Inside This Issue

3 Daily News Dose - In Case You Missed It
4 News Bits
5 Welcome NPA President, Fred Massoomi
7 Legislative Bill Summary
14 Continuing Pharmacy Education Lesson #1 - The Patient Protection and Affordable Care Act and Its Impact on Pharmacy
23 University of Nebraska Medical Center College of Pharmacy News
24 Creighton University School of Pharmacy & Health Professions News
25 Continuing Pharmacy Education Lesson #2 - New Therapies in Diabetes Management
32 Annual Convention Program & Registration
42 Continuing Pharmacy Education Lesson #3 - Cataracts and Glaucoma
50 APhA - Hub on Policy & Advocacy
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Publisher
The Nebraska Mortar & Pestle (M&P) (ISSN 0028-1891) is owned and published by the Nebraska Pharmacists Association (NPA) to provide continuing pharmacy education, drug information, news and trends in the profession of pharmacy. Opinions expressed by the contributors, whether signed or otherwise, do not necessarily reflect the attitudes of the publisher nor are they responsible for them.

The M&P is published six times a year at the end of the months of February, April, June, August, October and December. The subscription rate for non-members is $30.00 per year. The Managing Editor is Joni Cover, joni@npharm.org. Office of publication is 6221 S 58th Street, Suite A, Lincoln, NE 68516-3687. Second class postage paid at Lincoln, Nebraska, and at additional mailing offices. Postmaster: Send address changes to the Nebraska Mortar & Pestle, 6221 S 58th Street, Suite A, Lincoln, NE 68516-3687 or email m&p@npharm.org.

We Hear That

Congratulations to Susie Crumley, PharmD, Nebraska City, on the birth of her son, Isaac. Susie is a former NPA rotation student and is a pharmacist with Walgreens.

Congratulations to Richard Ternes, RP, Lincoln, who celebrated his 70th birthday on the day he retired from the Saint Elizabeth Regional Medical Center after 47 years. Richard started as a pharmacy student at the old hospital on South Street in Lincoln.

Congratulations to Tom Whitcomb, RP, Green Valley, Arizona, and his wife, Betty, on celebrating their 60th wedding anniversary.

NPA Past President, Mike Swanda, RP, Cozad, passed away on December 31, 2013. Mike was a Pharmacist Mate in the Navy and served in WWII. He graduated from the University of Nebraska-Lincoln in 1951 and worked as a pharmacist in Central City, David City and Wilbur until 1955. He then moved to Cozad where he owned and operated Swanda Pharmacy until 1979. During this time, Mike also served on the Nebraska Board of Pharmacy. In 1980, Mike left the store and began work as a pharmacy inspector and investigator for the Nebraska Department of Health & Human Services until he retired in 2012. Our condolences to the Swanda family.

Lifetime member, Warren Barth, RP, Cozad, passed away on January 7, 2014. After graduating from the University of Nebraska-Lincoln in 1949, Warren served in the Air Corps where he was based in London, England. He was the owner and operator of Barth Drug & Hardware, which was the longest family owned and operated drug store in the state of Nebraska at that time. Our condolences to the Barth family.

Lifetime member, Ron Taddiken, RP, Lincoln, passed away on February 4, 2014. After graduating from the University of Nebraska-Lincoln in 1941, Ron served as an Army medic during WWII in the South Pacific Theater. Ron worked as a pharmacist in Lincoln for over 60 years. Even in his late 80’s to early 90’s, Ron drove to the NPA office to turn in his M&P CPE quizzes! Our condolences to the Taddiken family.

Check out the new look of our more mobile friendly website! www.npharm.org

NEW LOOK!
Daily News Dose
In Case You Missed It

Your NPA member benefit includes a daily email with important drug and health information, as well as answers to member questions. Below is a partial list of some of the most recent Daily News Dose items that you may have missed. If you are not receiving your Daily News Dose, be sure to update your email address by calling the office at 402-420-1500 or sending an email to enews@npharm.org.

Nebraska Medicaid Change for Zolpidem
The Nebraska Drug Utilization Review (DUR) Board recommended that claims should deny for patients taking doses exceeding the revised FDA recommendation for zolpidem. Nebraska Medicaid accepted this recommendation, and beginning on January 23, 2014 claims were denied for women exceeding 5 mg and for men exceeding 10 mg of the immediate-release zolpidem.
http://www.fda.gov/drugs/drugsafety/ucm352085.htm

Small Reminder Makes a Big Difference
Manufacturers of injectable drugs will have to comply with new labeling standards that help ensure that important warnings - warnings that can help prevent life-threatening situations - are obvious and clear. In short, this USP standard states that warning messages - for example, “Warning - Paralyzing Agent” or “Dilute Before Using” - are the only markings that should appear on ferrules and cap overseas of injectable drugs. The ferrules and cap overseas must remain clear of any markings, including logos, except for markings intended to prevent an imminent life-threatening situation.

Minimum Pharmacy Equipment List
In the past, there was a list of equipment that was required in a Nebraska pharmacy. It included a balance, glass stirring rods, graduates, mortar and pestles, etc. There was also a list of references that each pharmacy had to maintain. The current requirements do not specify a list, but rather must show accessibility as outlined in Title 175 of the Nebraska Administrative Code, Chapter 8 (8-007) “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.” In regard to required references, “The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe practice of pharmacy or any specialty practice of pharmacy in the facility. These references must be up to date, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy.”

Board of Pharmacy Elected Officers
In January, the Nebraska Board of Pharmacy elected their new officers. Bob Marshall was elected as Chairman; Jennifer King will serve as Vice Chair; and Patty Gollner will be the Secretary. Other Board members include: Ken Saunders, RP and Mike Losee (Public Member). The Board of Pharmacy agendas, minutes and meeting materials can be found on the DHHS website.
http://dhhs.ne.gov/publichealth/Pages/crl_medical_pharm_pharmlic_board.aspx

Updated Prescribing Authority Chart
The Nebraska Board of Pharmacy updated the Prescribers and Prescribing Authority Chart on November 18, 2013. This chart is a helpful tool to determine if a drug class can be prescribed by a certain type of practitioner or for a particular treatment area. The chart can be found on the NPA website, on the Members Only Pages (click on NPA Legislative Updates).

PBM & Audit Issues
LB 524 Pharmacy Audit Integrity Act, was introduced last year, carried over to this year’s legislative session, and remains in the Health & Human Services Committee.

The bill seeks to provide standards for a PBM when performing a pharmacy audit. LB 524 will not advance from Committee this year. Many of our members continue to deal with audit issues. In preparation for potential PBM legislation in 2015, we need to hear from you! Please send Executive Vice President, Joni Cover, specific examples of the types of audit issues you are facing. This information will help determine what law changes are necessary, both on a state and federal level. Comments may also be made by calling NPA Independent Network Chair, Rick Clabaugh, at 402-223-3591.

Nebraska Immunization Rules
While many employers require their employee pharmacists be certified to administer immunizations, it is not required by Nebraska law. See Pharmacist; powers, Nebraska Revised Statute Section 38-2866. http://nebrasklegislature.gov/laws/statutes.php?statute=38-2866

Immunizations can be administered by a pharmacist by prescription or through a pharmaceutical care agreement with protocols. The pharmaceutical care agreement is between a prescriber and the immunizing pharmacist(s). See Pharmaceutical Care Requirements, Title 172 Nebraska Administrative Code Chapter 128-013

Medical Marijuana
LB 1102 was introduced with the intent to authorize the medical use of hemp oil extract which contains no more than three-tenths of one percent tetrahydrocannabinols for the treatment of epilepsy. The bill was withdrawn on February 4, 2014.
Compounding Quality Act
On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA) legislation that contains important provisions relating to the oversight of compounding of human drugs. Facilities that compound human drugs (outsourcing facilities) may elect to register with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 353b), as added by the DQSA. An outsourcing facility will be able to qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use, but not the exemption from CGMP requirements. Outsourcing facilities:

- must comply with CGMP requirements,
- will be inspected by FDA according to a risk-based schedule, and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

If compounders register with the FDA as outsourcing facilities, hospitals and other health care providers can provide their patients with drugs that were compounded in outsourcing facilities that are subject to CGMP requirements and federal oversight. If a compounder chooses not to register as an outsourcing facility and qualify for the exemptions under section 503B, the compounder could qualify for the exemptions under section 503A of the FDCA. Otherwise, it would be subject to all of the requirements in the FDCA applicable to conventional manufacturers. FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. The Agency also intends to continue to cooperate with State authorities to address pharmacy compounding activities that may be violative of the FDCA.

NPA Legislative Notes
This legislative session, several bills that impact pharmacy were introduced:

- LB 858 - Pharmacists as Health Care Providers, was introduced to add pharmacists to the list of health care providers within Nebraska's insurance code to allow pharmacists to be reimbursed for pharmacists services, separate from the dispensing and counseling responsibilities. Thank you to NPA Legislative Committee Co-Chair, Ken Kester, RP, for testifying on behalf of the NPA.

- LB 869 - Uniform Controlled Substances Act was introduced as part of the Pharmacy Practice Update. Definitions within the Act were updated to conform to current statutory drafting standards. The Act was updated to allow electronic prescribing of controlled substances as authorized in federal law. Clarifications were included to distinguish between written, oral, and electronic prescriptions, and requirements for each for filing and record keeping. Additions to the Act included the definition of compounding; the requirements for a controlled substance prescription; and language transferred from other sections. Thank you to NPA Legislative Committee Co-Chair, Kevin Borcher, RP, for testifying on behalf of the NPA.

- LB 1017 would create a Prescription Drug Safety Act, as well as make numerous changes to the Pharmacy Practice Act, including changing the technician ratio to allow pharmacists to supervise 3 individuals (any combination of pharmacy technicians and pharmacist interns, up to 3 individuals). Thank you to Past NPA President, Chris Shaffer, RP, for testifying on behalf of the NPA.

- LB 1072 would authorize the Nebraska Board of Pharmacy to create a Prescription Drug Monitoring Program.

The NPA Legislative Bill Summary can be found on page 7. NPA Legislative updates can be found in the NPA Daily News Dose and Legislative Update emails, as well as on the NPA website under the Members Only pages.
Welcome NPA President, Fred Massoomi

In December 2013, the NPA Board of Directors accepted the resignation of President-Elect, Angela Ward, as she took a new pharmacy position in Texas. To fulfill Angela’s term, the Board unanimously appointed Firouzan ‘Fred’ Massoomi as the new NPA President beginning January 1, 2014. In addition, the Board also welcomed new Board members: President-Elect, Jennifer Tilleman; District I Representative, Trevor Bertsch; and District III Representative, Dana Griess.

Fred received his Doctor of Pharmacy Degree from the University of Kansas School of Pharmacy in Lawrence, Kansas. He has worked at Nebraska Methodist Hospital in various pharmacy positions since 1992, and is currently the Pharmacy Operations Coordinator. Throughout Nebraska and across the country, Fred is known for his work with emergency preparedness (disaster and terrorism) and pharmaceutical waste management in health systems. He is married to a pharmacist, Christine Sanz, who is a graduate of the Creighton University School of Pharmacy.

Below is Fred’s inaugural address to the NPA membership:

I am humbled by Angela’s recommendation for me to represent her as the Nebraska Pharmacists Association President for 2014. Angela’s recommendation was further supported by the Nebraska Pharmacists Association Board of Directors, to whom I am grateful for their confidence in President-Elect Ward’s selection. We wish Angela all the best.

As I received the ceremonial gavel from 2013 President Brenda Kiolbasa, RP, I realized the honorable legacy with which I have been charged. The Nebraska Pharmacists Association is an association that has a robust history that dates back to 1881. The conceptual covenant of the Nebraska Pharmacists Association is to be the professional association for Nebraska pharmacists that supports the concept of a unified voice for pharmacy. Pharmacists continually remain among the most trusted professionals in the United States. The work of the Nebraska Pharmacists Association champions this trust and respect that pharmacists bring to the healthcare team. As a profession, pharmacy represents the most accessible healthcare provider to communities. Our profession generously provides consultative information to better the lives we serve.

As the country embarks on the implementation of the Affordable Care Act (ACA), many exciting opportunities and challenges face our profession. Many questions need to be answered: What is pharmacy’s role in the changes associated with the ACA? What will the reimbursement model look like? How and where can pharmacy provide the most benefit? Can pharmacists bill for cognitive services and participate in population based healthcare management? You can be assured that the NPA is actively addressing these tough questions with the parties who manage the healthcare resources for the state.

As a representative voice of the profession of pharmacy, the Nebraska Pharmacists Association continues to protect the professional services provided to Nebraskans. However, the Nebraska Pharmacists Association only represents one-third of the licensed pharmacy professionals in the state. The strength of the NPA’s voice is tied to the number of individuals who believe that the association is worth supporting. My vision for the Nebraska Pharmacists Association is to heed our founders covenant as the one unified voice that represents the profession of pharmacy. Through your continued support and continued recruitment of members, our association will become the one unified voice our profession needs for the communities we serve.

Thank you for your continued support of the Nebraska Pharmacists Association and I look forward to our journey as the “One Voice” of pharmacy.
Dedicated to the profession and community, the NPA Career Center is a valuable search and recruitment resource for pharmacists and employers in Nebraska. The NPA Career Center offers simple and easy-to-use tools to make searching for career opportunities and finding qualified professionals fast, efficient and successful.

**Tools for Job Seekers**

The NPA Career Center gives job seekers access to inside opportunities available only through the association and provides the tools needed to quickly find and apply for jobs.

