DISCUSSION AND DETERMINATION – MARCH 2016

PRESCRIPTION OTC’S

Recently Board staff received a complaint as follows:

- A veterinarian wrote a prescription for insulin for a canine just recently diagnosed with diabetes, and with specific instructions for dosage. The primary reason for the prescription by the vet was to ensure that the pet owner would be counseled on how to draw-up, inject and store the insulin, since the pet owner had no experience with injectables whatsoever. The pet owner took the prescription to a pharmacy where it was tendered to a pharmacy tech. After looking at the Rx, the tech told the customer that a prescription was not necessary for insulin, and to step to the next window where it was sold to her along with a box of syringes and no mention of the instructions. When the pet owner asked how much to give on the syringe, the response was simply “it’s on the syringe”. The pet owner returned home; filled the syringe; injected the dog; then watched as the dog bottomed out to near coma. Rushing the dog to the vet’s office, it was discovered that she had overdosed the pet tenfold, and had no clue as to how to dose the insulin.

For you to ponder:

- Should a pharmacy be required to put a prescription for an OTC product through the prescription filling process?
- Should the patient make that choice? Or the prescriber?
- Does the pharmacy have an obligation to counsel the patient on an OTC prescription that is simply purchased?
- Should pharmacy staff be trained to take such prescriptions to the pharmacist prior to simply selling the product to the patient?
- Does the pharmacy’s responsibility “go away” if they choose to sell the product OTC rather than fill the prescription?

Board staff seeks some guidance.

NRS 639.211 however mandates that the adjudication of insanity or mental illness or voluntary admission to any hospital for a mental illness deems that person’s license immediately suspended. Adjudication may take a while.

Further, NRS 639.210 gives the Board authority (not the Executive Secretary) to suspend or revoke a license for a myriad of reasons. Obviously this requires the Board to meet, and again that may take a while.

On occasion (including a recent one), staff is informed of a pharmacist or tech showing up to work under the influence or who has tested positive for an illicit drug (cocaine; meth; heroin). Staff feels powerless in such instances to fulfill our duty to protect the
REGULATIONS PERTAINING TO THE FILLING AND VERIFYING OF PRESCRIPTIONS

In January the Board received a request from a pharmacy to amend NAC 639.921. Currently the regulation allows companies under common ownership to share information between their computer systems. The proposed amendment would expand that ability to share information to companies that are unrelated, but have contractually agreed to share information and filling services. The proposed amended language is attached as Addendum #1.

The Board also entered an order in January reaffirming the obligations and responsibilities of a pharmacist who participates in a segmented filling process, where the filling process is divided into distinct tasks that are performed by 2 or more pharmacists, some of whom may be performing their assigned task from facilities located in other states. That Board Order is attached as Addendum #2.

Further, the Board has existing regulations that relate to the filling process, and in particular, place specific responsibilities on the pharmacist on duty, the managing pharmacist, the owner of a pharmacy, and pharmacists performing supervisory functions. A copy of several of those regulations are attached as Addendum #3. In its consideration of the proposed amendment to NAC 639.921, Board Staff recommends a broader discussion and possible determination(s) regarding the interplay between existing law, the Board's order(s) and trends within the industry. Nevada-licensed pharmacies and pharmacists benefit from a clear understanding of the law and their responsibilities when engaged in the practice of pharmacy.
ADDENDUM #1

Proposed Revisions to NAC 639.921

NAC 639.921 Sharing information between systems: Conditions and requirements. (NRS 639.070, 639.0745, 639.236)

1. Information concerning prescriptions may be shared between the computerized systems of two or more pharmacies licensed by the Board if:

(a) The pharmacies are commonly owned or, if not commonly owned, have a written agreement that outlines the services to be provided and the accountabilities of each pharmacy in compliance with federal and state law; and

(b) The computerized systems for recording information concerning prescriptions share a common database that:

1) Except as otherwise provided in subsection 3, contains all the information concerning a patient that is contained in each computerized system that has access to the common database;

