DISCUSSION AND DETERMINATION – OCTOBER 2016

1) PMP DATA INPUT

Board and PMP staffs are both constantly dealing with pharmacies that incorrectly input and transmit data to the PMP (usually a tech using a drop-down screen, picking the wrong patient, drug, or practitioner). The consequences of this misinformation are obvious, given our current environment of opiate awareness. The PMP is only as good as its input. Linking a practitioner to prescriptions for patient they do not even know; or to drugs that they have not prescribed, may lead to wrong accusations and then legal issues. Currently, upon learning of such misinformation, staff contacts the pharmacy and asks for corrections. In reality, all of these incidents are misfills (because of the mislabeling), so the discussion staff is seeking is the level of discipline you as a Board expect, especially with repeat offenders. The significance of accurate PMP data simply cannot be overstressed.

2) COMPREHENSIVE ADDICTION AND RECOVERY ACT OF 2016

On July 22, 2016, Senate Bill 524 was signed into law. Please see the NABP summary enclosed for discussion and NAC 453.460.

3) DISCHARGE PRESCRIPTIONS FROM MEDICAL FACILITIES

Discussion item requested by President Basch (see enclosed).

4) REQUEST FOR AD HOC COMMITTEE OR TASK FORCE

See attached request from William J. Stilling, Attorney at Law of Parsons Behle & Latimer
TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: September 1, 2016
RE: Comprehensive Addiction and Recovery Act of 2016

On July 22, 2016, in an effort to address the prescription opioid abuse crisis, Senate Bill 524, titled the Comprehensive Addiction and Recovery Act of 2016 (Act), was signed into law. The Act amended the Controlled Substances Act to allow a pharmacist to partially fill a prescription for a Schedule II controlled substance (CS), such as a prescription opioid painkiller. Whereas previously, according to 21 Code of Federal Regulations §1306.13(a), partially filling a Schedule II CS was only permissible if the pharmacist was unable to supply the full quantity as issued on the prescription and required that the remaining portion be filled within 72 hours.

The Act specifically amends 21 United States Code §829 by adding subsection (f), which allows for the partial filling of a Schedule II CS prescriptions if the following conditions are met:

- it is not prohibited by state law;
- the prescription is written and filled in accordance with federal and state law;
- the partial fill is requested by the patient or the practitioner who wrote the prescription; and
- the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

The Act also provides that the remaining portion of a partially filled Schedule II CS prescription may be filled not later than 30 days after the date on which the prescription was written. However, if the partial filling of a Schedule II CS is the result of an emergency situation oral prescription, the pre-existing partial fill time frame of 72 hours after the prescription was issued remains.

As the intent of the law is to decrease the amount of unwanted and unused prescription opioid medications in households across the county, NABP encourages state boards of pharmacy to allow for partial fills as provided for in the Act. NABP is aware that many states mirror federal laws and regulations, and as such, recognizes that some states may need to amend existing laws and regulations to allow pharmacists to partially fill Schedule II CS prescriptions in line with the new federal provisions. If necessary, NABP Member Relations and Government Affairs staff is available to assist you with this endeavor and can be contacted at GovernmentAffairs@nabp.net.

cc: NABP Executive Committee
dispensing practitioner shall make a copy of the prescription blank for each of the other prescriptions written on that prescription blank and file the copy of the prescription blank in the appropriate file maintained pursuant to NAC 453.480. Each copy of the prescription blank filed must include:

(a) A reference to the serial number of the prescription for a controlled substance listed in schedule II; or

(b) If the prescription blank contains more than one controlled substance listed in schedule II, a reference to the serial number of the first prescription for a controlled substance listed in schedule II.

3. Except as otherwise provided in this subsection, a pharmacist shall return, upon request by a patient or a patient’s agent or representative, any written prescription for a controlled substance listed in schedule II. If the pharmacist verifies that the prescription has previously been filled and dispensed to the patient, the pharmacist shall not return the prescription to the patient or the patient’s agent or representative.

4. A practitioner who wishes to issue a prescription for a controlled substance listed in schedule II on which it is indicated that the prescription may not be filled until a future date must use the phrase “Do not fill before (date)” or “Do not dispense until (date)” or other similar words on the prescription to indicate that the prescription may not be filled before the date indicated. The date indicated by the practitioner must not be later than 3 months after the date on which the prescription is written. The date indicated by the practitioner is the date of issue for the purposes of subsection 4 of NRS 453.431. No combination of prescriptions issued pursuant to this subsection may exceed a 90-day supply based on the date indicated for the earlier of the prescriptions. Any prescription issued pursuant to this subsection must not be included on a prescription blank or other document prescribing any other dangerous drug or controlled substance.