**Advanced Job Search**
Find the most relevant pharmacy jobs from top employers across the state.

**Customized Job Alerts**
Stay up-to-date on the latest opportunities by receiving automated notifications.

**Apply for Jobs**
Create an anonymous profile and resume to quickly apply for jobs and have employers come to you.

**Advantages for Employers**

Employers can fill positions faster and at a lower cost than other job websites by reaching a highly qualified and targeted audience of Nebraska pharmacists.

**Recruit Top Talent**
Target NPA members and job seekers committed to the advancement of the pharmacy profession.

**Low-Cost Posting Packages**
Reduce recruitment costs with flexible, affordable posting options.

**Proactive and Direct Recruitment**
Take advantage of search, email and online advertising options to recruit candidates.

**Visit the NPA Career Center**

Discover the difference the NPA Career Center can make for you. To search jobs, post jobs or learn more, visit www.npharm.org.
# LEGISLATIVE BILL SUMMARY

One Hundred Third Legislature, Second Session  
current as of February 21, 2014

Not all of the bills introduced to the 2014 Legislative Session are listed below.  
If you have questions about a bill not shown, call the Legislative Bill Office at (402) 471-2609  
to request a copy of a bill or visit the Nebraska Unicameral web site at www.nebraskalegislature.gov.

<table>
<thead>
<tr>
<th>Bill</th>
<th>Senator</th>
<th>Committee</th>
<th>Hearing Date</th>
<th>Description</th>
<th>NPA Position</th>
<th>Bill Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>LB 4</td>
<td>Krist</td>
<td>Appropriations Committee</td>
<td>3/25/13</td>
<td>Nebraska Health Care Cash Fund Would extend transfers required from the Nebraska Medicaid Intergovernmental Trust Fund and the Nebraska Tobacco Settlement Trust Fund to the Nebraska Health Care Cash Fund through July 15, 2017.</td>
<td>Watch</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 20</td>
<td>Nordquist</td>
<td>Appropriations Committee</td>
<td>3/25/13</td>
<td>Rural Health Provider Incentive Program Would state intent of legislature to appropriate an additional $600,000 from General Funds and Cash Funds for FY 2013-14 and FY 2014-15 to the Rural Health Provider Incentive Act.</td>
<td>Watch</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 54</td>
<td>Wightman</td>
<td>Health &amp; Human Services Committee</td>
<td>1/25/13</td>
<td>Display and Advertisement of Credentials Would require credential holders to wear name tags while in a healthcare facility or health care practitioner facility in which they have direct patient-care interaction. Would require advertisements to refrain from providing deceptive information about credentials. Would require students or residents in medical training to identify themselves as a student or resident as authorized by their respective practice acts pursuant to Uniform Credentialing Act, to wear name tag while in a health care facility or health care practitioner facility.</td>
<td>Neutral Comments</td>
<td>General File with Amendments</td>
</tr>
<tr>
<td>LB 58</td>
<td>Larson</td>
<td>Business &amp; Labor Committee</td>
<td>1/28/13</td>
<td>Workplace Privacy Act Would prohibit employers from requiring employees or job applicants to share their social network passwords with the employer. Would also prevent public or private employers from forcing employees to display their Facebook or Twitter pages to allow for inspection by the employer and would deny an employer access to an employee's social networking account through any third party. Would establish a cause of action in favor of the employee against the employer for violations of the Act.</td>
<td>Watch</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 61</td>
<td>Murante</td>
<td>Judiciary Committee</td>
<td>1/30/13</td>
<td>Financial Data Protection and Consumer Notification of Data Security Breach Act Would require notification of a breach of the security of a computerized data system to be given to the affected Nebraska residents and to the Attorney General. Would require notice to the Attorney General to include the nature of the breach of the security system or unauthorized acquisition or use and the names and addresses of residents of Nebraska affected by the breach or unauthorized acquisition or use. Would make failure to comply with the requirements a deceptive trade practice under the Uniform Deceptive Trade Practices Act.</td>
<td>Watch</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 76</td>
<td>Nordquist</td>
<td>Health &amp; Human Services Committee</td>
<td>2/22/13</td>
<td>Health Care Transparency Act Would adopt the Health Care Transparency Act and create a Health Care Database Advisory Committee to make recommendations regarding the creation and implementation of the Nebraska Health Care Database to provide a tool for objective analysis and healthcare costs and quality, promote transparency for health care consumers, and facilitate the reporting of health care and health quality data.</td>
<td>Watch</td>
<td>Approved By Governor 2/13/14</td>
</tr>
<tr>
<td>LB 86</td>
<td>McGill</td>
<td>Judiciary Committee</td>
<td>3/7/13</td>
<td>Return of Prescription Drugs - Staff Secure Juvenile Facilities Would extend the “facilities” in which prescription drugs or devices may be returned to include staff secure juvenile facilities.</td>
<td>Watch</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 95</td>
<td>Dubas</td>
<td>Business &amp; Labor Committee</td>
<td>2/11/13</td>
<td>Employee Credit Privacy Act Would prohibit discrimination based upon an individual’s credit history or credit report unless such information directly relates to a bona fide occupational qualification for employment.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>Bill Number</td>
<td>Sponsor</td>
<td>Committee</td>
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<td>LB 108</td>
<td>Karpisek</td>
<td>Gov't-Military &amp; Veterans Affairs Committee</td>
<td>1/30/13</td>
<td><strong>Prohibit Local Imposition of Credentialing Requirements</strong> Would prohibit any county, city, or village from requiring a person to be credentialed to conduct business or engage in any profession or occupation within the county, city, or village.</td>
<td>Watch In Committee</td>
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<tr>
<td>LB 119</td>
<td>Cook</td>
<td>Appropriations Committee</td>
<td>3/25/13</td>
<td><strong>Local Public Health Departments</strong> Would appropriate $3,600,000 in FY 2013-14 and FY 2014-15 for local public health departments to improve preventative health programs.</td>
<td>Watch In Committee</td>
<td></td>
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<tr>
<td>LB 228</td>
<td>Nordquist</td>
<td>Banking, Commerce &amp; Insurance Committee</td>
<td>3/5/13</td>
<td><strong>CoPayments/CoInsurance/Deductibles</strong> Would prohibit an insurer from charging an insured copayment, coinsurance, or deductible for services under health benefit plan rendered for each date of service by a physical therapist, occupational therapist, audiologist, or speech-language pathologist that is greater than the copayment, coinsurance, or deductible charged to the insured for services for a licensed primary care physician or a licensed osteopath. Would apply to all health benefit plans delivered or issued for delivery or renewed on or after January 1, 2014.</td>
<td>Watch In Committee</td>
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<tr>
<td>LB 239</td>
<td>Wightman</td>
<td>Banking, Commerce &amp; Insurance Committee</td>
<td>2/12/13</td>
<td><strong>Nebraska All-Payer Patient-Centered Medical Home Act</strong> Would promote patient-centered medical home care (health care delivery model in which a patient establishes an ongoing relationship with a physician in a physician-directed team to provide comprehensive, accessible, and continuous evidence-based primary and preventative care and to coordinate the patient's health care needs across the health care system in order to improve quality, safety, access, and health outcomes in a cost-effective manner). Would mandate coverage of patient-centered medical home care for all health insurance policies not otherwise exempted by federal law.</td>
<td>Watch In Committee</td>
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<tr>
<td>LB 245</td>
<td>Nordquist</td>
<td>Health &amp; Human Services Committee</td>
<td>2/1/13</td>
<td><strong>Medical Assistance Act/Preferred Drug List</strong> Would allow a health care provider to prescribe a prescription drug not on the preferred drug list to a Medicaid recipient without prior authorization by the Department if the provider certifies that the recipient is achieving therapeutic success with the course of anticonvulsant medication, including benzodiazepines for the treatment of epilepsy.</td>
<td>Watch In Committee</td>
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<td>LB 246</td>
<td>Larson</td>
<td>Judiciary Committee</td>
<td>2/7/13</td>
<td><strong>Correctional Facility Health Care</strong> Would require jail inmates or committed offenders to make a copayment of not less than $10 for each non-emergency visit to a health care provider which is initiated by such inmate or offender. Would deduct the copayment from any existing balance in the inmate's or offender's personal account, or if the account balance was insufficient to cover the copayment, 50 percent of each deposit to the account would be withheld until the copayment has been paid in full, with the proceeds of each copayment to be credited to the general fund of the county.</td>
<td>Watch In Committee</td>
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<td>LB 285</td>
<td>Conrad</td>
<td>Appropriations Committee</td>
<td>3/25/13</td>
<td><strong>Nebraska Health Care Cash Fund</strong> Would extend transfers required from the Nebraska Medicaid Intergovernmental Trust Fund and the Nebraska Tobacco Settlement Trust Fund to the Nebraska Health Care Cash Fund to July 15, 2015 and every July 15, thereafter.</td>
<td>Watch In Committee</td>
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<td>LB 333</td>
<td>Schumacher</td>
<td>Revenue Committee</td>
<td>3/20/13</td>
<td><strong>Sales and Use Taxation</strong> Would, effective July 1, 2013, reinstate the sales and use tax collection fee to allow collectors of the tax to deduct and withhold from the amount of taxes collected two and one-half percent of the first $3,000 remitted each month and one-half of one percent of all amounts in excess of $3,000 remitted each month as reimbursement for the cost of collecting the tax.</td>
<td>Support In Committee</td>
<td></td>
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<td>LB 421</td>
<td>McGill</td>
<td>Health &amp; Human Services Committee</td>
<td>2/8/13</td>
<td><strong>Uniform Credentialing Act</strong> Would allow professional boards to (a) provide for use of a current and valid credential from another jurisdiction to obtain a credential under the Uniform Credentialing Act by a person who is leaving service in the Unites States Armed Forces; or to (b) provide for use of an expired credential issued under the Uniform Credentialing Act to practice temporarily in order to obtain a current credential under the Act by a person who is leaving service in a reserve component of the United States Armed Forces. Would also allow professional boards to consider the ability of veterans to meet the requirements for its credentialed profession using military training, education and experience.</td>
<td>Watch In Committee</td>
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<td>Bill Number</td>
<td>Description</td>
<td>Text</td>
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<td>LB 422</td>
<td>Uniform Credentialing Act</td>
<td>Would allow professional boards to specify minimum standards required for an expedited temporary practice permit to a spouse of a veteran or a spouse of active military personnel licensed, certified, or registered in another jurisdiction while the spouse is satisfying the requirements for credentialing under the Uniform Credentialing Act if that jurisdiction has licensure, certification, or registration standards substantially equivalent to the standards required in this state. Would also allow professional boards to evaluate the ability of spouses of veteran and spouses of active military personnel to meet the requirements for its credentialed profession using training and experience obtained in other jurisdictions.</td>
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<td>LB 460</td>
<td>Immunizations</td>
<td>Would require, effective July 1, 2014, every student entering the seventh grade and at age 16 to have a booster immunization containing meningococcal conjugate vaccine meeting the standards approved by the United States Public Health Service for such biological products, as such standards existed on January 1, 2013.</td>
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<td>LB 489</td>
<td>Sales and Use Tax</td>
<td>Would establish the state sales and use tax, commencing October 1, 2013, at a yet to be determined rate.</td>
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<tr>
<td>LB 490</td>
<td>Income Taxation</td>
<td>Would establish individual income tax rates commencing January 1, 2014, at a yet to be determined rate.</td>
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<td>LB 503</td>
<td>Child Protection and Family Safety Act</td>
<td>Would require any person with reasonable cause to believe that a child has been subject to child abuse or neglect or has observed such child being subject to conditions or circumstances which reasonably would result in child abuse or neglect, to report such incident to the Department of Health and Human Services.</td>
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<td>LB 505</td>
<td>Mandated Benefits</td>
<td>Would require health insurance coverage for the screening, diagnosis and treatment of autism spectrum disorders for individuals up to age 21. (defines pharmacy care to mean a medication that is prescribed by a licensed physician and any health-related service deemed medically necessary to determine the need or effectiveness of the medication). [Senator Coash Priority Bill]</td>
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<tr>
<td>LB 523</td>
<td>Health Insurance/CoPayments/CoInsurance and Deductibles</td>
<td>Would prohibit an insurer from charging an insured a copayment, coinsurance, or deductibles under a health benefit plan for services rendered by a physical therapist, occupational therapist, audiologist, speech-language pathologist, chiropractor, or chiropractic physician that is greater than the copayment, coinsurance, or deductible charged to the insured for the services of the physician or osteopathic physician.</td>
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<td>LB 524</td>
<td>Pharmacy Audit Integrity Act</td>
<td>Would establish a program to provide standards for audits of pharmacy records carried out by a pharmacy benefits manager or any entity that represents pharmacy benefits managers.</td>
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<td>LB 526</td>
<td>Optometry Practice Act</td>
<td>Would expand the practice of optometry to include the performance of minor surgical procedures required for the removal of superficial eyelid, conjunctiva, and corneal formed bodies and the treatment of cysts or infected or inflamed glands of the eyelids; and the injection of pharmaceutical agents (pharmaceutical agents for therapeutic purposes, also means, pharmaceutical agents injected for treatment of anaphylaxis or pharmaceutical agents injected into the eyelid for treatment of cysts or infected or inflamed glands of the eyelids) for specified purposes.</td>
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<tr>
<td>LB 527</td>
<td>Optometry Practice Act</td>
<td>Would expand the practice of optometry to include the performance of minor surgical procedures required for the removal of superficial eyelid, conjunctiva, and corneal formed bodies and the treatment of cysts or infected or inflamed glands of the eyelids; and the injection of pharmaceutical agents (pharmaceutical agents for therapeutic purposes, also means, pharmaceutical agents injected for treatment of anaphylaxis or pharmaceutical agents injected into the eyelid for treatment of cysts or infected or inflamed glands of the eyelids) for specified purposes. Would also include steroids and immunosuppressive agents as pharmaceutical agents.</td>
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<td>Bill Number</td>
<td>Sponsor</td>
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<td>LB 535</td>
<td>Senator Lathrop</td>
<td>Health &amp; Human Services Committee</td>
<td>3/15/13</td>
<td>Prescription Monitoring Program Act: Would establish and maintain a program to monitor the prescribing and dispensing of controlled substances and other drugs identified by the Department of Health and Human Services as demonstrating a potential for abuse by all prescribers or dispensers in this state. Would require dispensers to submit to the Department information regarding each prescription dispensed for a controlled substance or other drug covered under the program. Would require reporting by electronic means of information, including, but not limited to, (a) dispenser identification number; (b) date prescription was filled; (c) prescription number; (d) whether prescription was new or a refill; (e) national drug code for drug dispensed; (f) quantity dispensed; (g) days' supply dispensed; (h) number of refills ordered; (i) patient identification number; (j) patient name; (k) patient address; (l) patient date of birth; (m) patient gender; (n) prescriber identification number; (o) date prescription issued by prescriber; (p) person who received the prescription from the dispenser other than the patient; and (q) source of payment for prescription. Would authorize the Department to issue a waiver to a dispenser unable to submit prescription information by electronic means.</td>
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<td>LB 560</td>
<td>Senator Mello</td>
<td>Business &amp; Labor Committee</td>
<td>2/4/13</td>
<td>Nebraska Fair Employment Practice Act/Nebraska Wage Payment and Collection Act: Would expand records retention requirements under the Nebraska Fair Employment Practice Act to require records to be retained for five years or longer if required by the Commission. Would make it unlawful to discriminate or retaliate against an individual who a) is opposed to any practice made unlawful by the Wage and Hour Act or b) has made a charge, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under the Act. Would require employers within 10 days after written request made by an employee to furnish the employee with a statement listing the wages earned and paydays and to furnish each employee on each payday with an itemized statement listing the wages earned and deductions made from the employees wages for each pay period that earnings and deductions were made.</td>
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<td>LB 564</td>
<td>Senator Nelson</td>
<td>Judiciary Committee</td>
<td>3/1/13</td>
<td>Health Care Freedom of Conscience Act: Would protect the basic civil right, the right of each health care provider or institution to decline to participate in any health care function that violates their respective consciousness. Would prohibit all forms of discrimination against any health care provider or institution that declines any health care function that violates their respective consciousness.</td>
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<tr>