2) Except as otherwise provided in subsection 3, contains all the information concerning a prescription that is contained in each computerized system that has access to the common database;

3) After a prescription has been filled, automatically decreases the number of refills remaining for the prescription, if any, regardless of which pharmacy filled the prescription;

4) Automatically stores any modification or manipulation of information concerning a prescription made by a pharmacy with access to the common database so that the modification or manipulation is available to each pharmacy with access to the common database;

5) Allows access only by a person who is authorized to obtain information from the common database;

6) Requires any person who is authorized to modify or manipulate information concerning a prescription, before modifying or manipulating the information concerning the prescription, to identify himself or herself in the computerized system by:

(I) Using a biometric identification technique; or

(II) Entering into the computerized system another unique identifier which is approved by the Board and which is known only to and used only by that person;

7) Makes and maintains an unchangeable record of each person who modifies or manipulates information concerning the prescription, that includes, without limitation:

(I) The name or initials of the person;
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(II) An identifier that can be used to determine the pharmacy in which the person modified or manipulated the information concerning the prescription; and

(III) The type of activity concerning the prescription that the person performed, including, without limitation, modifying or manipulating the information concerning the prescription;

(8) Contains a scanned image of the original prescription if the original prescription is a written prescription; and

(9) Provides contact information for the first pharmacist who verifies the correctness of the information contained in the common database concerning the prescription.

2. If a pharmacy is the initial pharmacy to receive a written prescription, a pharmacist shall ensure that:

(a) The written prescription is numbered consecutively in accordance with NAC 639.914; and

(b) The image of the prescription is scanned into the computerized system of the pharmacy.

3. If a pharmacy other than the pharmacy that initially received a prescription enters information concerning a prescription into a computerized system for recording information concerning prescriptions, the information must not be accessible from the common database for the purpose of filling or dispensing a prescription until a pharmacist verifies the correctness of the information entered into the computerized system. After verifying that information, the pharmacist shall enter a notation in the computerized system that includes the pharmacist's name, contact information and the date on which he or she verified the information.

4. A pharmacy that fills a prescription using the information from the common database, other than the pharmacy that initially received the prescription, shall:

(a) Process the prescription in the same manner as a prescription that is initially received by the pharmacy;

(b) Except as otherwise provided in paragraph (c), dispense the prescription in the same manner as a prescription that is initially received by the pharmacy; and

(c) Place on the label of the container in which the prescription will be dispensed:

(1) The number assigned to the prescription by the pharmacy that initially received the prescription; and

(2) An additional number or other identifier that ensures that the number placed on the label pursuant to subparagraph (1) is not confused with a prescription number of the pharmacy that is filling the prescription.

5. The filling of a prescription pursuant to the provisions of subsection 4 shall not be considered a transfer of the prescription.
This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, January 13, 2016, in Las Vegas, Nevada. S. Paul Edwards, Esq., represented the Board in his capacity as its General Counsel. William J. Stilling, Esq., of Parsons Behle & Latimer, filed an Answer and Notice of Defense and appeared at the hearing on behalf of Respondents Tina Rizzolo, RPh., Certificate of Registration No. 17665; Lucas Meyers, RPh., Certificate of Registration No. 16064; Walgreens Pharmacy #3922, Certificate of Registration No. PHN01127 (Walgreens Retail); and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964 (Walgreens Mail Service).

Prior to the hearing, the Parties agreed to and entered into a written Stipulated Facts, a copy of which was filed and made part of the record in this action at the beginning of the hearing. Based on the Stipulated Facts, the Parties further entered into a Stipulation and Order resolving the Second, Third and Fifth Causes of Action in their entirety. The Stipulation and Order also partially resolved the Fourth Cause of Action as to Walgreen Retail’s responsibility for Ms. Rizzolo’s counselling error (Third Cause of Action).
With written stipulations in the record as to the facts and a majority of the causes of action, only two issues remained open for decision by the Board during the hearing:

(1) Whether a pharmacist who participates in a segmented prescription filling process is responsible for an error that a previous pharmacist in that process failed to detect and subsequently approved as accurate; and

(2) Whether a pharmacy that dispenses an incorrect medication under the circumstances described in issue one above is responsible for that dispensing error.