[Nbd. of Pharmacy, § 453.260, eff. 6-26-80]—(NAC A by R164-01, 12-17-2001; R039-04, 5-25-2004; R035-07 & R042-07, 12-4-2007; R049-08, 6-17-2008)

NAC 453.460 - Partial filling of prescription. (NRS 453.221, 453.385, 639.070)

1. A pharmacist may partially fill a prescription for a controlled substance listed in schedule II:

(a) If the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remaining portion of the prescription may be filled within 72 hours after the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing practitioner. No further quantity may be supplied beyond the 72-hour period without a new prescription.

(b) For a patient in a facility for long-term care or for a patient who has been diagnosed as having a terminal illness. The pharmacist shall record on the prescription that the patient is a “LTC patient” or “terminally ill.” The date of the partial filling, the quantity of the medication that is dispensed, the remaining quantity which is authorized to be dispensed, and the signature or initials of the pharmacist must be recorded on the back of the prescription. The total quantity of the controlled substance that is dispensed in all partial fillings must not exceed the total quantity of the controlled substance that is prescribed. A prescription is valid for 60 days after the date of the prescription unless the prescription is terminated earlier by the discontinuance of medication.

2. A pharmacist may partially fill a prescription for a controlled substance listed in schedule III, IV or V. A partial filling pursuant to this subsection does not constitute a full refill for the purposes of subsection 3 of NRS 453.256. A full refill of a prescription does not occur until the total quantity dispensed in all partial fillings equals the total quantity prescribed. Whenever a patient requests a partial filling, the pharmacist shall:

(a) Create and maintain a record of each partial refill that reflects the total quantity dispensed for any particular prescription;

453-13
(b) Ensure that the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
(c) Refuse to fill or partially fill any prescription more than 6 months after the date on which the prescription was issued.
3. As used in this section, "facility for long-term care" means a medical facility that provides 24-hour nursing services.
   [Bd. of Pharmacy, § 453.280, eff. 6-26-80]—(NAC A 3-17-92; R021-98, 4-17-98; R019-01, 11-1-2001; R049-07, 1-30-2008)

NAC 453.470 Information to be affixed to package for prescription. (NRS 453.221, 639.070) A person authorized by the Board to dispense controlled substances who fills a written prescription for a controlled substance listed in schedule II, III or IV, or an emergency oral prescription for a controlled substance listed in schedule II, shall affix to the package a label showing:
   1. The name and address of the pharmacy;
   2. The serial number and date of initial filling of the prescription;
   3. The name of the patient;
   4. The name of the prescribing practitioner; and
   5. Any directions for use and cautionary statements contained in the prescription or required by law.
   [Bd. of Pharmacy, § 453.290, eff. 6-26-80]—(NAC A 1-10-94)

NAC 453.475 Initial and biennial inventory of controlled substances by new managing pharmacist. (NRS 453.221, 453.246, 639.070)
1. A pharmacist who is hired or promoted to manage a pharmacy pursuant to the provisions of NRS 639.220 shall:
   (a) Within 48 hours after first reporting for duty as the managing pharmacist, conduct an inventory of the controlled substances of the pharmacy with the pharmacist who preceded him or her as the managing pharmacist. The pharmacists shall sign the inventory.
   (b) After the date on which the inventory required pursuant to paragraph (a) was taken, conduct an inventory of the controlled substances of the pharmacy at least once every 2 years during the course of his or her employment as managing pharmacist at the pharmacy. The managing pharmacist may conduct the biennial inventory on any date which is within 2 years of the date on which the previous biennial inventory was conducted.
2. An inventory required by subsection 1 must be:
   (a) Conducted according to the method prescribed by the provisions of 21 C.F.R. Part 1304; and
   (b) Placed in the records of the controlled substances of the pharmacy.
   (Added to NAC by Bd. of Pharmacy, eff. 8-10-89; A 7-7-94; R022-98, 4-17-98; R015-01, 11-1-2001)