<td>LB 577</td>
<td>Senator Campbell</td>
<td>Health &amp; Human Services Committee</td>
<td>2/28/13</td>
<td>Federal Health Care Reform Act: Would provide Medicaid coverage for individuals making less than 138 percent of the federal poverty level. [Senator Campbell Priority Bill]</td>
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<tr>
<td>LB 578</td>
<td>Senator Nordquist</td>
<td>Health &amp; Human Services Committee</td>
<td>2/28/13</td>
<td>Health Care Access and Support Fund: Would create the Health Care Access and Support Fund to support the Medicaid program. Would divert the first $10 million in premium and related retaliatory taxes imposed on insurers for credit to the Health care Access and Support Fund in fiscal year 2013-14, the first $18 million for fiscal year 2014-15 and the first $23 million for fiscal year 2015-16 and in each fiscal year thereafter.</td>
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<td>LB 752</td>
<td>Senator Lathrop</td>
<td>Judiciary Committee</td>
<td>1/23/14</td>
<td>Assault on a Healthcare Professional: Would expand the provisions relating to assault on a healthcare professional to include emergency responders, firefighters, out-of-hospital emergency care providers and healthcare professionals. (Does not cover pharmacists in a pharmacy) [Senator Harr Priority Bill]</td>
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<tr>
<td>LB 811</td>
<td>Senator Schilz</td>
<td>Judiciary Committee</td>
<td>Hearing</td>
<td>Uniform Controlled Substances Act: Would change provisions and penalties relating to “designer drugs” and imitation controlled substances under the Uniform Controlled Substances Act.</td>
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<tr>
<td>LB 827</td>
<td>Senator Harms</td>
<td>Appropriations Committee</td>
<td>2/10/14</td>
<td>Community Health Center Appropriations: Would appropriate $1.5 million to the Department of Health and Human Services for the six community health centers in the state.</td>
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<td>LB 831</td>
<td>Senator Christensen</td>
<td>Banking Commerce &amp; Insurance Committee</td>
<td>2/18/14</td>
<td>Medical Equipment: Would require designated insurance policies to apply medical equipment costs to the deductible year in which the request for approval of coverage of the medical equipment was received by the insurer. Would also make the unreasonable delaying of a request for pre-approval of coverage for medical equipment an unfair claims settlement practice.</td>
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<td>LB 854</td>
<td>Senator Krist</td>
<td>Health &amp; Human Services Committee</td>
<td>2/5/14</td>
<td>Long-Term Care Request for Proposals Would prohibit the Department of Health and Human Services from releasing a request for proposals relating to procurement of managed care for long-term care services and support prior to September 1, 2015. [HHS Committee Priority Bill]</td>
<td>Support</td>
<td>General File</td>
</tr>
<tr>
<td>LB 858</td>
<td>Senator Howard</td>
<td>Banking Commerce &amp; Insurance Committee</td>
<td>2/18/14</td>
<td>Pharmacists Health Care Services Would require insurance policies to recognize pharmacists as health care providers who have the authority to provide health care services including, but not limited to, medication therapy management services, chronic disease management services, comprehensive medication review, and other such professional services provided to patients by pharmacists. Would require payment for such services to be separate and distinct from dispensing and counseling services provided by pharmacists or as a part of a pharmacy's ordinary course of business. Would also require insurance policies to provide partial or total reimbursement for services provided by a pharmacy that are provided by other designated medical providers. [NPA Bill]</td>
<td>Support</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 859</td>
<td>Senator Krist</td>
<td>Health &amp; Human Services Committee</td>
<td>1/24/2014</td>
<td>Health Care Facilities On Site Vaccinations Would clarify that the requirement to annually offer onsite influenza vaccinations to all hospital employees does not apply to individual cases when contraindicated or if a national shortage of the vaccine exists.</td>
<td>Watch</td>
<td>General File</td>
</tr>
<tr>
<td>LB 860</td>
<td>Senator Nordquist</td>
<td>Banking Commerce &amp; Insurance Committee</td>
<td>2/11/14</td>
<td>Health Insurance Coverage Limitations Would prohibit insurance policies from establishing a) lifetime limits on the dollar value of benefits for any participant or beneficiary; or b) unreasonable annual limits on the dollar value of benefits for any participant or beneficiary. Would exclude insurance policies that are not required to provided essential health benefits from these prohibitions. Would also prohibit insurance policies from rescinding the plan or coverage with respect to an enrollee once the enrollee is covered under the plan or coverage and would prohibit imposition of preexisting condition exclusions with respect to such plan or coverage.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 861</td>
<td>Senator Karpisek</td>
<td>General Affairs Committee</td>
<td>1/27/14</td>
<td>Tobacco Products Would prohibit the sale or distribution of cigarettes, cigars, vapor products, or tobacco through a self-service display (a retail display that contains a tobacco product and is located in an area openly accessible to a retailer's customers and from which such customers can readily access tobacco products without the assistance of a sales person).</td>
<td>Support</td>
<td>General File with Amendments</td>
</tr>
<tr>
<td>LB 862</td>
<td>Senator Lathrop</td>
<td>Judiciary Committee</td>
<td>2/21/14</td>
<td>Nebraska Hospital-Medical Liability Act Would increase the dollar amount recoverable under the Nebraska Hospital-Medical Liability Act from $1,750,000 to $2,500,000, for any occurrence after December 31, 2014.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 869</td>
<td>Senator Gloor</td>
<td>Health &amp; Human Services Committee</td>
<td>1/24/14</td>
<td>Uniform Controlled Substances Act Would amend and update the pharmacy practice provisions of the Nebraska Controlled Substances Act. Would allow electronic prescribing of controlled substances as authorized under federal law. Would distinguish between written, oral, and electronic prescriptions and the filing and record keeping requirements of each type of prescription. Would also revise the definition of compounding, and the requirements for controlled substance prescriptions. [NPA Bill]</td>
<td>Support</td>
<td>General File with Amendment</td>
</tr>
<tr>
<td>LB 883</td>
<td>Senator Nordquist</td>
<td>Banking Commerce &amp; Insurance Committee</td>
<td>2/18/14</td>
<td>Anti-Cancer Medications Insurance Coverage Would repeal the December 31, 2015, &quot;sunset” date for insurance coverage of certain anti-cancer medications.</td>
<td>Watch</td>
<td>General File</td>
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<tr>
<td>LB 887</td>
<td>Senator Campbell</td>
<td>Health &amp; Human Services Committee</td>
<td>1/29/14</td>
<td>Medicaid Expansion/Wellness in Nebraska Act Would adopt the 2014 version of the “Medicaid expansion.” Would combine a mix of private insurance, wellness incentives, cost sharing and expansion of Medicaid coverage. [Senator Campbell Priority Bill]</td>
<td>Support</td>
<td>In Committee</td>
</tr>
<tr>
<td>LB 893</td>
<td>Senator Seiler</td>
<td>Judiciary Committee</td>
<td>2/21/14</td>
<td>Nebraska Hospital Medical Liability Act Would increase the dollar amount recoverable under the Nebraska Hospital-Medical Liability Act from $1.75 million to $2 million for any occurrence after December 31, 2014.</td>
<td>Watch</td>
<td>In Committee</td>
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<td>Bill Number</td>
<td>Sponsor</td>
<td>Committee</td>
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<td>LB 897</td>
<td>Senator Cook</td>
<td>Revenue Committee</td>
<td>Hearing 2/12/14</td>
<td>Income Taxation Would provide an income tax credit to employers of public assistance recipients for tax years beginning on or after January 1, 2015. Would limit the credit to not more than two years in the amount of 20 percent of the employer's annual expenditures for basic education services; health or dental insurance; childcare services and programs for transportation to and from work.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 903</td>
<td>Senator Lathrop</td>
<td>Business &amp; Labor Committee</td>
<td>Hearing 2/3/14</td>
<td>Nebraska Wage Payment and Collection Act Would require employers, on each regular payday, to delivery to each employee, by mail or electronically, or to provide at the employee's normal place of employment during the normal employment hours a wage statement showing, at a minimum, the identity of the employer, the hours the employee worked, the wages earned by the employee, and deductions made for the employee.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 905</td>
<td>Speaker Adams</td>
<td>Appropriations Committee</td>
<td>Hearing 2/3/14</td>
<td>Deficit Appropriations Would make reductions in the appropriations for the Medicaid Prescription Drug Act administration and contains provisions for a $450,000 FY 2013-14/2014-15 appropriation from the Nebraska Healthcare Cash Fund for state plan amendment covering tobacco-use cessation (costs of tobacco-use counseling and tobacco-use pharmaceuticals).</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 916</td>
<td>Senator Crawford</td>
<td>Health &amp; Human Services Committee</td>
<td>Hearing 1/31/14</td>
<td>Nurse Practitioners Would eliminate the requirement for integrated practice agreements for nurse practitioners. [Senator Watermeier Priority Bill]</td>
<td>Watch</td>
<td>General File with Amendments</td>
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<tr>
<td>LB 931</td>
<td>Senator Bolz</td>
<td>Health &amp; Human Services Committee</td>
<td>Hearing 1/30/14</td>
<td>Nebraska Mental Health First Aid Training Act Would require the Department of Health and Human Services to establish a mental health first aid training program to help the public identify and understand the signs of a mental illness or substance abuse problem or a mental health crisis and to provide the public with skills to help such a person.</td>
<td>Watch</td>
<td>In Committee</td>
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<tr>
<td>LB 943</td>
<td>Senator Nordquist</td>
<td>Business &amp; Labor Committee</td>
<td>Hearing 2/3/14</td>
<td>Minimum Wage Would increase the state's minimum wage from $7.25 to $7.65 an hour in 2015; to $8.35 an hour in 2016; and to $9.00 an hour in 2017.</td>
<td>Watch</td>
<td>General File with Amendments</td>
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<tr>
<td>LB 953</td>
<td>Senator Howard</td>
<td>Banking Commerce &amp; Insurance Committee</td>
<td>Hearing 2/18/14</td>
<td>Health Information Initiative Act Would establish a public-private state-wide initiative that operates a health information exchange facilitating the secure exchange of clinical information among physicians and other healthcare providers in real time at the point of care. Would allocate $1 million from the premium and related retaliatory insurance taxes to the Health Information Initiative Support Fund.</td>
<td>Watch</td>
<td>In Committee</td>
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<td>LB 974</td>
<td>Senator Mello</td>
<td>Appropriations Committee</td>
<td>Hearing 1/30/14</td>
<td>Department of Health and Human Services Budget Strategy Would require the division of Medicaid and Long-Term Care of the Department of Health and Human Services, beginning with the biennium ending June 30, 2017, as a part of the appropriations request process, to include a strategic plan identifying the main purpose or purposes of each program, verifiable and auditable key goals that the division believes are fair measures of its progress in meeting such program's main purpose or purposes, and benchmarks for improving performance on the key goals. [Appropriations Committee Priority Bill]</td>
<td>Watch</td>
<td>General File with Amendments</td>
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<tr>
<td>LB 1001</td>
<td>Senator Wallman</td>
<td>Judiciary Committee</td>
<td>Hearing 2/2/12</td>
<td>Industrial-Hemp Would allow for the planting, growing, harvesting, possession, processing, selling, and buying of industrial hemp (all parts and varieties of the plant cannabis sativa whether growing or not that contains one percent or less concentration of tetrahydrocannabinols by dry weight). Would also exempt industrial hemp from the Uniform Controlled Substances Act. [Senator Wallman Priority Bill]</td>
<td>Watch</td>
<td>In Committee</td>
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<td>LB 1017</td>
<td>Senator Krist</td>
<td>Health &amp; Human Services Committee</td>
<td>Hearing 2/12/14</td>
<td>Prescription Drug Safety Act Would establish the Prescription Drug Safety Act and require any practitioner that stores, dispenses incident to practice, administers or otherwise provides any drug to a patient to comply with the Act. Would revise the definition of compounding to require compliance with the standards of Chapters 795 and 797 of the United States Pharmacopoeia and the National Formulary. Would also add medication therapy management to the definition of the practice of pharmacy. Would authorize a pharmacist to supervise any combination of pharmacy technicians and pharmacists interns at any time up to a total of three people, not including a pharmacist intern receiving experiential training directed by the accredited pharmacy program in which he or she is enrolled. [NPA Bill]</td>
<td>Support</td>
<td>In Committee</td>
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<td>Bill Number</td>
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<td>LB 1051</td>
<td>Public Health Leadership and Development Act</td>
<td>Would direct the University of Nebraska Medical Center to establish a community health worker certification pilot program that includes standardized core competencies (communication skills, interpersonal skills, capacity-building skills, advocacy skills, organizational skills, case management, knowledge of specific health issues, and documentation for community health workers) and is based upon consistent themes found in natural research. The pilot program would include adoption of a standardized payer system to incorporate community health workers into the Center for Medicare/Medicaid services and commercial payers and would appropriate $250,000 from the General Fund for the first year of the pilot program.</td>
<td>Watch</td>
<td>In Committee</td>
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<td>LB 1072</td>
<td>Prescription Monitoring and Health Information Exchange Act</td>
<td>Would require the Board of Pharmacy to establish and maintain a program to monitor the prescribing and dispensing of controlled substances and additional drugs identified by the Board as demonstrating a potential for abuse and to contract with an organization which facilitates the secure exchange of critical information among physicians and other healthcare providers in real time at the point of care. Would require each dispense to submit information regarding each prescription dispensed for a controlled substance or a drug identified pursuant to the Act, containing information prescription information required by the Board. Would require, beginning two years after the operative date of the Act, all dispensers to electronically record prescription information in accordance with the requirements of the dispense's e-Prescriber platform not more than one hour after the time each prescription was dispensed, with the Board authorized to issue a waiver to a dispense that is unable to record the prescription information by electronic means.</td>
<td>Neutral</td>
<td>Seek Amendments</td>
<td>In Committee</td>
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<td>LB 1076</td>
<td>Medical Assistance Act</td>
<td>Would provide, effective January 1, 2014, that there shall be no reduction in reimbursement rates and no limitation on services, for Medicaid authorization and payment for home health care services until the Balancing Incentive Programs have been completed and the Department of Health and Human Services has reviewed the results of the programs with the goal of assessing and improving Nebraska’s provision of Medicaid home health services.</td>
<td>Watch</td>
<td>General File with Amendments</td>
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<td>LB 1078</td>
<td>Nebraska Telehealth Act</td>
<td>Would establish designated health care professionals, including pharmacists, to establish a provider-patient relationship either through an in-person meeting or by seeing the patient through the use of a real-time, two-way electronic video conference. Would require insurance policies not otherwise exempted to include coverage for treatment provided using telehealth if the health care provider has determined the use of telehealth as appropriate and if such treatment is covered when provided when in person. Telehealth means the use of medical information electronically exchanged from one site to another, whether synchronously or asynchronously, to aid a health care provider in the diagnosis or treatment of a patient.</td>
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<td>LB 1090</td>
<td>Healthy Families and Workplaces Act</td>
<td>Would allow employees to accrue a minimum of one hour of paid sick time for every thirty hours worked, with a maximum of forty hours of paid sick time accrued in a calendar year, with the employee entitled to use accrued paid sick time beginning on the 90 calendar day following commencement of employment. Would authorize paid sick time for (a) an employee's mental or physical illness, injury, or health condition; (b) an employee's need for medical diagnosis, care, or treatment of a mental or physical illness, injury, or health condition; (c) an employee's need for preventative medical care; (d) care of a family member with a mental or physical illness, injury, or health condition; (e) care of a family member who needs medical diagnosis, care or (f) treatment of a mental or physical illness, injury, or health condition; or care of a family member who needs preventative medical care.</td>
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<td>In Committee</td>
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<td>LB 1102</td>
<td>Medical Marijuana</td>
<td>Would authorize the medical use of hemp oil extract which contains no more than three-tenths of one percent tetrahydrocannabinols for the treatment of epilepsy.</td>
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<td>Bill Withdrawn</td>
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<td>LB 1107</td>
<td>Medical Assistance Program</td>
<td>Would change payment provisions relating to encounters with multiple health care professionals at a federally qualified health center to provide that encounters with more than one healthcare professional and multiple encounters with the same healthcare professional taking place on the same day at a federally qualified health center constitute a single visit (would exclude such encounters with designated health care providers including pharmacists).</td>
<td>Support</td>
<td>In Committee</td>
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The Patient Protection and Affordable Care Act (ACA) and Its Impact on Pharmacy