RELEVANT FACTS

Walgreens Mail Service is a Nevada-licensed mail service pharmacy located in Orlando, Florida. In May 2015, it was providing data verification support for Walgreens Retail located in Las Vegas, Nevada. Respondent Mr. Meyers worked for Walgreens Retail in Las Vegas at the time of the events alleged in the Accusation.

Those events began in May 2015, when a Nevada patient delivered to Walgreens Retail a prescription for thirty (30) Zoloft 200 mg. tablets with instructions to take 200 mg. by mouth daily. A pharmacy technician at Walgreens Retail performed data entry for the prescription and, rather than entering the medication prescribed, inadvertently entered Zocor 20 mg. tablets. The technician sent that erroneous prescription data into a data entry verification queue for pharmacist approval.

A pharmacist at Walgreens Mail Service in Florida, who was not licensed to practice pharmacy in Nevada, retrieved the data from the queue and verified it as accurate. That pharmacist did not detect the technician’s error in entering Zocor, rather than Zoloft. The Florida pharmacist then put the prescription back into a queue for retrieval and filling by Walgreens Retail in Nevada.

Back in Nevada, another pharmaceutical technician retrieved the prescription information from the queue and filled the prescription with simvastatin (generic for Zocor). The technician staged the prescription for a pharmacist to conduct product verification. The verifying pharmacist, Respondent Mr. Meyers, purported to verify the product as accurate by comparing the label, the leaflet and the product in the prescription bottle to see that they matched. Mr. Meyers did not review the original prescription or a
copy of the prescription as part of the product verification process, and failed to detect that the prescription called for Zoloft, rather than the simvastatin he approved for dispensing. After completing product verification, Mr. Meyers placed the prescription bottle in Will Call for customer pickup.

Respondent Ms. Rizzolo, R.Ph., subsequently retrieved the prescription from Will Call and sold it to the patient. Neither she nor the patient detected the error.

ADDITIONAL FINDINGS

1. Mr. Meyers was the pharmacist on duty and had direct supervisory responsibility over the pharmaceutical technician who erred by entering Zocor rather than Zoloft as prescribed.

2. Mr. Meyers was the pharmacist on duty when the prescription returned to Walgreens Retail in Nevada and proceeded through the filling process.

3. Mr. Meyers performed product verification and personally failed to detect that the pharmacy was preparing to dispense the wrong medication.

4. The written prescription has a preprinted heading indicating that it was written by psychiatrist at a psychiatric practice.

5. Both the written prescription and a scanned copy of the prescription were available for Mr. Meyers to review at the time of product verification. Mr. Meyers did not review the prescription as part of the product verification process.

6. The foregoing findings are supported by the Answer(s) filed by the Respondents, the Stipulated Facts previously entered into the record, and testimony presented to the Board during the hearing.

CONCLUSIONS OF LAW

7. The Board has jurisdiction over this matter because, at the time of the conduct at issue, Respondent Mr. Meyers was a pharmacist licensed by the Board, and Respondent Walgreens Retail was a pharmacy licensed by the Board to operate in Nevada.

8. The Board is charged with protecting the health and safety of the public. NRS 639.070(1) (a). Pursuant to that charge, the Board has declared any “[failure to] strictly . . . follow the instructions of
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[a] person writing, making or ordering a prescription or chart order as to its filling or refilling, the content of the label of the prescription or giving a copy of the prescription or chart order to any person....” to be “unprofessional conduct and conduct contrary to the public interest . . . .” NAC 639.945(1) (d).

