

NPA Convention – Law Review

I. Legislation –

LB 308 – Automated Medications Systems Act

- i. *Defines Remote Order Entry*
- ii. *AMS & Requirements*
 1. *Automated medication distribution machine – administration*
 2. *Prescription medication distribution machine – dispensing*
 3. *All AMS require Policies & Procedures (outlined in statute)*
 4. *Pharmacist must be part of AMS process!!*
- iii. *Defines “telepharmacy” and adds telepharmacy to pharmacists responsibilities in the practice of pharmacy*

LB 902 – Oripavine & Annual CS Inventory

- iv. *Oripavine – Schedule II*
- v. *Requires pharmacies to perform an annual controlled substances inventory for all schedules (Schedule I–V)*

LB 830 – Preferred Drug List for Medicaid

- vi. *Required the State of Nebraska to implement a preferred drug list for the Nebraska Medicaid Program – by July 1, 2010.*

LB 1022 – Veterinary Drug Distributor Licensure Act

- vii. *Defines and requires licensure of Veterinary Drug Distributors. Allows VDD to distribute animal medicines to end users on the valid order of a licensed Veterinarian.*

Budget – Hold Harmless; Tobacco Cessation; Regional Poison Center

- viii. *Hold Harmless language: If the Federal AMP goes into effect, and if the state saves money on the new calculation, the money saved will come back to the pharmacies in the form of higher dispensing fees.*
- ix. *Tobacco Cessation: \$500,000 for the Nebraska Medicaid program to implement a tobacco cessation program for Medicaid recipients. Pharmacists and other providers can be paid for counseling services and product costs.*
- x. *\$440,000 provided for the Regional Poison Center in Omaha.*

II. Controlled Substances

Q: What can be written/changed on a Controlled Substance prescription?

A: *“The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.” However, “a corresponding liability rests upon the pharmacist...who fills a prescription not prepared in the form prescribed by DEA regulations.” Therefore, “after consultation with the prescribing practitioner, the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is never permitted to make changes to the patient’s name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber’s signature.” “Keep in mind that the DEA’s emphasis is to stop drug diversion. DEA is not out to interfere with legitimate medical or pharmacy practice.” “If you make a change on a C-II Rx, be sure to document why you changed it...and that you got authorization from the prescriber.”*

Q: Tamper Resistant Prescriptions - what can be written on CII's?

A: *Written Medicaid prescriptions must be on tamper-resistant prescription blanks as of April 1, 2008. They must meet 1 of 3 requirements – all three requirements by October 1, 2008.*

According to the CMS, all written prescriptions for Medicaid clients must be on tamper-resistant prescription blanks. Failure to adopt and enforce the requirement would put Federal funding for Medicaid at risk. Pharmacies are allowed to contact prescribers and request that the prescriber either phone, fax or e-prescribe a new prescription when they receive non-compliant prescriptions. Since that's not possible with CII's, CMS has clarified that pharmacies may verify a CII prescription via a call to the prescriber to verbally confirm that the written prescription is in fact his/hers and is accurate (or have the prescriber's office fax a copy of the prescription or send it via e-prescription for the same purpose. Since there's also an audit requirement in the Federal law, pharmacies will have to document such action on the prescription. Thus, inspectors may begin seeing documentation of such verification on or attached to CII prescriptions.

III. Pharmacy Technicians

Q: Who needs to register, and where do I find information?

A: *Effective 9/1/2007, all pharmacy technicians employed by a facility licensed under the Health Care Facility Licensure Act are required to be registered with the State of NE. Pharmacy technicians must apply for registration within 30 days after being hired by a pharmacy or facility. Information about the registry, fees, and pharmacy technician responsibilities can be found at:*

<http://www.dhhs.ne.gov/crl/medical/pharm/Pharmtech/pharmtech.htm>

Q: Can a pharmacy technician administer immunizations in NE?

A: *A pharmacy technician shall only perform tasks which do not require professional judgment (71-1,147.66);*

➤ *In my opinion, professional judgment is required for administration of vaccines and therefore this task would not be appropriate for technicians;*

Pharmacy technicians can only perform the duties listed in the pharmacy's technician manual/guidelines ... before a technician could administer immunizations, that activity would have to be listed and be approved by the Nebraska Board of Pharmacy. It is our opinion that the Board would not approve such a listing for the above reason.

Q. Is it required that my pharmacy have an NPA Tech manual?

A: *No – the NPA Manual is only a guideline.*

Q: Does each pharmacy have to have its own Tech Manual – or can I have one and have it apply to each of my stores?

A: *Each pharmacy or facility shall, before using pharmacy technicians, file with the board a copy of its written control procedures & guidelines (71-1,147.67(4));*

▪ *Prior to use of technicians in a pharmacy, a copy of the written control procedures & guidelines must be submitted to the Department and approved by the Board. The original, approved, written control procedures & guidelines must be retained at the pharmacy (175NAC8-006.01D)*

**In my opinion, you could have a template for use by each store, but each store must have its own approved document on file in the store.*

Q: Must I have a tech manual before I employ a technician?

