacist for Summerlin Pharmacy, Gretta Woodington, and the poison control center and began internet research to determine whether there was an antidote for a zinc overdose. The possible antidote was determined to be EDTA. Some time after 8:00 a.m., when Mr. Yu went off shift and left Summerlin Pharmacy, a compounded order for EDTA was received from a private retail pharmacy and was administered to Alyssa Shinn.

15. Unfortunately, the EDTA did not reverse Alyssa Shinn's overdose. At approximately 4:20 p.m. on November 9, 2006, Alyssa Shinn was declared dead. The Clark County Coroner ruled that the cause of Alyssa Shinn's death was zinc intoxication.

16. At hearing, Ms. Woodington testified that she took over in July 2006 as the seventh managing pharmacist in approximately four years as a result of being hired as a consultant when Summerlin Hospital made the transition from a contract operator of the pharmacy to Summerlin retaking management of the pharmacy. Ms. Woodington testified that she had been reviewing and changing all of the pharmacy's operations and that, unfortunately, review and changes to the TPN compounding process had not yet made it to her attention by November 8, 2006 because of other issues she had been reviewing and dealing with. Ms. Woodington testified that the day after Alyssa Shinn's death, November 10, 2006, she conducted a root-cause analysis regarding the error. As a result of the error, she instituted several changes in policy. One change was to add "hard stops" and "medium stops" into the BAXA devices computer programming. A "hard stop" would not allow pharmacy personnel to go forward with the compounding because the amount of a component was too high. A "medium stop" would require pharmacist review and intervention before the order could be further processed because the amount of a component had crossed a threshold indicating that the amount should be questioned. Ms. Woodington also changed the policy regarding TPNs to require that trace minerals be manually added and no longer included in the BAXA compounding. Ms. Woodington also changed Summerlin Pharmacy's policy and procedure regarding the final verification of a TPN by a pharmacist so that the pharmacist is now required to review the entire order and compare the order with the printout and label from the BAXA device. Finally, Ms. Woodington explained that Summerlin Hospital changed the Neonatal TPN Order form so that all of the routine components of a neonatal TPN were required to be written consistently with the templates contained in the BAXA device so that all physicians ordering neonatal TPNs must now write the orders in a way that no recalculation by pharmacy or nursing staff will be required.

17. Ms. Shinn told the Board that she is a practicing nurse of many years' experience, so she understood medically what had happened with her throughout her and her husband's attempts to conceive, the complications with her pregnancy, and Alyssa's medical condition. Ms. Shinn testified that she and Richard had determined to start a family and that their first pregnancy terminated by miscarriage. Ms. Shinn explained that Alyssa was conceived as the result of a lengthy and costly process of in vitro fertilization and that her pregnancy was difficult and complicated. Alyssa was born prematurely by caesarian section because of medical complications that threatened Ms. Shinn's and Alyssa's life. When Alyssa was born, she was one pound, four ounces. Ms. Shinn explained that up to November 8, 2007, Alyssa was progressing well. Alyssa was able to breathe without a respirator, had just begun consuming some milk provided by Ms. Shinn, and had gained almost three-fourths of a pound. Thus, according to Ms. Shinn, up until the zinc overdose, all signs regarding Alyssa seemed to be positive.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter because Respondents Goff, Rezvan, and Yu are pharmacists licensed by the Board; Respondent Cornelius is a pharmaceutical technician registered with the Board; Summerlin Pharmacy is a pharmacy licensed with the Board.

2. In entering the amount of zinc for Alyssa Shinn's TPN order incorrectly by entering the order for milligrams instead of micrograms, Ms. Goff violated NRS 639.210(4) and NAC 639.945(1)(i).

3. In failing to catch the one thousand times overdosing of zinc on the label prepared by Ms. Goff for Alyssa Shinn's TPN order when verifying the accuracy of Ms. Goff's data entry regarding the order, Ms. Rezvan violated NRS 639.210(4) and NAC 639.945(1)(i).

4. In failing to verify the correctness of the entirety of Alyssa Shinn's TPN order as prepared by and presented to him by Ms. Cornelius, especially where the label and bag size would have reasonably indicated that the order might be incorrect, Mr. Yu violated NRS 639.210(4) and NAC 639.245(1)(b) and (c), 639.252(1), 639.467(3), 639.475(2)(d), and 639.945(1)(i).