9. The Board does not dictate a specific process that a pharmacy or its pharmacists must follow to comply with NAC 639.945(1) (d), nor does it prohibit pharmacies and pharmacists from segmenting the filling process such that it is completed by more than one pharmacist. However, where licensees opt to segment the filling process, they are still expected to develop and maintain policies and procedures that ensure that medication is dispensed correctly. A comparison of the original prescription, the label, the leaflet and the product to be dispensed would be a prudent element of that process.

10. Regardless of the process a pharmacy elects, if an error does occur, the Board’s long-standing position has been to hold responsible, at a minimum, the pharmacist who made the error and the pharmacist who performed the product verification and approved the product for dispensing.

11. The Board’s practice of holding pharmacies and pharmacists responsible for the actions of others is not foreign to Nevada pharmacy law. NRS 639.220, for example, states that a “managing pharmacist is responsible for the activities of [his or her] designee,” where a staff pharmacist is left in charge of a pharmacy in the manager’s absence.

Similarly, NAC 639.252 states that a “pharmacist supervising [a] pharmaceutical technician is responsible for the filled prescription,” including verification of the “selection and strength of the drug . . . [t]he dosage form; and . . . [t]he labeling of the prescription.” That is true, even where the pharmacist did not personally make the error. A pharmacist’s responsibility over the actions of others in his or her charge is further set forth in NAC 639.702, which states:

The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission.

(Emphasis added.)
Moreover, NAC 639.268 makes a pharmacist responsible for the acts of any pharmaceutical technician under his/her supervision; NAC 639.945(2) makes a supervising pharmacist responsible for the acts of any intern pharmacist under his/her supervision; and NAC 639.467 states that “a staff pharmacist [in a medical facility] is responsible for any delegated act performed by pharmaceutical technicians under his or her supervision.”

12. Consistent with those authorities and the Board’s long-standing position that a final verifying pharmacist can be held responsible for approving an error, even if it was previously approved and passed along by other pharmacists in the filling process, the Board concludes here that Respondent Mr. Meyers violated NAC 639.945(1)(d) and (i) by unskillfully failing to strictly follow the instructions of patient A.P.’s physician and verifying as accurate simvastatin 20 mg. tablets, instead of the Zoloft 200 mg. tablets the patient’s physician prescribed.

13. Mr. Meyers is responsible for that error on multiple levels. He was the pharmacist on duty and had direct supervisory responsibility over the pharmaceutical technician who entered during data entry.

14. Mr. Meyers, as the pharmacist on duty, is likewise responsible for the error of Walgreens Mail Service employee Ms. Wagner—who, due to her unlicensed status in Nevada, the Board deems to be “other personnel who are not pharmacists working in or for the pharmacy.” Ms. Wagner failed to detect the technician’s data entry error during data verification.

15. Mr. Meyers was still the pharmacist on duty when the prescription returned to Walgreens Retail in Nevada and proceeded through the filling process. Mr. Meyers performed product verification and personally failed to detect the error. He approved simvastatin, a medication indicated for high cholesterol, when the patient’s physician prescribed Zoloft, a medication indicated for depression. In doing so, the Board concludes that Mr. Meyers failed to strictly follow the instructions of the patient’s physician as alleged in the First Cause of Action.

16. Those violations are grounds for discipline pursuant to NRS 639.255.

17. During the hearing, Respondents argued that Mr. Meyers should not be held responsible due to the Board’s findings and conclusions in Nevada State Board of Pharmacy v. Doan et al., Case No.
14-076-RPH. The Board concludes that the Doan case is factually distinguishable from the instant matter. In Doan, the prescription required a prior authorization. The pharmacy prepared the authorization, but input the wrong medication and sent it to the prescriber for approval. The prescriber did not detect the error, authorized the fill, and returned the authorization, which the pharmacy scanned into its computer system as the prescription. Since the authorization indicated the wrong medication, the Board found that even if the pharmacist had reviewed the original document during product verification, that document contained no information that would have alerted the pharmacist to the error.