A: *Yes! Before you can employ a pharmacy technician, you must file with the NE Board of Pharmacy a copy of your written control procedures & guidelines and receive approval of those written control procedures & guidelines from the Board (71-1,147.67(4)) & 175 NAC 8-006.01D.*

Q: What is the technician/intern ratio in NE. Does the ratio apply to hospitals?

A: *172 NAC 128-012.01 A pharmacist may supervise pharmacist interns and pharmacy technicians in the following ratios:*

- 1. A pharmacist may supervise up to two pharmacy technicians at any time, unless prohibited by a disciplinary action. (1:2)*
- 2. A pharmacist may supervise up to three pharmacist interns at any time, unless prohibited by a disciplinary action. (1:3)*
- 3. A pharmacist may supervise any combination of pharmacy technicians and pharmacist interns at any time up to a total of three people, as long as no more than two are pharmacy technicians. (1:3)*
- 4. The supervision ratios of these regulations do not apply to pharmacist interns who are receiving experiential training directed by the accredited pharmacy program in which he or she is enrolled.*

IV. Other

Q: E-prescribing/faxing/signatures/verification?

A: *A written prescription for a CIII-V must be signed by the prescriber, and that signature must be in the practitioner's own handwriting. In this instance, a prescription that is signed by the prescriber in his/her own handwriting, then faxed to the pharmacy by the prescriber or prescriber's agent is a valid prescription. If a CIII - V prescription is electronically signed and is faxed or electronically transmitted via computer, then the prescription should be treated as a verbal prescription, and must be verified by the pharmacist prior to the prescription being filled. Prescriptions that are not for controlled substances may be accepted electronically (fax, email, computer to computer) and can be signed electronically. The pharmacist should use professional judgment and verify the authenticity or validity if there is any question about those prescriptions. CII's shall not be dispensed without the written prescription bearing the signature of a practitioner authorized to prescribe, except in emergency situations as stated in Neb. Rev. Statute Section 28-414.*

Q: Do I need to be certified to administer immunizations in NE?

A: *The Practice of Pharmacy includes the administration of drugs or devices (71-1,142(1)(d)); there are no provisions about required training or certification associated with this definition.*

- *Nebraska law does not require pharmacists to be certified to administer immunizations.*
- *Standard of practice would dictate that a pharmacist be appropriately prepared to provide a service, therefore, certification to assure that one is as current as possible re immunizations would certainly be prudent.*

- *Pharmacists must have a prescription or protocol/collaborative practice agreement to administer medications including immunizations (legend drugs).*

Q: Explain Rule 59 – EpiPens in schools?

A: *The NE Department of Education mandated (in 2003-04) the Attack on Asthma program that stipulates that all schools must have the education, training and medications to respond to anyone experiencing a life-threatening asthma or anaphylaxis emergency at school. Pharmacists are asked to fill prescriptions from physicians for standing orders of albuterol for nebulizers and EpiPens which are part of an emergency kit located in a Nebraska schools. The prescription/protocol must be written annually, include both a quantity and a prescriber's signature, and labeled by a pharmacist as "For emergency use" per Health & Human Services.*

Q: What is the status of the Federal AMP legislation?

A: *The court case filed by NCPA & NACDS continues. It is headed into discovery where both sides can request info/documents from the other. Ultimately, a legislative fix is needed and we are currently pursuing a legislative delay. The delay would be until next year, but with a pending lawsuit, everything is on hold. We are trying to get an AMP delay and prompt pay in to the Medicare bill that Senator Baucus is working on.*

Q: Med D & DMEPOS & QI Programs – what is the latest?

A: *According to CMS, In order to participate in the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program, suppliers must meet quality standards and be accredited by a CMS-approved Deemed Accreditation Organization. Suppliers that are interested in bidding in the **second round** of the program must be aware of changes to two key deadlines:*

- *Suppliers must be accredited or have applied for accreditation by **July 21, 2008** (change from May 14, 2008) to submit a bid for the second round of competitive bidding. CMS cannot accept a bid from any supplier that is not accredited or that has not applied for accreditation by July 21, 2008.*
- *Suppliers will need to be accredited to be awarded a contract. The accreditation deadline for the second round of competitive bidding is **January 14, 2009** (change from October 31, 2008). Suppliers must be accredited before this date to be awarded a contract. Suppliers should apply for accreditation immediately to allow adequate time to process their applications.*

*CMS has extended these deadlines because a significant number of suppliers in the 70 metropolitan statistical areas (MSAs) included in Round Two of the DMEPOS Competitive Bidding Program have not yet applied for accreditation. **Suppliers in these MSAs that do not meet these accreditation deadlines cannot become DMEPOS competitive bidding contract suppliers and will therefore be unable to furnish competitively bid items to any beneficiary residing in any part of the competitive bidding area during the contract period.***

****Nebraska counties included in the 2nd round – Cass, Douglas, Sarpy, Saunders, and Washington*

A: Med D contract language may require you to have a QI program implemented in your pharmacy. If so, Pharmacy Quality Commitment program available from NPA.