This CPE lesson was written by Abby Winter, PharmD, MPA, PGY-1 Community Pharmacy Practice Resident, Creighton University Medical Center, who has no financial or conflict of interest disclosures.

Goal
The goal of this continuing pharmacy education lesson is to review the Patient Protection and Affordable Care Act (ACA), specifically looking at the impact it will have on pharmacy practice, including potential opportunities for pharmacy.

Objectives (for Pharmacists & Technicians)
At the conclusion of this lesson, participants should be able to:
1. Identify the basic provisions of the Patient Protection and Affordable Care Act (ACA).
2. List provisions of the ACA in chronological order of implementation.
3. Describe potential effects from the ACA on pharmacy.
4. Identify opportunities for pharmacy to impact patient care under the ACA.

Background
On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (ACA), commonly referred to as “the healthcare reform bill,” or “Obamacare.” The main goals of the ACA are to increase access to health care and health insurance, improve health outcomes, and lower costs of healthcare for all Americans. Since the time of inception of the ACA, there have been a number of changes that have impacted the healthcare system across the country, and there are still many more to come. The ACA will also help to improve overall management of healthcare. This will be of great benefit considering the rather fragmented management many patients are currently receiving from various healthcare providers with a lack of centralization.

Pharmacists and pharmacies will be impacted by the Affordable Care Act in many ways. As some of the nation’s most accessible healthcare providers, we have come to expect patients to approach us with questions relating not only to medications, but also to healthcare in general. The complexity of the ACA and the nature by which it will accept continuous alterations and changes will likely create more opportunities for new and existing patients to utilize or require our services and knowledge. This CPE program will provide an overview of general provisions of the Affordable Care Act, and will discuss the potential impact that healthcare reform will have on community pharmacy, long-term care pharmacy, and health system pharmacy.

Overall Goals and Impact

Increase Access
The Affordable Care Act has multiple aspects set up to improve access to healthcare and health insurance including: Medicaid expansion, an individual mandate, employer requirements, and insurance exchanges.

Medicaid Expansion
Under the ACA, states were originally required to adopt expansion of their individual Medicaid programs. After the Supreme Court upheld the law in 2012, justices ruled that states now have the choice to opt out of the ACA mandated Medicaid expansion, allowing individual states the opportunity to institute their own program to improve access to healthcare and reduce the number of uninsured Americans. Medicaid expansion, as outlined in the ACA, would provide expanded coverage for individuals up to 133% of the federal poverty level (in 2013, the federal poverty level was up to $15,282 for a single person or $25,975 yearly for a family of 3), adding a potential 16 million more individuals to programs across the nation. Although there is no deadline as to when states must make a decision, delaying will result in states paying the price. At stake is the changing federal contribution payment rate for state Medicaid programs. As it is established in the ACA, if a state opts to adopt Medicaid expansion as described in the law, the federal government will cover 100% of the coverage costs for all new enrollees from 2014-2016. The federal share will decline to 95% in 2017, and eventually to 90% in 2022 and thereafter. Individual states will be responsible for the remainder.

Local Impact of Medicaid Expansion Decisions
When faced with the ACA option of Medicaid expansion, Nebraska and Iowa chose different routes. While the state of Nebraska, among many others, has rejected the expansion citing increased costs as reason, Iowa has developed their own version entitled the Iowa Health and Wellness Plan. Under this Iowa plan, those making 101%-138% of the federal poverty level will be called to enroll in commercial health plans, but their monthly premiums will then be paid by Medicaid. In the second year of the Iowa Health and Wellness Plan, many participants will be required to pay a $10 monthly premium, but the premium would be waived for those opting to participate in a wellness program. With this set-up, Iowa legislators explain that participants will receive incentives to invest in their own health.

Individual Mandate
On January 1, 2014, most Americans were required to obtain health insurance, either through their employer, or by qualifying for Medicare, Medicaid, or other public insurance programs (e.g. Tricare). If health insurance is not obtained, all nonexempt Americans will be required to pay a penalty to the IRS at the end of the tax year. There are few exceptions to this mandate, including individuals who cannot afford coverage (cost of premiums exceeding 8% of total household income), or Americans...
Table 1.

<table>
<thead>
<tr>
<th>Household Income</th>
<th>Individual</th>
<th>Family</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-200%</td>
<td>1/3 HSA</td>
<td>1/3 HSA</td>
</tr>
<tr>
<td>($1,083.33)</td>
<td>($1,775)</td>
<td>($2,150)</td>
</tr>
<tr>
<td>200-400%</td>
<td>1/2 HSA</td>
<td>1/2 HSA</td>
</tr>
<tr>
<td>($1,775)</td>
<td>($3,250)</td>
<td>($6,450)</td>
</tr>
<tr>
<td>300-400%</td>
<td>2/3 HSA</td>
<td>2/3 HSA</td>
</tr>
<tr>
<td>($2,166.67)</td>
<td>($4,300)</td>
<td></td>
</tr>
<tr>
<td>Greater than 400%</td>
<td>100% HSA</td>
<td>100% HSA</td>
</tr>
<tr>
<td>($3,250)</td>
<td>($6,450)</td>
<td></td>
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</tbody>
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whose household income is below the minimum threshold for filing a tax return. The Congressional Budget Office estimates that approximately 24 million people will be exempt come 2016. For reference, Table 1 describes maximum out-of-pocket expenses for individuals and families as outlined in the ACA.\(^7\)\(^8\)

Under the ACA, insurance companies can no longer deny individuals health insurance coverage nor can insurance companies charge more money due to pre-existing health conditions. The only exception to this mandate is for grandfathered plans, or individual insurance plans not purchased through an employer. Part of the rationale behind the Individual Mandate stems from this provision. With this new stipulation in place and no individual mandate, it would be possible for many Americans to hold off on obtaining health insurance until they became sick, ultimately resulting in a larger increase in premiums for sick individuals. The penalty fee for failure to comply with the mandate will originally be up to $95 per adult and $47.50 per child, or 1% of total family income, whichever is greater. This fine will increase over time. By 2016, the fees will reach $695 per adult and $347 per child (up to $2,085 for a family) or 2.5% of income, whichever is greater.\(^7\)\(^8\)\(^9\)

The ACA dictates that insurance companies are now held accountable for providing affordable healthcare to their policy holders. Table 2 highlights additional requirements for insurance companies as well. Starting in 2012, insurance companies who do not spend at least 80% of premium dollars on healthcare are now required to provide rebates to their customers. This is referred to as the “80/20 rebate”. The 80/20 rebate will apply to all individual, small group, and large group health plans. In 2012 alone, over 12.8 million customers received these rebates.\(^10\) These rebates are either provided in the form of a check to the policy holder, a credit to the account used to pay the premium, or a discount on a future premium. Employers have the option to provide the rebate as listed previously, or they may apply the rebate in a way that will benefit its employees. Policy holders must be notified if they or their employer will be receiving a rebate. Insurance companies will not be required to provide rebates if there are fewer than 1,000 enrollees in a particular designated region or state.\(^6\)\(^11\)

**Employer Requirements**

Starting in 2016, employers with 50 or more employees (Full-Time Equivalents) must provide health insurance to their employees or pay a “responsibility payment” penalty. Individuals who obtain insurance through their employer may be eligible for subsidized coverage through an Insurance Exchange if their premiums are unaffordable (greater than 9.5% of total household income), or if the plan being offered is inadequate, paying less than 60% of the cost of covered benefits. Beginning in 2016, large employers may incur penalties if their employees receive premium subsidies through the Insurance Exchanges, as a result of the employer-offered insurance providing inadequate or expensive coverage. Additionally, employers with greater than 200 employees that are offering at least one health plan must automatically enroll their employees in the program, with the hope of increasing employer participation. Employees do have the opportunity to opt out of their employer-provided coverage, but must still abide by the new ACA laws regarding health insurance coverage under the Individual Mandate. In addition, small businesses with fewer than 25 full-time equivalent employees and average annual wages of less than $50,000 who pay at least half of the cost of health insurance for their employees will be eligible for a tax credit under the ACA.\(^2\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^10\)\(^11\)\(^12\)