18. The facts in Doan are distinguishable from the facts here. Here, Walgreens Retail had the original prescription. It was available for Mr. Meyers to review. Looking at the prescription to verify that it matched the label, leaflet and product could have alerted Mr. Meyer to the error. In any event, the findings and conclusion in Doan are not necessarily binding on the Board here, and do not bar it from finding against Mr. Meyers in this action.

19. Based upon the foregoing finding of guilt, Mr. Meyers shall, related to the violations alleged in the First Cause of Action, (i) pay a fine of $250.00, and (ii) complete two one-hour CE units on the topics of pharmacy record keeping (1 CE) and proper error prevention techniques (1 CE).

20. During the hearing, the Board made no findings or conclusions regarding Walgreens Retail’s responsibility for Mr. Meyer’s error. The Board hereby dismisses the Fourth Cause of Action as to that issue only.

21. Each party is to bear its own costs and attorney fees.

22. The two (2) CEs ordered in the foregoing paragraph are in lieu of the two (2) addition CEs Mr. Meyer’s agreed to in the Stipulation and Order, are in addition to the CEs Mr. Meyer is ordinarily required to complete for maintenance of licensure, and must be completed within thirty (30) days of entry of this order.

23. Respondents shall pay the fines set forth herein 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 thirty (30) days of the effective date of this Order. If circumstances so merit, Board Staff
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has the discretion and authority to establish a payment plan under which any of these Respondents may pay the fine(s) set forth herein through installments without further action or vote by the Board.

24. Respondents shall pay the administrative fees set forth herein by cashier's or certified check of money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office within thirty (30) days of the effective date of this Order.

25. Any failure by any Respondent to comply with any term in this Order may result in additional discipline, up to and including suspension or revocation of that respondent's registrations/licenses until all terms have been satisfied. Furthermore, any failure to pay any fine, fee, or cost ordered herein may result in such legal action as Board Staff determines to be necessary to collect the unpaid fine, fee, or cost.

IT IS SO ORDERED.

Signed and effective this 4th day of February, 2016.

[Signature]
Leo Basch, President
REGULATIONS PERTAINING TO THE FILLING AND VERIFYING OF PRESCRIPTIONS

NAC 639.252 Initialing of prescriptions, records and reports; responsibility for filled prescriptions. (NRS 639.070, 639.1371)

1. A prescription and any record or report prepared by a pharmaceutical technician must bear the legible initials of the pharmaceutical technician and the pharmacist who is supervising him or her.

2. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including, but not limited to, verifying:
   (a) The selection and strength of the drug;
   (b) The dosage form; and
   (c) The labeling of the prescription.

(Added to NAC by Bd. of Pharmacy, eff. 11-15-93)

NAC 639.702 Responsibility for acts and omissions of personnel who are not pharmacists. (NRS 639.070) The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission.

(Added to NAC by Bd. of Pharmacy, eff. 11-15-93)

NAC 639.700 Performance of certain acts by pharmacists and pharmaceutical interns only. (NRS 639.070) Except as otherwise provided in subsection 2 of NAC 639.245, the following acts may be performed only by a registered pharmacist, or by a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist:

1. Taking new orders for prescriptions or chart orders over the telephone;
2. Identifying, evaluating and interpreting a prescription;
3. Interpreting the clinical data contained in a patient's medication system or chart;
4. Consulting with a prescribing practitioner, nurse or other health care professional, or the authorized agent thereof;
5. Determining the efficacy of a drug, a regimen, the substitution of a generic drug for a drug prescribed by brand name or the substitution of one drug therapy for another;
6. Taking responsibility for all activities of pharmaceutical technicians to ensure that those activities are performed completely, safely and without risk of harm to patients;
7. Counseling a patient or a person caring for a patient and rendering any other advice or information regarding drugs or medications; and
NAC 639.245 Maintenance and availability of records regarding certain pharmaceutical personnel on duty; activities of pharmaceutical technicians. (NRS 639.070, 639.1371)

1. A written record must be kept available for inspection showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business. This record must be:
   (a) Readily retrievable; and
   (b) Retained for 2 years.