Q: What requirements must pharmacies meet with regard to disaster planning?

A: Per Nebraska regulations 175 NAC 8-004.10: The pharmacy must notify the Department in writing by electronic mail, facsimile, or postal service within 24 hours of any change in environment which will adversely affect the potency, efficacy, safety or security of the drugs, devices or biological in the pharmacy. The notification may be made by telephone if the event has affected the licensee's capability to communicate. AND

175 NAC 8-006.07: The pharmacy must establish and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety and security of the drugs, devices, or biological in the pharmacy in instances of natural (tornado, flood, etc.) or other disasters, disease outbreaks, interruption of utility services, or other similar situations.

Such plans and procedures must address and delineate:

- 1. How the pharmacy will provide for the storage of drugs, devices, and biological at the proper temperature;*
- 2. How the pharmacy will provide for the disposal of drugs, devices, and biological if the pharmacy determines their potency, efficacy, or safety has been adversely affected;*
- 3. How the pharmacy will secure the drugs, devices, and biological from the public; and*
- 4. How the pharmacy will maintain patient records and inventory records.*

Q: Can a physician prescribe Controlled Substances for a family member?

A: Yes, "in the case of a medical emergency, to one's spouse or child".

Q: What is the status of Long Term Care pharmacy practice in Nebraska?

A: NPA has a LTC Task Force to address changes that need to be made in the pharmacy practice act to address LTC pharmacy practice. LTC pharmacy practice has evolved and does not always follow the "retail pharmacy" model as outlined in Nebraska law. In many instances, LTC practice is following the "hospital" model, but that model is not allowed in Nebraska law.

Q: Is it illegal to flush medications? As a pharmacist, can I participate in a community Take Back Program?

A: There is no law that prohibits flushing of medications. Pharmacists are allowed to participate in Take Back programs. The Take Back program should NOT be located at a pharmacy, and MUST include law enforcement. The pharmacist's role is to identify medications. The NPA consulted the Nebraska Board of Pharmacy regarding controlled substances. A pharmacist participating in a Take Back program will not be considered having "possession of a controlled substance" as long as Law Enforcement is present during the entire Take Back program, as Law Enforcement's responsibility is to maintain the "chain of custody" of the medications, and to ultimately ensure proper disposal of those medications.

Q: What is the law regarding Dispensing Practitioners?

A: *As authorized by the Uniform Credentialing Act, the practice of pharmacy may be engaged in by a pharmacist, a pharmacist intern, or a practitioner with a pharmacy license. The practice of pharmacy shall not be construed to include:....*

(2) Practitioners, other than veterinarians, certified nurse midwives, certified registered nurse anesthetists, and nurse practitioners, who dispense drugs or devices as an incident to the practice of their profession, except that if such practitioner regularly engages in dispensing such drugs or devices to his or her patients for which such patients are charged, such practitioner shall obtain a pharmacy license (71-1,143).

Q: Which law enforcement officials have access to pseudoephedrine log books?

A: *According to the DEA office in Kansas City, pseudoephedrine log books are accessible "as appropriate to the Attorney General, state & local law enforcement" without a search warrant. Unless state pharmacy inspectors are considered "law enforcement" in the state (no clarification per HHS), pharmacy inspectors do not have access to the log books.*

Q: How long is a prescription valid?

A: *All medical orders shall be valid for a period stated in the medical order, except that if the order is for a controlled substance, such period shall not exceed six (6) months from the date of issuance and if the order is for a drug or device that is not a controlled substance or is an order for pharmaceutical care, such period shall not exceed twelve (12) months (71-1,146.01; 28-414(1)(a); 28-414(2)(a))*

Q: When can I dispense Methadone on a prescription?

A: *Methadone can only be prescribed for the treatment of pain and cannot be prescribed for detoxification treatment or maintenance treatment of an addict.*

Q: Where can I find the mandatory equipment list?

A: *A mandatory equipment list no longer exists ... equipment required to provide services depends on the practice of pharmacy in each setting*

- *The pharmacy must provide the pharmacist access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy (175NAC8-007.01);*
- *On Application for Licensure (175NAC8-003.01A(3)(m)), applicant must provide a description of how the pharmacy meets the following requirements: (4) The pharmacy must provide the pharmacist access to all equipment appropriate for the accurate, efficient and safe provision of services available in that pharmacy. List all services intended to be provided by the pharmacy;*
- *On the Pharmacy Quality Assurance Report (175NAC8-005.03), the report must provide information on the following: (6) required equipment is available.*

Q: Must facilities display the Pharmacists' names?

A: *No longer required*