NAC 453.480 Maintenance of files of prescriptions. (NRS 453.221, 453.246, 639.070) In maintaining files of prescriptions, a pharmacy or dispensing practitioner must elect one of the following options:
1. To maintain two files:
   (a) One file for substances in schedule II; and
   (b) The other file for substances in schedules III, IV and V and for noncontrolled substances if the prescriptions for controlled substances are:
      (1) Stamped in the lower right-hand corner with the letter "C" in red ink at least 1 inch in height; or
      (2) Not stamped because the pharmacy uses a computerized system to record information concerning prescriptions that meets the requirements of 21 C.F.R. § 1304.04(h)(2).
From: Leo Basch <gogreenv@yahoo.com>
Sent: Wednesday, September 21, 2016 8:15 AM
To: LARRY L. PINSON; David Wuest; Shirley Hunting; Paul Edwards
Cc: evan.goudge@optioncare.com
Subject: Fw: request for discussion
Attachments: image001.jpg; SKM_454e16091915320.pdf

Good morning Larry, Dave, Paul and Shirley,

I'd like to have a discussion around discharge orders (prescriptions) to see if there is anything the Board can do to improve patient care and patient safety. Currently many players in the home health pharmacy community turn a blind eye to the requirement of a "wet signature" on certain discharge orders. For the other players patient care is sometimes delayed. If all players in the market followed our current regulations, many times patient care would be delayed and considerable pharmacists resources would be used to be compliant instead of patient care.

I think we have discussed this in the past, but a current conversation might help clear up a few things, or at minimum provide information on what needs to be done with regard to NRS which is outside of the Board's control.

The attached document is from Evan Gouge at Option Care.

Please let me know if you have any questions or concerns.

Thank you,

Leo

Leo Basch PharmD RPh
President, Nevada State Board of Pharmacy
702-630-9867

--- On Mon, 9/19/16, Goudge, Evan <evan.goudge@optioncare.com> wrote:

> From: Goudge, Evan <evan.goudge@optioncare.com>
> Subject: request for discussion
> To: "gogreenv@yahoo.com" <gogreenv@yahoo.com>
> Date: Monday, September 19, 2016, 3:43 PM
> >
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RESPECTFULLY REQUESTED FOR DISCUSSION:

CLARIFICATION OF DEFINITIONS, SUCH THAT NRS 639.004 (CHART ORDER DEFINED), NRS 639.013 PRESCRIPTION DEFINED 1. (b) “A CHART ORDER WRITTEN FOR AN INPATIENT IS TO TAKE HOME UPON DISCHARGE” AND NRS 639.2353 1. (d) “TRANSMISSIONS MADE FROM A FACSIMILE MACHINE TO ANOTHER FACSIMILE MACHINE...” BE CLARIFIED/COMBINED TO ALLOW A CHART ORDER THAT IS ELECTRONICALLY SIGNED (NOT PEN TO PAPER) WITH THE INTENT FOR USE AFTER DISCHARGE, TO BE FAXED FROM THE HOSPITAL, FACILITY FOR INTERMEDIATE CARE OR FACILITY FOR SKILLED NURSING TO THE FULFILLING PHARMACY. THE FULFILLING PHARMACY TO VERIFY THAT THE ORDER HAS COME FROM THE HOSPITAL/FACILITY. NOT VALID FOR CONTROLLED SUBSTANCES. PLEASE SEE NRS 639.004, NRS 639.013, NRS 639.2353, NRS 639.032 AND AN EXAMPLE DISCHARGE CHART ORDER (WITH ELECTRONIC SIGNATURE). THANK YOU FOR YOUR TIME AND CONSIDERATION.
"Chart order" defined. "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

(Added to NRS by 1967, 1651; A 1971, 683; 1973, 774; 1979, 1683; 1985, 1768)
NRS 639.013  “Prescription” defined.

1. “Prescription” means:

(a) An order given individually for the person for whom prescribed, directly from the practitioner to a pharmacist or indirectly by means of an order signed by the practitioner or by an electronic transmission from the practitioner to a pharmacist.

(b) A chart order written for an inpatient specifying drugs which the inpatient is to take home upon discharge.