**Insurance Exchanges**

On October 1, 2013, Insurance Exchanges, also called the Health Insurance Market, were implemented. These Insurance Exchanges allow individuals and small businesses to “shop” for insurance coverage, providing more options and hopefully more affordable health insurance coverage. Two types of exchanges were established by the ACA including Health Insurance Exchanges for individuals, as well as Small Business Health Options Program (SHOP) exchanges. The Exchanges for individuals will allow those who are not offered health insurance from their employer to purchase insurance on their own at a discounted rate. The SHOP Exchanges will allow small businesses to combine forces and purchase health insurance in a larger group; therefore, lowering the cost for all policy holders. Enrollment in these exchanges continues through March 2014, but those who enroll early will receive coverage beginning January 1, 2014. Each state could opt to create their own exchange, otherwise they could defer

<table>
<thead>
<tr>
<th>Table 2. New Insurance Company Requirements at a Glance</th>
</tr>
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<tbody>
<tr>
<td>• Extend coverage for children up to the age of 26 on their parents’ health insurance plan</td>
</tr>
<tr>
<td>• Can no longer deny coverage based on pre-existing conditions</td>
</tr>
<tr>
<td>• Provide free preventative services</td>
</tr>
<tr>
<td>• Provide preventative services for women (including FDA-approved contraceptive methods)</td>
</tr>
<tr>
<td>• No longer allowed to arbitrarily deny health insurance due to illness</td>
</tr>
<tr>
<td>• No more yearly or lifetime dollar limits on coverage for essential health benefits</td>
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</tbody>
</table>
to the established federal exchange. States also had the option to merge their two individual and small business exchanges, combine with other states to create Multi-State exchanges, or even create multiple exchanges within their state based on specific geographic areas. No matter with whom or how the exchanges are formed, states are responsible for licensing, rate and form review, consumer complaints, and market conduct for each exchange.\textsuperscript{3,4,13-15}

For the second year of exchange operations, individual states will have another opportunity to transition between models.

In order to enter into the health insurance exchange program, insurance companies must offer the established essential health benefits, shown in Table 3.\textsuperscript{10} However, the law does not define the specific services that must be covered, the amount, duration, or scope of these services, as that is left up to the Secretary of Health and Human Services. In 2016, these essential health benefits will be open for reexamination. This provides a potential opportunity for pharmacy to have a voice, once it can assess how well the established essential health benefits are supporting care for patients.\textsuperscript{5}

With all of these additional programs and requirements, an increased number of Americans will now have health insurance. We need to ensure there are providers and healthcare professionals in place to meet the increased number of patients and patients’ needs, and the field of pharmacy is no exception.

**Health Information Exchanges** The Affordable Care Act has outlined new ways for healthcare services to be provided and paid for, with an ultimate goal of improving patient care coordination and quality of care. In order to adequately provide improved quality care, improved health information exchange (HIE) is strongly encouraged through the ACA. States are responsible for facilitating a data exchange among providers. A variety of methods, technologies, and strategies can be adopted in order to provide adequate exchange of important health information between providers, while also allowing patients access to their information. Electronic HIE will allow greater access to patient information for those who require it in order to provide adequate care while reducing redundancies and enhancing collaboration of care. HIE can also improve patient safety, allowing providers to have access to a more robust patient health record. With increased access, coordination and quality of patient care will improve, while still maintaining appropriate safety and security of information. Many health systems have developed their own private HIE systems, and HIE is a near necessity for Accountable Care Organizations (ACOs) to perform as desired. The ultimate goal is for providers to adopt HIE as a standard of providing patient care.\textsuperscript{4,16}

<table>
<thead>
<tr>
<th>Table 3. Ten Essential Health Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ambulatory patient services</td>
</tr>
<tr>
<td>• Doctor’s visits and outpatient services</td>
</tr>
<tr>
<td>2. Emergency services</td>
</tr>
<tr>
<td>3. Hospitalizations</td>
</tr>
<tr>
<td>4. Maternity and newborn care</td>
</tr>
<tr>
<td>5. Mental health and substance use disorder services</td>
</tr>
<tr>
<td>• Including behavioral health treatment</td>
</tr>
<tr>
<td>6. Prescription medications</td>
</tr>
<tr>
<td>7. Rehabilitative and habilitative services and devices</td>
</tr>
<tr>
<td>• Habilitative services include helping a person keep, learn, or improve skills and functioning for daily living</td>
</tr>
<tr>
<td>8. Laboratory services</td>
</tr>
<tr>
<td>9. Preventative and wellness services, and chronic disease management</td>
</tr>
<tr>
<td>10. Pediatric services</td>
</tr>
<tr>
<td>• Including oral and vision care</td>
</tr>
</tbody>
</table>

**Improve Outcomes & Decrease Cost**\textsuperscript{2,3,9,14,17,18}

There are multiple programs and initiatives being implemented to help improve health outcomes and decrease healthcare costs across various facets of the healthcare system as a result of the ACA. Most notable for the profession of pharmacy are Accountable Care Organizations or ACOs. ACOs provide an emphasis on transition of care and care coordination for patients. Pharmacists play an integral role as a part of the patient care team.

ACOs are interprofessional care teams made up of various health care professionals designed to provide the highest quality medical care possible through improved coordination of care and cooperation among providers, which could assist in lowering healthcare costs. Most often the patient population served by an ACO consists of Medicare beneficiaries, though some may also include Medicaid enrollees, patients with employer-offered health insurance, and homeless or uninsured individuals. In an ACO, provider reimbursement is tied to quality of care and reduction in total cost of care for an assigned group of patients. Provider financial incentives are also increased. For each 12-month period that an ACO meets the quality and performance standards set by the Centers for Medicare & Medicaid Services (CMS), providers in that ACO will be eligible to receive a portion of any savings, if the per capita expenditures of their assigned beneficiaries is significantly below their specified benchmark amount. Essentially, providers will be paid more if they keep their patients well, rather than being paid for the number of patients they see. The ACA established an initial set of guidelines that must be met in order for any group of physicians, hospitals, or other healthcare providers to participate in an ACO, though the design of the ACO model is meant to evolve over time. Any provider or provider organization may assume the leadership role of running an ACO. In addition, community health centers, rural health clinics, and critical access hospitals are also allowed to lead ACOs and participate in the shared savings program.
The ACA outlines the following list of providers of Medicare-covered services that an ACO may include:

- ACO professionals (practitioners meeting the statutory definition) in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint ventures arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other Medicare providers and suppliers as determined by the Secretary of HHS

In addition to primary care physicians (the only required participant in an ACO), ACOs may include specialists, hospitals, post-acute providers, or even private companies. As of February 2013, approximately 14% of the American population was being serviced by an ACO. Many of these ACOs are also serving non-Medicare beneficiaries, with possible expansion to serve all of their patients under an ACO model. Under the Affordable Care Act, ACOs must serve a minimum of 5,000 Medicare beneficiaries for at least 3 years in order to meet minimum requirements. Providers have the option of entering an ACO accepting zero risk, or they may enter with partial ownership of overall savings by accepting risk of losing money if they opt for the potential of a bigger reward. Health and Human Services estimates that if implemented and utilized as outlined, ACOs could save Medicare up to $940 million within their first 4 years of implementation. ACOs maintain a fee-for-service model in which hospitals and providers are paid for each test and procedure, but ACOs also impose savings incentives through which bonuses are offered to those providers who keep healthcare costs down. Patients in an ACO still have complete freedom to choose their own providers and locations for receiving medical care, and most patients will not even realize they are being treated under an ACO (though notification to beneficiaries is required). The biggest noticeable change beneficiaries can expect to see is improved healthcare due to better coordination.

Each ACO must establish a governing body representing the ACO providers. In addition, ACOs are required to perform self-assessment, monitoring, and reporting of the care provided. Monitoring of ACO performance must be completed in order to ensure compliance with eligibility and program requirements, including the analysis of claims and financial and quality data, site visits, and beneficiary surveys. CMS agreement termination may be warranted if ACOs do not comply with outlined performance standards.

**Pharmacy-Specific Considerations**

Over time, the impact of the ACA on the profession of pharmacy will likely be more visible as pharmacists become integral members of new and existing healthcare teams. This is especially prominent with the implementation of ACOs. According to a recent article in the *Pharmacy Times*, the likely impact of the ACA will be "strengthening the public’s perception of the pharmacist as an integral part of the medical care team".

Multiple states have come up with innovative ways of incorporating pharmacists into various healthcare models. Of note is Hawaii’s “Pharm2Pharm” program, through which formal personal relationships are established between community pharmacists and hospital pharmacists in order to improve patient care, especially at times of transition. This innovative idea earned Hawaii an award of $14.3 million dollars to implement the program, from which an estimated $27.1 million in cost savings will be seen over a 3-year period.

The demand for pharmacist services and knowledge will also result in heightened professional practice and perhaps new opportunities for income, specifically in a community-based system. With the implementation of the ACA, Medicare will be required to provide reimbursement for three different billing codes that pharmacists will be able to use to bill for face-to-face patient consultations for eligible patients. This action will hopefully provide a push for private insurers to also initiate coverage of these billing codes for cognitive services provided by pharmacists. This will further strengthen our push toward being recognized and reimbursed not only for products, but also for the intellectual services pharmacists are capable of providing.

The ACA is viewed by some as a natural progression for the profession of pharmacy after the Omnibus Budget Reconciliation Act of 1990 (OBRA’90) and Health Insurance Portability and Accountability Act (HIPAA) of 1996, as it establishes and recognizes pharmacists’ roles as patient care providers, educators, and counselors.

**Community Pharmacy**

One way community pharmacies will see a likely noticeable impact from the ACA is with the vast increase in the number of patients now carrying health insurance. This will likely result in an increase in the number of prescriptions filled, as well as increased opportunities to communicate with patients who may not have sought out healthcare in the recent past. In addition, from 2010-2020, the Medicare Part D coverage gap, also referred to as the “donut hole,” will be gradually reduced to a 75% discount on all covered brand-name and generic drugs (see Table 4), resulting in a potential increase in prescription count for many pharmacies serving Medicare beneficiaries. The ACA also assists with drug-coverage and improves eligibility for low-income Medicare beneficiaries in a number of ways. Copays will be eliminated for beneficiaries who receive home-based and community-based services who are eligible for both Medicare and Medicaid. The ACA also implemented a reduction in the number of low-income beneficiaries required to change plans each year in order to maintain a zero premium, and allows widows and widowers to obtain low-income eligibility more easily. The numerous changes this patient population will face with the implementation of the ACA will present pharmacists with many additional opportunities for education. Not only will patients have questions regarding the changes occurring from ACA implementation, but patients may begin filling more prescriptions and

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The Nebraska Mortar & Pestle 17
new prescriptions as the accessibility of healthcare improves and the number of patients covered by health insurance increases. This additional new medication counseling will provide a great opportunity for pharmacists to make an impact.

The ACA improved the Medicaid definition of the Average Manufacturer Price (AMP) to include only manufacturers’ sales to retail pharmacies. It also directs the Centers for Medicare and Medicaid Services (CMS) to set the Medicaid Federal Upper Limit (FUL) for reimbursement of generic medications at a rate of “no less than 175% of average weighted AMP”. This was a great step forward for community pharmacy as the struggle for competitive reimbursement has been at the forefront of many pharmacy associations and interest groups over the years.

Also in 2010, the ACA implemented an added requirement that pharmaceutical companies must increase the rebate percentages they pay to Medicaid programs for brand-name drugs dispensed to Medicaid patients. A rebate increase from 15.1% to 23.1% will be seen for most drugs.

In 2011 the list of over the counter (OTC) products that can be reimbursed through flex spending accounts (FSA) shrank significantly. OTC products not prescribed by a provider are no longer reimbursable through FSAs. Community pharmacists should also be aware that starting in 2014, a number of new medications will be covered by Medicaid that previously were on the excludable drug list. These medications include over the counter and prescription smoking cessation medications, barbiturates, and benzodiazepines.

Furthermore, under the ACA most pharmacies will be exempt from accreditation requirements previously needed to provide durable medical equipment (DME) to Medicare patients. This accreditation is still required of all pharmacies that submit a competitive bid, but the remaining pharmacies will be exempt contingent on a pharmacy falling under the following criteria:17,18,20,22

- Having total Medicare DME billings that are 5% or less of total prescription sales
- Having no adverse fraud/abuse determination for the past 5 years
- Submitting an attestation that total Medicare DME, prosthetics, orthotics, and supplies billings are (and continue to be) less than 5% of total pharmacy sales for a rolling 3-year average
- Submitting documentation to the secretary of Health and Human Services that would allow the secretary to verify the information (done for a random sample of pharmacies)

Medication Therapy Management

Over $290 billion in annual healthcare expenditures result from inappropriate medication use or nonadherence to medications. There is a Medication Therapy Management (MTM) grant program in place as part of the ACA to help test new and innovative methods to provide MTM services to eligible patients. Starting in 2014, Medicare Part D Prescription Drug Plans must include a comprehensive review of medications (either in person or via telehealth technology) and provide a written summary of the review to the patient and insurance company as part of their MTM programs.6,18,23

Long Term Care Pharmacy

An additional provision in the ACA outlined new rules for Long Term Care (LTC) pharmacy practice. Having the greatest proposed impact on LTC pharmacy is Section 3310: “Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and Medicare Part D plans,” also referred to as the “short cycle rule”, intended to reduce medication waste associated with filling a 30-day supply of medication as is typically done for patients in LTC facilities. This provision sets out specific dispensing techniques that should be used when dispensing Medicare Part D covered medications to beneficiaries living in a LTC facility. These techniques include “weekly, daily, or automated dose dispensing,” rather than 30-day, or monthly dispensing. This provision took effect January 1, 2012.2

Though many are in agreement that there will be cost savings experienced from reducing the amount of wasted medications, the additional time, labor costs, and dispensing fees could end up outweighing that benefit.