5. In establishing and enforcing the policies and procedures and in owning and operating the pharmacy in which all of the above factual allegations and legal violations occurred, Summerlin Pharmacy violated NRS 639.210(4) and NAC 639.945(1)(i).

6. The Third Cause of Action is dismissed.

ORDER

Based Based upon the foregoing, the Board hereby orders the following regarding the Respondents in this matter:

1. Ms. Goff shall pay a fine of $5,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.

2. Ms. Rezvan shall pay a fine of $2,500.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.

3. Mr. Yu shall pay a fine of $2,500.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.

4. Summerlin Pharmacy shall pay a fine of $10,000.00 by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within 90 days of the effective date of this Order.

5. Summerlin Pharmacy shall pay the Board's costs and attorney's fees of $12,467.38 and the Board's administrative fee of $295.00, for a total of $12,762.38 by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" to be received by the Board's Reno office within 90 days of the effective date of this Order.

6. The licenses of Ms. Rezvan and Mr. Yu shall each be suspended for 30 days commencing August 22, 2007 and ending September 21, 2007. During the period of suspension, neither Ms. Rezvan nor Mr. Yu may work in any capacity in any business or facility licensed or registered by this Board.

7. Ms. Goff, Ms. Rezvan, and Mr. Yu shall each participate in the Your Success Rx pharmacist’s remedial program (hereinafter “the program”) according to the terms and conditions imposed by the program. Each shall contact the program within ten days of the effective date of this Order to arrange for her or his participation in the program.
a. Each pharmacist shall cooperate fully and genuinely with the needs, demands, and requirements of the program.
b. Each pharmacist shall inform and assure that her or his employing pharmacy is made aware of his participation in the program and that her or his employing pharmacy accommodates the program’s needs regarding her or his time needed to participate in the program and the program’s potential need to be present in the employing pharmacy.
c. Each pharmacist shall pay the costs of her or his participation in the program. After receiving an invoice from Your Success Rx, Board Staff shall pay the invoice and shall inform the pharmacist of the amount due for the invoice, which the pharmacist shall pay to the Board by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" within 30 days of being notified by Board Staff of the amount due.
d. When each pharmacist has completed the program, the program shall submit to Board Staff a final report regarding each’s participation in the program. Board Staff may set an item on the Board’s subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board’s agenda, the pharmacist may be required by Board Staff to be present for the Board’s discussion, which may be held in open or closed session at the discretion of the Board.
e. Mr. Yu shall complete 10 hours of continuing education specifically addressed to parenteral nutrition or error prevention. The hours of continuing education shall be completed before Mr. Yu renews his pharmacist’s license and shall be in addition to the continuing education hours required for renewal of his license.

8. Ms. Goff’s pharmacist’s license shall be on probation for a period of one year from the effective date of this Order, during which probation she shall comply with all laws related to the practice of pharmacy, whether state or federal and whether statutory or regulatory.

9. Summerlin Pharmacy shall participate in the Your Success Rx pharmacist’s remedial program (hereinafter “the program”) according to the terms and conditions imposed by the program. Summerlin Pharmacy shall contact the program within ten days of the effective date of this Order to arrange for its participation in the program.
a. The purpose of the program’s involvement with Summerlin Pharmacy is to review the pharmacy’s policies and procedures, working conditions, staffing, and actual operations so that the program can assess and analyze the present operations, make findings regarding the quality of the present operations, and make recommendations regarding the present operation to improve its safety and service in the public interest.
b. Summerlin Pharmacy and all of its personnel shall cooperate fully and genuinely with the needs, demands, and requirements of the program. Summerlin Pharmacy shall make available to the program any documents, access to personnel, or use of the facilities as the program deems necessary to complete the program’s work under this Order.
c. Summerlin Pharmacy shall assure that its personnel are made aware of its participation in the program and that it and its personnel accommodate the program’s needs regarding the time needed to participate in the program and the program’s potential need to be present in the employing pharmacy.
d. Summerlin Pharmacy shall pay the costs of its participation in the program. After receiving an invoice from Your Success Rx, Board Staff shall pay the invoice and shall inform Summerlin Pharmacy of the amount due for the invoice, which Summerlin Pharmacy shall pay to the Board by cashier's or certified check or money order made payable to "Nevada State Board of Pharmacy" within 30 days of being notified by Board Staff of the amount due.
e. When the program has completed its work regarding Summerlin Pharmacy, the program shall submit to Board Staff a final report regarding its findings and recommendations. Board Staff shall set an item on the Board’s subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board’s agenda, appropriate and knowledgeable members of Summerlin Pharmacy or management for Summerlin Hospital may be required by Board Staff to be present for the Board’s discussion, which may be held in open or closed session at the discretion of the Board. The Board retains its jurisdiction to order further action regarding Summerlin Pharmacy based upon the recommendations from the program, which additional action shall be part of the agenda item regarding the program’s report to the Board.
f. One year from the program’s completion of its report, the program shall revisit Summerlin Hospital under the same terms and conditions as are set out in this Order to assess and analyze whether the recommendations made in the report have been implemented and whether the pharmacy is operating safely and in the public interest. The program