2. The term does not include a chart order written for an inpatient for use while he or she is an inpatient.

(Added to NRS by 1967, 1652; A 1973, 774; 1979, 343, 1684; 1987, 1650; 1991, 1948)
NRS 639.2353  Transmission of prescription to pharmacist; contents of written prescription; specific directions for use; requirements for written prescription; authentication of prescription given by electronic transmission. Except as otherwise provided in a regulation adopted pursuant to NRS 453.385 or 639.2357:

1. A prescription must be given:

   (a) Directly from the practitioner to a pharmacist;

   (b) Indirectly by means of an order signed by the practitioner;

   (c) By an oral order transmitted by an agent of the practitioner; or

   (d) Except as otherwise provided in subsection 5, by electronic transmission or transmission by a facsimile machine, including, without limitation, transmissions made from a facsimile machine to another facsimile machine, a computer equipped with a facsimile modem to a facsimile machine or a computer to another computer, pursuant to the regulations of the Board.

2. A written prescription must contain:

   (a) Except as otherwise provided in this section, the name and signature of the practitioner, and the address of the practitioner if not immediately available to the pharmacist;

   (b) The classification of his or her license;

   (c) The name of the patient, and the address of the patient if not immediately available to the pharmacist;

   (d) The name, strength and quantity of the drug prescribed;

   (e) The symptom or purpose for which the drug is prescribed, if included by the practitioner pursuant to NRS 639.2352;
(f) Directions for use; and

(g) The date of issue.

3. The directions for use must be specific in that they indicate the portion of the body to which the medication is to be applied or, if to be taken into the body by means other than orally, the orifice or canal of the body into which the medication is to be inserted or injected.

4. Each written prescription must be written in such a manner that any registered pharmacist would be able to dispense it. A prescription must be written in Latin or English and may include any character, figure, cipher or abbreviation which is generally used by pharmacists and practitioners in the writing of prescriptions.

5. A prescription for a controlled substance must not be given by electronic transmission or transmission by a facsimile machine unless authorized by federal law and NRS 439.581 to 439.595, inclusive, and the regulations adopted pursuant thereto.

6. A prescription that is given by electronic transmission is not required to contain the signature of the practitioner if:

(a) It contains a facsimile signature, security code or other mark that uniquely identifies the practitioner;

(b) A voice recognition system, biometric identification technique or other security system approved by the Board is used to identify the practitioner; or

(c) It complies with the provisions of NRS 439.581 to 439.595, inclusive, and the regulations adopted pursuant thereto.

NAC 639.032  "Facsimile machine" interpreted. (NRS 639.070, 639.0745, 639.2353)  As used in NRS 639.0745 and 639.2353, the Board will interpret the term "facsimile machine" to include, without limitation, a computer that has a facsimile modem through which documents can be sent and received.

(Added to NAC by Bd. of Pharmacy by R112-99, eff. 11-3-99)
St Rose Dominican Hospital–Siena Campus
3001 St Rose Parkway
Henderson, 89052

Patient Information

MRN: [redacted]
Name: [redacted]
Location: SRB 4MSE
Room: 0477 F
Date of Birth: [redacted]
Age: [redacted]
Sex: M
Height: 177.8 cm
Weight: 104.5 kg
Admitting Diagnosis: R FOOT CELLULITIS
Allergies: No Known Medication Allergies

Ordering Information

Order: CONSULT TO CASE MANAGEMENT
Order Date/Time: 09/19/16 10:44:00 PDT
Frequency: once
Stop Date/Time: 09/19/16 10:44:00 PDT
PRN: No
Constant Indicator: No
Frequency Schedule Id: 74

Comments: ok to d/c from ID point of view on:
IV dapomycin 4mg/kg q24hr until 9/30/16 (2 week course).
IV cefazolin 2g q12hr until 9/30/16.
po flagyl 800mg tid until 9/30/16.
po probiotics until 10/7/16.
side effect of dapomycin discussed with pt. wife including rhabdomyolysis, myalga.
side effect of cefazolin discussed with pt. wife including GI upset, e. coli infection.
(see patient chart for more information)

Electronically Signed By: Uche, Chukwudum MD
Order Date/Time: 09/19/2016 10:44 AM PDT
Communication Type: Written/Fax
September 16, 2016

VIA EMAIL AND U.S. MAIL

Larry Pinson
Executive Director
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

Re: Request for Task Force to Evaluate and Harmonize Rules Governing Responsibilities in Various Prescription Filling Processes

Dear Larry:

I am asking the Nevada Board of Pharmacy itself or Board staff to create an ad hoc committee or task force to evaluate Nevada pharmacy rules with the goal of harmonizing the standards for prescription processing models and allocation of responsibility for pharmacists in such models. Regardless of one’s views about the how responsibility should be allocated in the various pharmacy models, it is clear that responsibility for prescription errors is not uniform across models for preparing prescriptions delivered to Nevada residents. Given the discussions in the last few months, some leaders in the pharmacy profession (many of whom attended the July 21 rule hearing) have suggested submitting rule changes. However, I think it would be best to get Board members involved early together with other interested parties before specific rule proposals are made. This has the benefit of obtaining the expertise, ideas, and concerns of individuals and institutions that dispense drugs to Nevada residents. The result of a task force recommendation will therefore arise from a broad array of input and any suggested rule change will come to the Board with consensus.

Several Board discussions this year highlight the confusion about current rules and the inconsistency of those rules as applied to different pharmacy models. Indeed, this confusion paralyzed the decision-making process for a rule to allow sharing of electronic information between two or more pharmacies not under common ownership (“NAC 639.921 Amendment”). Most surprising was the fact that the proposed rule had nothing to do with allocation of responsibility for prescription errors, yet every Board discussion circled back to that question. The chronology of those discussions demonstrates that the allocation of responsibility issue dominated and ultimately undermined passage of a rule, the substance of which was not controversial.
1. January 14, 2016: BriovaRx of Nevada and Tel-Drug requested a rule change to allow pharmacies not under common ownership to share prescription databases under NAC 639.921. Board members raised questions about who would be responsible for data-entry errors in the BriovaRx fulfillment model under NAC 639.7125 and how responsibility was different under other prescription processing models. Board staff explained the differences between responsibility under such a model and other models in Nevada.

2. March 2, 2016: The topic arose twice—first during a D&D under the agenda item Regulations Pertaining to the Filling and Verifying of Prescriptions, and then during the workshop soliciting comments for the NAC 639.921 Amendment. During the D&D, Board members expressed varying views about responsibility of pharmacists in different prescription processing systems such as work load balancing systems, out-of-state mail order systems, fulfilment-dispensing pharmacy systems, etc. Again, there was no consensus about how to resolve issues of responsibility for segments of the filling process under some of these models. The Board also raised the issue of whether pharmacies had the ability to contractually delegate their responsibilities.

3. June 1, 2016: During the first public hearing on the NAC 639.921 Amendment, the Board again raised the question of “who would be held responsible if an error occurred . . . .” The Board also discussed at length the issue of who would be held responsible in various prescription filling systems. Board members expressed disappointment that there was no public comment on the amendment and ultimately tabled the amendment until the June Board meeting. Most interestingly, the Board was not concerned about the data sharing, which was the substance of the NAC 639.621 Amendment, but instead wanted to hear comments about allocation of responsibility in the prescription filling process.

4. July 21, 2016: The Board held another hearing on the NAC 639.921 Amendment. Although BriovaRx, the entity that originally sought a change to NAC 639.921, did not attend, many leaders of the profession attended to listen and to provide input about allocation of responsibility among pharmacists in various prescription filling models. The testimony at that hearing demonstrated concerns and confusion about Nevada rules addressing, or not, new prescription filling processes.

In the end, the Board rejected the NAC 639.921 Amendment, even though there was not controversy about its substance. Rather, the Board rejected the amendment because there was no resolution to the issue of allocation of responsibility for errors.
Rather than wait for interested parties to propose multiple rules piecemeal, I ask that a committee or task force be appointed to: (i) evaluate current rules and current pharmacy practice models; (ii) review current trends in pharmacy practice to anticipate technological and other practice changes for the future; and (iii) propose amendments to the Nevada Pharmacy Rules to clarify and harmonize responsibilities of pharmacists in current and anticipated practice models. Representatives from each of the following would be important: (i) the Board of Pharmacy; (ii) Board staff; (iii) independent or small chain pharmacies; (iv) national chain pharmacies; (v) out-of-state mail service pharmacies; (vi) central fill or central processing pharmacies; (vii) fulfillment-dispensing pharmacies; and (viii) institutional pharmacies. I expect there are other interested parties that Board staff and Board members would add to this list.

Based on our phone conversation in late August, I would appreciate you placing this request on the agenda for the October 12-13 meeting in Las Vegas. Please contact me if you have any questions or comments.

Sincerely,

PARSONS BEHLE & LATIMER

William J. Stillings

cc: Dave Wuest by email
Paul Edwards by e-mail