Health-System Pharmacy

Medication Reconciliation

Medication reconciliation activities will be of extreme importance when working toward reducing readmission rates and meeting established quality measures set up in the ACA. Studies have shown that when a medication reconciliation is performed by a pharmacist, it is more likely that potential interventions, such as medication errors, omissions, and therapeutic duplications, will be found when compared to medication reconciliations performed by a nurse, or other health care professional. “When performed by pharmacists, medication reconciliation can reduce the frequency and severity of hospital medication errors that could potentially result in patient harm. Pharmacists have demonstrated high rates of patient interventions; interventions per patient; and documentation of medications, medication interactions, drug-related admissions, and previous drug failures.”24

| Table 4. Percentage of medication cost patients will pay in the Medicare Part D Coverage Gap |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Brand-Name | 47.5% | 47.5% | 45% | 45% | 40% | 35% | 30% | 25% |
| Generic | 79% | 72% | 65% | 58% | 51% | 44% | 37% | 25% |
A pilot study performed by Nester and Hale looked at medication histories completed by both a nurse and a pharmacist at the time of admission and found that overall, pharmacists found a significantly larger number of medication errors or potential clinical interventions than nurses (34% vs. 16%, respectively) when performing medication histories. In addition, Nester and Hale showed that pharmacists are more likely than nurses to contact a patient’s community pharmacy to clarify a medication list, resulting in a more effective and likely more accurate medication reconciliation. An additional study showed that pharmacists uncover a significantly higher number of average medications per patient than nurses do when performing medication reconciliations (5.3% vs. 4.0% respectively).

340B Program Expansion
Currently, the 340B program allows various facilities who serve low-income and uninsured populations to purchase prescription medications at a significantly discounted price. Effective in January 2010 under the ACA, additional entities are now be eligible for pharmacetical discounts with the 340B program. The expanded list now includes children’s hospitals, free-standing cancer hospitals, and a variety of types of rural hospitals including critical access hospitals, sole community hospitals, and rural referral centers. An additional requirement for newly-eligible facilities includes exceeding the threshold for Disproportionate Share Hospital (DSH) percentages for their specific type of facility (11.75% for children’s hospitals and cancer centers, and 8% for sole community hospitals and rural referral centers). In addition, children’s hospitals and cancer centers may not obtain drugs covered by the plan through a group purchasing organization, though the other newly-eligible enrollees may. It has been estimated that up to 1,500 additional facilities will now be eligible to participate in the 340B program.

Covered entities are responsible for implementing systems to document compliance and prevent prohibited practices (such as utilizing drugs obtained through 340B for inpatient use, transferring or reselling drugs obtained through 340B to those who are not patients of the facility, or obtaining a Medicaid rebate for drugs purchased this way). The integrity of the 340B program will also be improved with the ACA. New program requirements will improve compliance by manufacturers, an administrative process for resolving claims of violations will be established, and clarifications about the ceiling price used to sell to 340B participants will be provided.

One of the main goals of the ACA is to get patients out of the hospital and to keep patients out of the hospital by helping patients get healthy and maintain that health. Pharmacists in health systems can make an impact in this aspect of patient care.

Conclusion
With the implementation of the Patient Protection and Affordable Care Act, many changes will be taking place in the coming months and years. It is hard to tell exactly what portions of the ACA will be most beneficial and what provisions may cause more difficulty or confusion among the population. Though the ACA provides many uncertainties, the opportunities for pharmacists to participate in healthcare reform and the new healthcare system are plentiful. Though the ACA lays out a few clear points of care for pharmacy intervention, even more lie under the surface waiting to be uncovered. Now is the time to work together to help advance the profession by taking advantage of any opportunities that arise to get our foot in the door to help impact the future of healthcare and our profession.
References

Policies for the Nebraska Mortar & Pestle (M&P) continuing pharmacy education lessons and quizzes:
1. M&P Quizzes are valid only for the membership year in which they are published. Quizzes for the 2014 Membership Year must be received by December 8, 2014. Quizzes cannot be carried over to another membership year.
2. If more than three questions are missed, the quiz will be returned. The quiz can be resubmitted.
3. CPE transcripts can be printed from the NPA web site at www.npharm.org.
4. CPE credits are sent to NABP by the 15th of each month. For example, M&P CPE quizzes completed in the month of August 2014, will be sent to NABP e-Profiles before September 15, 2014.
5. Pharmacy technicians may submit pharmacist/ACPE-accredited CPE activities for recertification to the Pharmacy Technician Certification Board (PTCB). However, it is the technician’s responsibility to determine whether the subject matter is acceptable for recertification. Programs relating to functions outside the scope of practice for pharmacy technicians will not be accepted by PTCB.

The Nebraska Council for Continuing Pharmacy Education (NCCPE) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This CPE home study lesson has been accredited for 1.50 contact hours or 0.15 CEUs. UAN #128-000-14-014-H03-P/T.

This lesson is a knowledge-based CPE home study lesson that is acceptable for recertification to the Pharmacy Technician Certification Board (PTCB). This CPE home study lesson has been accredited for 1.50 contact hours or 0.15 CEUs. UAN #128-000-14-014-H03-P/T.

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This lesson is a knowledge-based CPE activity targeted to pharmacists.

The authors and the Nebraska Pharmacists Association disclaim any liability to you or your patients resulting from reliance solely upon the information contained herein.

Quiz Answers may be submitted:
1. Online: www.npharm.org
2. Fax: 402-420-1406
3. Email: m&p@npharm.org
4. Mail: NPA Mortar & Pestle 6221 S 58th St, Ste A Lincoln, NE 68516
The Patient Protection and Affordable Care Act (ACA) and its Impact on Pharmacy
Quiz #1, January/February 2014, UAN #128-000-14-014-H03-P/T

1. Which of the following is NOT a provision of the Patient Protection and Affordable Care Act?
   a. If a patient does not make enough money to file an income tax return, they do not have to comply with the Individual Mandate.
   b. Mental health and substance abuse services are part of the required essential health benefits that must be covered by insurance companies wishing to participate in the Health Care Exchange.
   c. All states must comply with Medicaid expansion.
   d. Individuals who do not fall under specified exemptions who do not obtain health insurance by 2014 (either through public programs, privately, or through an employer), will be required to pay a penalty to the IRS at the end of the year.

2. Which of the following is true regarding the local impact of the Affordable Care Act?
   a. In Nebraska, Medicaid expansion will now provide coverage for all citizens making up to 133% of the federal poverty level.
   b. All Iowans qualifying for Medicaid will be required to pay a monthly premium starting in 2014.
   c. Both Iowa and Nebraska adopted Medicaid Expansion as laid out in the Affordable Care Act.
   d. None of the above

3. Which of the following is true under the Affordable Care Act?
   a. Medication Therapy Management (MTM) services must be provided for eligible Medicare Part D beneficiaries.
   b. If you currently have Medicare, you must also purchase insurance through the Health Insurance Exchange.
   c. Being covered by Medicaid does not fulfill the Individual Mandate requirement.
   d. Pharmaceutical companies must now provide a 15% rebate to Medicaid programs for brand-name drugs dispensed to Medicaid patients.

4. In what year will the Medicare Part D prescription coverage gap (also known as the “donut hole”) be eliminated?
   a. 2014
   b. 2020
   c. It already has been eliminated.
   d. It will never be fully eliminated.

5. For those states opting to participate in Medicaid Expansion as outlined in the Affordable Care Act, the federal government will cover ___ % of the costs for new enrollees during the first year.
   a. 100
   b. 95
   c. 90
   d. 75

6. Of the following patient populations, who has the potential to be a part of an ACO?
   a. Medicare beneficiary
   b. Medicaid enrollee
   c. Patient with employer-offered health insurance
   d. All of the above

7. Which of the following would deem a patient exempt from the individual mandate and/or the penalty associated with failure to comply?
   a. Cost of premiums exceeding 8% of total household income.
   b. Household income up to 399% of the federal poverty level.
   c. Household income below the threshold for filing a tax return.
   d. a and c

8. The employer responsibility (requiring businesses with more than 50 FTE’s to provide health insurance) take effect date was/will be:
   a. March 23, 2010
   b. October 1, 2013
   c. January 1, 2014
   d. January 1, 2016

9. As provisions of the Affordable Care Act take effect, which of the following present potential opportunities for pharmacy involvement?
   a. Medication Reconciliation activities at points of transition of care.
   b. Education for the increased number of patients now receiving health insurance.
   c. Providing Medication Therapy Management (MTM) services for Medicare Part D Beneficiaries.
   d. All of the above

10. For first time sign-up, how long does one have to enroll with a Health Insurance Exchange?
    a. End of October, 2013
    b. End of March, 2014
    c. End of 2013
    d. End of 2014

Keep the TOP portion for your records. Return the BOTTOM portion to the NPA office.
Or, take this quiz online at www.npharm.org

Name ________________________________________________________
Mailing Address  _______________________________________________
City/State/Zip _________________________________________________

*NABP e-Profile # ______________   *Date of Birth (MMDD) _______________
*Required for ACPE credit.

Circle one (1) Answer:
1. a b c d  6. a b c d
2. a b c d  7. a b c d
3. a b c d  8. a b c d
4. a b c d  9. a b c d
5. a b c d  10. a b c d

CPE Home Study Evaluation
1. Rate this lesson:  (Excellent) 5 4 3 2 1 (Poor)
   ____Yes  No
2. Did this lesson meet each of its objectives?  ____Yes  No
3. Was the content without commercial bias?  ____Yes  No
4. Did the lesson meet your educational/practice needs?  ____Yes  No
5. Comments/future topics are welcome.___________________________

The deadline for this quiz is December 8, 2014
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Pharmacy students shine in national competition

Caroline Jamison and Ashley (Paseka) Schenk, students in the College of Pharmacy, recently advanced to the national finals in the American Society of Health-System Pharmacists (ASHP) Clinical Skills Competition (CSC).

The national contest was held Dec. 7-8 at the ASHP’s Midyear Clinical Meeting in Orlando, Fla. More than 120 schools and colleges of pharmacy took part in the national contest, and the UNMC team of Jamison and Schenk finished in the top 10. They were the only third-year pharmacy students to make the national finals.

According to the ASHP’s website, the CSC is an interactive, team-based analysis of clinical scenarios for hospital/health-system pharmacists. It provides pharmacy students the opportunity to enhance their skills in collaborative practice with physicians in providing direct patient care.

On the first day, the students wrote a pharmaceutical treatment plan based on a video of a physician and a pharmacist consulting on a patient who came in with COPD—a patient who actually also unknowingly had multiple myeloma cancer. After advancing through the written round of the competition, the top 10 finalists made final oral presentations during an open session. They had to defend their initial recommendations and answer questions from a panel of judges.

Jamison and Schenk each won access to ASHP’s PharmPrep Online, a case-based board preparatory tool and an iPad Mini device preloaded with a one-year subscription to Lexi-Complete with AHFS Essentials.

Patrick Fuller, Pharm.D, pharmacy staff development coordinator and PGY1 residency program director at The Nebraska Medical Center, and adjunct assistant professor of pharmacy practice, also attended the event.

“They represented the college at the highest professional level,” Dr. Fuller said.

SHARING students create outreach project

In front of a classroom of about 20 fifth and sixth-grade students, Ashley Neumann asks about over-the-counter medications. Do the kids know what those are? Answers are shouted out: *Pepto-bismol!* *Cough drops!*

Neumann, a third-year student in the College of Pharmacy, is taking part in an educational outreach project by the SHARING Clinics. The project, a brainchild of SHARING’s Youth Outreach Committee, sends UNMC students to Jackson Elementary School once a month to speak with the children and present activities on health-related topics. Today, Neumann is drawing on her pharmacy education to discuss medication and safety.

“When we came up with the idea, we wanted to get all of the colleges involved based on different topics that they would be presenting,” said Tom Marston, one of the project’s initiators.

Neumann’s presentation is the third one the group has put on. Student Rashelle Smith gave a nutrition lesson that involved measuring the amount of sugar in certain popular snack foods. For a presentation on hand hygiene, the students hands were covered in glitter, which is hard to remove with water alone, but much easier with water and soap.

The educators at Jackson Elementary applauded the UNMC student’s efforts. “They’re really good. They’re very interactive,” said Isai Peralta, who runs the Completely Kids afterschool program at Jackson Elementary. “The kids are enjoying it.”

Instructor Tyler Erb agreed. “This is good stuff for the kids to know,” he said. “Some of it, I didn’t even know.”

Presenting to young people involves a learning curve, the UNMC students said. “The first time was definitely difficult, because it’s hard to keep their attention focused on what you are saying,” Neumann said. “They like to shout things out, so you have to calm them down. I think it’s easier if we do more hands-on things.”

The toughest part, Marston said, is crafting a presentation that is both educational and interesting—”not so heavy,” he said.