shall submit a report to the Board at the completion containing its findings and recommendations, if any. Board Staff shall set an item on the Board's subsequent agenda regarding the report to discuss the report with the Board. If Board Staff determines to set an item on the Board's agenda, appropriate and knowledgeable members of Summerlin Pharmacy or management for Summerlin Hospital may be required by Board Staff to be present for the Board's discussion, which may be held in open or closed session at the discretion of the Board. The Board retains its jurisdiction to order further action regarding Summerlin Pharmacy based upon the recommendations from the program, which additional action shall be part of the agenda item regarding the program's report to the Board.
g. The program may, in its discretion, employ such experts or consultants as it deems necessary to complete the evaluation, analysis, and reporting required of the program by this Order. Such costs of experts or consultants will be included as part of the program's invoice.

10. The failure by any pharmacist to comply with any term in this order shall result in the immediate suspension of her or his license and will also result in further discipline, up to and including revocation of the her or his license. The failure by Summerlin Pharmacy to comply with any term in this order shall result in a fine of $1,000 per day for every day that it has failed to comply with the Order until the Order is fully complied with, up to a total fine not to exceed $30,000, and will also result in further discipline, up to and including revocation of the its license. Signed and effective this 9th day of August, 2007.
J. David Wuest, President Nevada State Board of Pharmacy

Conclusion

Medication errors cannot be prevented, but they can be managed. Working together and sharing responsibility, pharmacists and managers can establish effective systems of risk management for the benefit of patients and for the benefit of the pharmacy. There is no generic error prevention program that will work in every pharmacy, because every pharmacy has unique challenges and unique needs. Those working in a pharmacy must join together to determine what techniques will work for them. Implementation of these techniques is the responsibility of everyone associated with the pharmacy, and evaluation of the techniques will teach lessons about what works and what does not work. Pharmacists constantly learn from the past and improve for the future, reducing medication errors that cause harm to patients.

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

List requirements for a safe healthcare system	Yes	No
Describe factors that contribute to pharmacy errors	Yes	No
Discuss techniques that can reduce errors	Yes	No
Describe media perceptions of pharmacy errors	Yes	No
Consider a case study in regulatory response	Yes	No
Discuss handling an error	Yes	No
2. Was the program independent & non-commercial	Yes	No

	Poor			Average		Excellent
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____

5. What did you like least about this lesson?_____

Please Select the Most Correct Answer

1. If patients have been taking a specific medication for a long time, receive a refill, & it looks different, the patient has no responsibility to tell the pharmacist.
   A. True
   B. False
2. Patients share a responsibility regarding the receipt of correct medications.
   A. True
   B. False
3. What is the most important portion of OBRA-90?
   A. Patient counseling
   B. DUR provisions
   C. Drug interaction considerations
   D. Screening patient compliance
4. What comment should be made to patients after an error is discovered?
   A. We'll never do this again
   B. This will be prevented in the future
   C. Make no promises to patients
   D. This error will be studied in a continuous quality improvement program.
5. What should pharmacists do when an error occurs?
   A. Call an attorney
   B. Deny the error
   C. Listen
   D. None of these
6. The most common pharmacy medication error is:
   A. Wrong drug
   B. Wrong patient
   C. Wrong directions
   D. None of these
7. Look-alike drugs should be placed on the shelf together.
   A. True B. False
8. Which of these is true?
   A. New prescriptions must be screened to determine if potential problems exist
   B. Potential problems must be resolved prior to dispensing
   C. DUR is more important than counseling
   D. All of these
9. Medication errors can be:
   A. Prevented
   B. Managed
   C. Reduced
   D. B & C
10. The pharmacy technician who initially prepared the TPN with the zinc overdose in the Shinn case created what impression with the Board of Pharmacy?
    A. Minimal competence
    B. Adequate competence
    C. Profound ignorance
    D. Lack of sincerity

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