2. A pharmaceutical technician under the direct supervision of a pharmacist may:
   (a) Prepackage and label unit dose and unit of use and repackaged drugs if a pharmacist:
       (1) Inspects the final products; and
       (2) Affixes his or her initials to the appropriate records for controlling quality.
   (b) Prepare, package, compound and label prescription drugs pursuant to prescriptions or orders for medication if a pharmacist:
       (1) Inspects the final product; and
       (2) Affixes his or her initials to the appropriate records for controlling quality.
   (c) Prepare bulk compounds if a pharmacist:
       (1) Inspects the final product; and
       (2) Affixes his or her initials to the appropriate records for controlling quality.
   (d) Distribute routine orders and stock medications and supplies in the pharmacy or areas where care is provided to patients.
   (e) Maintain inventories of supplies of drugs.
   (f) Maintain pharmaceutical records.
   (g) Request authorization to refill a prescription from the prescribing practitioner.
   (h) Transfer a prescription through a computer network if the:
       (1) Pharmaceutical technician is employed by a pharmacy that:
           (i) Has more than one location; and
           (ii) Maintains a computer network which provides information between its pharmacies; and
       (2) Prescription is transferred to one of the pharmacies within its computer network.
           (i) Enter information into the pharmacy's computer system, including, without limitation, information contained in a new prescription concerning the prescription drug and the directions for its use.

3. A pharmaceutical technician may not:
   (a) Perform any action requiring a judgmental decision regarding a drug, the interpretation of a prescription or the instructions for the preparation of a prescription.
   (b) Take new prescription or chart orders by telephone.
   (c) Distribute medications pursuant to a chart order or dispense a prescription unless the order or prescription has been verified by a pharmacist.
4. A pharmaceutical technician shall prepare and distribute drugs only pursuant to written procedures and guidelines established by the pharmacy in which the pharmaceutical technician performs his or her duties.

[Bd. of Pharmacy, § 639.205, eff. 6-26-80]—(NAC A 12-3-84; 6-16-86; 3-27-90; 11-15-93; R214-99, 3-13-2000; R037-07, 1-30-2008)

NAC 639.010 Definitions. (NRS 639.070) As used in this chapter, unless the context otherwise requires:

1. “Board” means the State Board of Pharmacy.
2. “Controlled substances” has the meaning ascribed to it in NRS 0.031.
3. “Dangerous drug” has the meaning ascribed to it in NRS 454.201.
4. “Direct supervision” means the direction given by a supervising pharmacist who is:
   (a) On the premises of the pharmacy at all times when the persons he or she is supervising are working at the pharmacy; and
   (b) Aware of the activities of those persons related to the preparation of medications, including the maintenance of appropriate records.
5. “Executive Secretary” means the Executive Secretary employed by the Board pursuant to NRS 639.040.
6. “Pharmaceutical technician” means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.
7. “Pharmaceutical technician in training” means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (e) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.
8. “Practitioner” has the meaning ascribed to it in NRS 639.0125.
9. “Prescription drug” means a drug or medicine as defined in NRS 639.007 which:
   (a) May be dispensed only upon a prescription order that is issued by a practitioner; and
   (b) Is labeled with the symbol “Rx only” pursuant to federal law or regulation.
10. “Public or nonprofit agency” means a health center as defined in 42 U.S.C. § 254b(a) which:
     (a) Provides health care primarily to medically underserved persons in a community;
     (b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and
     (c) Is not a medical facility as defined in NRS 449.0151.
11. “Surgical center for ambulatory patients” has the meaning ascribed to it in NRS 449.019.

[Bd. of Pharmacy, § 639.010, 6-26-80]—(NAC A 3-27-90; 6-14-90; 10-1-93; 11-15-93; 5-22-96; 10-24-97; R014-99, 11-3-99; R019-03, 10-21-2003; R041-04, 5-25-2004; R036-07, 1-30-2008)