“We’re trying with all of our activities to increase the hands-on stuff to get the message across,” Neumann added. “It’s really helped. Right now, Marston said, the plan is to keep the project rolling through May, and then consider continuing for the next school year. The group is even archiving presentations to create permanent lesson plans.”

“It’s good to get this information to the students, but I really feel that we benefit from this project as well,” Neumann said.
Fourth-year campus pharmacy students Abby Coleman and Kevin Flynn were recognized in the top 10 teams placing in the Clinical Skills Competition held during the American Health-Systems Pharmacists (ASHP) national meeting in Orlando, Florida December 2013. The Creighton team was ranked as a top 10 finalist team in the national competition, among 124 teams competing. Coleman and Flynn were selected to represent Creighton in Orlando by Creighton faculty Drs. Kelli Coover, Michele Faulkner and Jenny Tilleman among several Creighton students. They presented their case at the national meeting the afternoon of Sunday, December 8, 2013 and were awarded at the Student Society Showcase later that evening.

“We feel incredibly honored and grateful,” said Coleman. “Thanks to Creighton and the pharmacy faculty for supporting us and giving us this opportunity. We will never forget it!”

HAMIK JOINS ALUMNI ADVISORY BOARD

Eric Hamik, BSpHa’91, joined the Creighton University School of Pharmacy and Health Professions Alumni Advisory Board in September 2013. Hamik is owner, president and pharmacist-in-charge of U-Save Pharmacy in Kearney, Nebr. He is past president and current member of the Nebraska Pharmacist Association, lifetime member of the National Community Pharmacist Association and of the Professional Compounding Centers of America and a long-time parishioner of Prince of Peace Catholic Church in Kearney. He and his wife Kim, also a 1991 Creighton pharmacy graduate, have two children, Madison, who was a member of the 2013 Creighton freshman class and son Creighton. His niece, Erica Hamik, is enrolled in the 2017 campus pharmacy class.

“I am a huge advocate of Creighton University and honored to served on the Alumni Advisory Board. I believe that my 15 years of service on various professional community board coupled with my passion for the pharmacy school will be an asset to this Board,” said Hamik.

CREIGHTON TOP 10 CLINICAL SKILLS

The textbook Pharmaceutics: Basic Principles and Application to Pharmacy Practice was released by Academic Press December 2013. Editors of the text were Creighton University Pharmacy Science faculty Alekha K. Dash, R.Ph., Ph.D., professor; Somnath Singh, Ph.D., associate professor and Justin Tolman, Pharm.D., Ph.D., assistant professor.

This new textbook was the best selling product for Academic Press at its unveiling during the American Association of Pharmaceutical Scientists meeting in San Antonio, Texas November, 2013.

STATE SENATORS VISIT CU

On September 27, 2013, Dean J. Chris Bradberry hosted Nebraska State Senators. Sue Crawford (District 45) and Sara Howard (District 9). The Senators were given an overview and tour of the School of Pharmacy and Health Professions. Dean Bradberry, along with School affiliates, discussed the School’s role in health science education and issues and opportunities surrounding health care reform.
New Therapies in Diabetes Management

This CPE lesson was written by Trenton Powell, PharmD, Community Pharmacy Resident, Creighton University School of Pharmacy & Health Professions, who has no financial or conflict of interest disclosures.

Objectives
At the conclusion of this lesson, participants should be able to:
1. Identify appropriate brand/generic names for newly approved diabetic medications.
2. List basic mechanisms by which diabetic medications lower blood glucose levels.
3. Match newly approved diabetic medications with their appropriate anti-diabetic medication class.
4. List common adverse effects of the newly approved diabetic medications.

Background
Approximately 25.8 million or 8.3% of Americans have diabetes, and the incidence of this disease steadily increases every year.1 Around 48% of diabetics are not reaching the recommended American Diabetes Association HbA1c goal of <7%.2,3 Uncontrolled blood sugars can lead to the progression of diabetes and can cause microvascular and macrovascular complications. Patients with diabetes are 2-4 times more likely to have heart disease or a stroke in the future. Diabetes can lead to hypertension, blindness, kidney disease, neuropathies, and amputations. Along with these complications, diabetes is very costly to the patient. It is estimated that $245 billion was the total cost spent on diabetes in 2012. A person with diabetes spends 2.3 times more money on health care costs than those without diabetes.1

The most effective way to prevent the development, slow the progression, or prevent complications of diabetes is by controlling serum blood sugar levels. Certain medications currently approved for treatment of diabetes have undesirable side effects. Sulfonylureas are commonly prescribed medications for the treatment of diabetes, but studies have shown they can lead to beta-cell burnout which allows for the progression of the disease. Insulin is another commonly prescribed medication for the treatment of diabetes, but it can cause weight gain and fat to accumulate around the abdominal region which can lead to insulin resistance.

Due to the high rates of Americans developing diabetes, the high rates of patients with uncontrolled diabetes, and unwanted side effects of current medications, drug companies are searching for ways to better control this disease. Since 2012, eight new drugs have been approved for the treatment of diabetes. Pharmacists should be up-to-date with information on the newly approved medications, and should also understand the mechanisms, adverse effects, and benefits of these new medications. Refer to Table 1 for approval dates and formulations of newly approved anti-diabetic medications.

<table>
<thead>
<tr>
<th>Drug Brand (generic)</th>
<th>Dosage Form</th>
<th>Strengths</th>
<th>FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bydureon (exenatide weekly)</td>
<td>Powder for injection</td>
<td>• 2 mg</td>
<td>January 2012</td>
</tr>
<tr>
<td>Janumet XR (sitagliptin/metformin ER)</td>
<td>Tablet</td>
<td>• 100 mg sitagliptin/1000 mg metformin ER&lt;br&gt;• 50 mg sitagliptin/500 mg metformin ER&lt;br&gt;• 50 mg sitagliptin/1000 mg metformin ER</td>
<td>February 2012</td>
</tr>
<tr>
<td>Jentadueto (linagliptin/metformin)</td>
<td>Tablet</td>
<td>• 2.5 mg linagliptin/500 mg metformin&lt;br&gt;• 2.5 mg linagliptin/850 mg metformin&lt;br&gt;• 2.5 mg linagliptin/1000 mg metformin</td>
<td>February 2012</td>
</tr>
<tr>
<td>Duetact (pioglitazone/glimepiride)</td>
<td>Tablet</td>
<td>• 30 mg pioglitazone/2 mg glimepiride&lt;br&gt;• 30 mg pioglitazone/4 mg glimepiride</td>
<td>January 2013</td>
</tr>
<tr>
<td>Nesina (alogliptin)</td>
<td>Tablet</td>
<td>• 6.25 mg&lt;br&gt;• 12.5 mg&lt;br&gt;• 25 mg</td>
<td>January 2013</td>
</tr>
<tr>
<td>Oseni (alogliptin/pioglitazone)</td>
<td>Tablet</td>
<td>• 25 mg alogliptin/15 mg pioglitazone&lt;br&gt;• 25 mg alogliptin/30 mg pioglitazone&lt;br&gt;• 25 mg alogliptin/45 mg pioglitazone&lt;br&gt;• 12.5 mg alogliptin/15 mg pioglitazone&lt;br&gt;• 12.5 mg alogliptin/30 mg pioglitazone&lt;br&gt;• 12.5 mg alogliptin/45 mg pioglitazone</td>
<td>January 2013</td>
</tr>
<tr>
<td>Invokana (canagliflozin)</td>
<td>Tablet</td>
<td>• 100 mg&lt;br&gt;• 300 mg</td>
<td>April 2013</td>
</tr>
</tbody>
</table>
Glucagon-like peptide-1 (GLP-1) receptor agonists

GLP-1 agonists mimic the action of the incretin, GLP-1 (also known as incretin mimetics). These drugs lower blood glucose levels by stimulating glucose-dependent insulin secretion, suppressing glucagon secretion, and slowing gastric emptying rates. Common side effects associated with GLP-1 agonists are nausea, diarrhea, vomiting, and constipation.4

Exenatide weekly (Bydureon®) is a newly approved GLP-1 agonist available as a subcutaneous injection, and is currently the only available GLP-1 agonist available as a once weekly injection. Unlike other GLP-1 agonists, exenatide weekly does not require dosing titrations. Patients must assemble this product right before administering it to themselves by reconstituting the dry powder into a solution form. This process requires extensive counseling from a pharmacist or healthcare professional in order to assure proper administration techniques. Patients should be counseled on where to appropriately inject this medication which includes the abdomen, thigh, or upper arm region. Patients should also be informed to rotate injection sites each week. Due to the kinetics of this medication, it takes 1-2 weeks before changes in blood sugars will be seen.

Adverse reactions with exenatide weekly are similar to other GLP-1 agonists and also include an injection site nodule which occurs in about 11% of users. Thyroid C-cell tumors are a boxed warning for this medication. These tumors were found when studies were performed on rats, but there was no association when studies were done in humans. Cases of acute pancreatitis have been reported in association with this medication, however, these reports are rare. This product is not recommended in patients with a CrCl < 30 ml/min, gastroparesis, a family history of medullary thyroid carcinoma, or multiple endocrine neoplasia syndrome type 2. Benefits of this medication include weight loss, once weekly injection formulation, and decreased GI adverse reactions compared to other medications in its class.4,5 See to Table 2 for cost comparison of available GLP-1 agonists.

DURATION-6 compared the efficacy and safety of exenatide once weekly with liraglutide once daily in patients with type 2 diabetes. This was a 26 week, open-label, randomized, parallel group study. The primary endpoint was the change in hemoglobin A1c (HbA1c) from baseline to week 26. There were 400 patients receiving exenatide and 391 patients receiving liraglutide. Baseline HbA1c was similar in both groups (8.5% in exenatide weekly and 8.4% in liraglutide). Exenatide weekly and liraglutide safely reduced HbA1c, however, it was found that liraglutide had a statistically significant reduction in A1c compared to exenatide weekly (-1.28% exenatide weekly, -1.48% liraglutide, p=0.0018). This study showed that 9% of patients receiving exenatide weekly reported nausea as an adverse event compared to 21% of patients reporting nausea who received liraglutide.5

Dipeptidyl Peptidase-4 Inhibitors

Dipeptidyl peptidase-4 (DPP-4) inhibitors lower blood sugar levels by inhibiting dipeptidyl peptidase-4 enzyme, which is responsible for breaking down endogenous incretin hormones. Common side effects associated with DPP-4 inhibitors are similar to placebo and include headache, urinary tract infections, and upper respiratory tract infections.7

Alogliptin (Nesina®) is a newly approved DPP-4 inhibitor that is dosed once daily with or without food. The maximum daily dose is 25 mg daily. This medication must be adjusted in renal impairment. Common side effects reported with alogliptin are nasopharyngitis, headache, and upper respiratory tract infection.7 Refer to Table 3 for cost comparison of available DPP-4 inhibitors.

DeFronzo et al. evaluated the safety and efficacy of alogliptin versus placebo in patients with type 2 diabetes and inadequate glycemic control. This was a randomized, double-blind, placebo-controlled, multicenter study. The primary outcome was change in HbA1c from baseline to 26 weeks. 131 patients received alogliptin and 64 patients received placebo. It was found that alogliptin safely reduced HbA1c by 0.59% which was statistically significant compared to placebo where only 0.02% reduction was found (p<0.001).8

DPP-4 Inhibitor/Biguanide Combinations (See mechanism and class adverse effects of DPP-4 inhibitors above.)

Currently, the only available biguanide is metformin. Metformin exhibits glucose lowering effects by decreasing hepatic glucose output and increasing peripheral glucose uptake and use. Common side effects associated with metformin are diarrhea and nausea. Metformin has a boxed warning for lactic acidosis. Products with metformin should be discontinued 48 hours before radiologic studies with IV contrast dye. Metformin is contraindicated in males with a Scr ≥ 1.5, females with a Scr ≥ 1.4, or patients with metabolic acidosis.9

Janumet XR® is a newly approved medication that is the combination of sitagliptin, a DPP-4 inhibitor, and metformin extended-release. The dose of

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### Table 2.
Cost Comparison of GLP-1 Agonists

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Cost Per 30 Days of Therapy*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bydureon</td>
<td>Exenatide weekly</td>
<td>$452.72</td>
</tr>
<tr>
<td>Byetta</td>
<td>Exenatide daily</td>
<td>$423.70</td>
</tr>
<tr>
<td>Victoza</td>
<td>Liraglutide daily</td>
<td>$589.69</td>
</tr>
</tbody>
</table>

*Cost based on RedBook average wholesale price*
Table 3. Cost Comparison of DPP-4 inhibitors

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Cost Per 30 Days of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nesina</td>
<td>Alogliptin</td>
<td>$309.96</td>
</tr>
<tr>
<td>Januvia</td>
<td>Sitagliptin</td>
<td>$309.92</td>
</tr>
<tr>
<td>Onglyza</td>
<td>Saxagliptin</td>
<td>$309.89</td>
</tr>
<tr>
<td>Tradjenta</td>
<td>Linagliptin</td>
<td>$304.56</td>
</tr>
</tbody>
</table>

*Cost based on RedBook average wholesale price

Table 4. Cost Comparison of DPP-4 Inhibitor/Biguanide Combinations

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Cost Per 30 Days of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janumet XR</td>
<td>Sitagliptin/Metformin ER</td>
<td>$309.90</td>
</tr>
<tr>
<td>Kombiglyze</td>
<td>Saxagliptin/Metformin ER</td>
<td>$309.90</td>
</tr>
<tr>
<td>Jentadueto</td>
<td>Linagliptin/Metformin</td>
<td>$304.56</td>
</tr>
<tr>
<td>Kazano</td>
<td>Alogliptin/Metformin</td>
<td>$309.96</td>
</tr>
<tr>
<td>Janumet</td>
<td>Sitagliptin/Metformin</td>
<td>$309.92</td>
</tr>
</tbody>
</table>

*Cost based on RedBook average wholesale price

Continuing Pharmacy Education Lesson #2

Table 3. Cost Comparison of DPP-4 inhibitors

<table>
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</tr>
<tr>
<td>Tradjenta</td>
<td>Linagliptin</td>
<td>$304.56</td>
</tr>
</tbody>
</table>

*Cost based on RedBook average wholesale price

Thiazolidinedione/Sulfonylurea Combination

Thiazolidinediones (TZDs) are peroxisome proliferator-activated receptor (PPAR) agonists which promote glucose uptake in skeletal muscle and adipose tissue. Side effects associated with TZDs are hepatotoxicity and edema. These drugs have a boxed warning for congestive heart failure and should be avoided in patients with NYHA class III or IV heart failure.

Sulfonylureas stimulate insulin secretion from the beta-cells of the pancreas. Side effects associated with this class of medication are weight gain, hypoglycemia, headache, nausea, and dizziness.

Seino et al. evaluated the safety and efficacy of alogliptin added to metformin versus metformin monotherapy in Japanese patients with uncontrolled diabetes. This was a 12 week, randomized, double blind trial. The primary outcome was change in HbA1c from baseline to 12 weeks. 96 patients received alogliptin and metformin and 100 patients received placebo and metformin. It was found that patients receiving alogliptin and metformin had a 0.64% reduction in HbA1c compared to 0.21% increase in HbA1c in patients receiving placebo (p<0.0001). Refer to Table 4 for cost comparison of the available DPP-4 inhibitor/Biguanide combinations.

Taskinen et al. evaluated the safety and efficacy of linagliptin administered as add on therapy to metformin. This was a 24 week, randomized, placebo-controlled, double blind, parallel-group study. The primary outcome was change in HbA1c from baseline to 24 weeks. 513 patients received linagliptin and metformin, and 175 patients received placebo and metformin. It was found that patients receiving linagliptin and metformin had a 0.49% reduction in HbA1c compared to 0.15% increase in HbA1c in patients receiving placebo (p<0.0001).11 Kazano® is a newly approved combination of alogliptin, a DPP-4 inhibitor, and metformin immediate release. The dose of this medication should be individualized based on the patient’s current regimen and should not exceed 100 mg sitagliptin and 2000 mg extended-release metformin. Patients should be advised to take this medication once daily with food. Common side effects reported with this medication are diarrhea, upper respiratory tract infections, and headache. There have not been any clinical efficacy or safety studies conducted with this combination to characterize its effect on HbA1c reduction. Approval of this medication was based on studies as a combination of 2 tablets or add on therapy, using metformin immediate release.9

Jentadueto® is a newly approved medication that is the combination of linagliptin, a DPP-4 inhibitor, and metformin immediate release. The dose of this medication should be individualized based on the patient’s current regimen and should not exceed a daily total of 5 mg linagliptin or 2000 mg metformin. Side effects reported with this medication include nasopharyngitis and diarrhea. Patients should be advised to take this medication up to twice daily with meals.10

Taskinen et al. evaluated the safety and efficacy of linagliptin administered as add on therapy to metformin. This was a 24 week, randomized, placebo-controlled, double blind, parallel-group study. The primary outcome was change in HbA1c from baseline to 24 weeks. 513 patients received linagliptin and metformin, and 175 patients received placebo and metformin. It was found that patients receiving linagliptin and metformin had a 0.49% reduction in HbA1c compared to 0.15% increase in HbA1c in patients receiving placebo (p<0.0001).11 Kazano® is a newly approved combination of alogliptin, a DPP-4 inhibitor, and metformin immediate release. The dose of this medication should be individualized based on the patient’s current regimen and should not exceed 100 mg sitagliptin and 2000 mg extended-release metformin. Patients should be advised to take this medication once daily with food. Common side effects reported with this medication are diarrhea, upper respiratory tract infections, and headache. There have not been any clinical efficacy or safety studies conducted with this combination to characterize its effect on HbA1c reduction. Approval of this medication was based on studies as a combination of 2 tablets or add on therapy, using metformin immediate release.9

Seino et al. evaluated the safety and efficacy of alogliptin added to metformin versus metformin monotherapy in Japanese patients with uncontrolled diabetes. This was a 12 week, randomized, double blind trial. The primary outcome was change in HbA1c from baseline to 12 weeks. 96 patients received alogliptin and metformin and 100 patients received placebo and metformin. It was found that patients receiving alogliptin and metformin had a 0.64% reduction in HbA1c compared to 0.21% increase in HbA1c in patients receiving placebo (p<0.0001).11 Refer to Table 4 for cost comparison of the available DPP-4 inhibitor/Biguanide combinations.
**Duetact** is a newly approved combination of pioglitazone, a TZD, and glimepiride, a sulfonylurea. The starting dose of this medication should be individualized based on a patient’s current regimen and the maximum dose is 30 mg pioglitazone and 2 mg glimepiride daily. Common side effects reported with this medication are upper respiratory tract infection, hypoglycemia, weight gain, edema, headache, diarrhea, nausea, and urinary tract infection. Patients should be counseled on the signs and symptoms of hypoglycemia and how to properly treat a hypoglycemic event. There have not been any clinical efficacy or safety studies conducted with this combination to characterize its effect on HbA1c reduction. Approval of this medication was based on efficacy and safety studies of the separate components.

**DPP-4 Inhibitor/TZD Combination** (See mechanism and class side effects above for DPP-4 inhibitors and TZDs.) Oseni® is a newly approved combination of alogliptin, a DPP-4 inhibitor, and pioglitazone, a TZD. The starting dose of Oseni should be individualized based on a patient’s current regimen and the maximum daily dose is 25 mg alogliptin and 45 mg of pioglitazone. Common side effects reported with this medication include nasopharyngitis, back pain, and upper respiratory tract infection. This medication should be adjusted in renal impairment.

Kaku et al. evaluated the safety and efficacy of alogliptin added to pioglitazone versus pioglitazone monotherapy in Japanese patients with inadequate glycemic control. This was a 12 week, randomized, double blind study. The primary outcome was change in HbA1c from baseline to week 12. 113 patients received alogliptin and pioglitazone and 92 patients received placebo and pioglitazone. It was found that patients who received alogliptin and pioglitazone had a 0.97 reduction in HbA1c compared to a 0.19% reduction in HbA1c in patients who received placebo and pioglitazone (p<0.0001).

**Sodium-glucose Co-transporter 2 (SGLT2) Inhibitors**

SGLT2 inhibitors work in the kidneys by inhibiting SGLT2, the enzyme responsible for reabsorbing glucose back into the bloodstream. Inhibition of SGLT2 results in decreased renal glucose reabsorption and increased urinary glucose excretion.

Invokana® is a newly approved and the only SGLT2 inhibitor available. The recommended starting dose is 100 mg once daily. This medication should be taken before the first meal of the day. If a patient is tolerating the medication and their eGFR is 60 or higher, the dose can be increased to 300 mg once daily if they require additional glycemic control. It is important to note that this medication requires dosing adjustments in renal impairment. If the eGFR is between 45 and 60 then the dose should be limited to 100 mg daily and this medication should be discontinued if eGFR is less than 45. The most common adverse reactions are female genital mycotic infections which occur in around 10-11% of patients; urinary tract infections occurred between 4-6% of patients, and increased urination occurred in around 5% of patients. Canagliflozin causes intravascular volume contraction so symptomatic hypotension could occur after this medication is administered. Studies found this medication can increase serum creatinine levels and decrease renal function. Hyperkalemia and increased LDL were also seen in studies of this medication. This medication is contraindicated in patients with eGFR<30mL/min/1.73m2 Additional benefits of Invokana include weight reduction (2.5-3.5kg average weight reduction) and blood pressure reduction.

Stenlof et al. evaluated the efficacy and safety of canagliflozin monotherapy in patients with uncontrolled diabetes. This was a 26 week, randomized, double blind, placebo-controlled, phase 3 trial. The primary objective was change in HbA1c from baseline to week 26. 197 patients received canagliflozin and 192 patients received placebo. It was found that patients who received canagliflozin had a 1.03% reduction in HbA1c compared to a 0.14% increase in HbA1c in those who received placebo (p<0.001). Refer to Table 5 for cost comparisons of newly approved anti-diabetic medications in their own class.

**Place in Therapy**

Lifestyle modification, including medically assisted weight loss, is the first line treatment for newly diagnosed diabetics. The first medication to be initiated in diabetics is metformin. If additional glycemic control is needed dual therapy, triple therapy, or insulin should be considered. Patient specific parameters should be taken into consideration when selecting regimens for controlling blood glucose levels in diabetics.

<table>
<thead>
<tr>
<th>Table 5. Cost Comparison of Anti-Diabetic Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand Name</strong></td>
</tr>
<tr>
<td>Duetact</td>
</tr>
<tr>
<td>Oseni</td>
</tr>
<tr>
<td>Invokana</td>
</tr>
</tbody>
</table>

*Cost based on RedBook average wholesale price*
Agents in the Pipeline
Several agents are in the pipeline to treat diabetes, and practitioners may see them come to the market in the next few years. Albiglutide, dulaglutide, and lixisenatide are all GLP-1 agonists that have completed their phase III trials and are currently under review by the FDA. Albiglutide and dulaglutide are both once weekly subcutaneous injections, while lixisenatide is a once daily subcutaneous injection. All three of these GLP-1 agonists have shown they can safely reduce HbA1c compared to placebo. There have been studies on dulaglutide showing better HbA1c lowering than exenatide daily and liraglutide. Lixisenatide has studies demonstrating its safe use in combination with basal insulin.

Empagliflozin and dapagliflozin are SGLT2 inhibitors indicated as a once daily oral medication for type 2 diabetes. Both of these have completed their Phase III trials and are under review by the FDA. Dapagliflozin has already been approved in Europe, but the FDA has postponed its decision to approve this medication in the United States due to concerns with the risk/benefit profile. The FDA was concerned that this medication may increase a person’s risk of developing cancer and believed that more studies needed to be performed. The developers of dapagliflozin presented longer term studies to the FDA and are now awaiting its approval. Now that the therapeutic effects of inhibiting SGLT2 are known, it is likely that additional drugs will come out targeting this receptor.

Degludec is long acting insulin with a half life longer than 25 hours. It is being studied as two different formulations: U100 and U200. Clinicians believe it would be beneficial to have basal insulin available as U200, because more patients who require high doses of basal insulin are having to inject themselves twice to achieve a full basal insulin dose. The U200 formulation could allow those patients on those high doses to only have to use 1 injection a day as opposed to 2, which could lead to better compliance rates with basal insulin. The FDA sent a complete response letter to the developers of Degludec requesting more data on cardiovascular outcomes, and those trials should be completed sometime next year.

Conclusion
Diabetes is a chronic, progressive disease with nearly half of patients inadequately controlled. There have been 8 new medications approved by the FDA since 2012. One of the newly FDA approved medications created a new class of anti-diabetic medications. Opportunity still exists for new medications to come out to try and better control this costly disease. Refer to Table 6 for a summary of the newly approved medications.

---

### Table 6. Summary of Newly Approved Medications

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Administration</th>
<th>Side Effects</th>
<th>Estimated Decrease in A1c</th>
<th>Additional Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bydureon</td>
<td>Exenatide weekly</td>
<td>Subcutaneous injection every 7 days</td>
<td>Nausea, Diarrhea, Injection-site nodule</td>
<td>1-1.5%</td>
<td>Weight loss</td>
</tr>
<tr>
<td>Janumet XR</td>
<td>Sitaglitin/Metformin extended-release</td>
<td>Oral, once daily, with food</td>
<td>Diarrhea, Upper Respiratory Tract Infection</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Jentadueto</td>
<td>Linagliptin/Metformin immediate-release</td>
<td>Oral, up to twice daily, with food</td>
<td>Diarrhea, Nasopharyngitis</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Duetact</td>
<td>Pioglitazone/Glimepiride</td>
<td>Oral, once daily, with first meal</td>
<td>Hypoglycemia, Weight increase, Edema</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Nesina</td>
<td>Alogliptin</td>
<td>Oral, once daily, with or without food</td>
<td>Nasopharyngitis, Headache</td>
<td>0.5-0.8%</td>
<td></td>
</tr>
<tr>
<td>Kazzano</td>
<td>Alogliptin/Metformin immediate-release</td>
<td>Oral, up to twice daily, with food</td>
<td>Nasopharyngitis, Diarrhea, Headache</td>
<td>1-1.5%</td>
<td></td>
</tr>
<tr>
<td>Oseni</td>
<td>Alogliptin/Pioglitazone</td>
<td>Oral, once daily, with or without food</td>
<td>Nasopharyngitis, Back pain</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Invokana</td>
<td>Canagliflozin</td>
<td>Oral, once daily, before first meal</td>
<td>Infections, Increased urination</td>
<td>1%</td>
<td>Weight loss, Lowers blood pressure</td>
</tr>
</tbody>
</table>
References

Policies for the Nebraska Mortar & Pestle (M&P) continuing pharmacy education lessons and quizzes:

1. M&P Quizzes are valid only for the membership year in which they are published. Quizzes for the 2014 Membership Year must be received by December 8, 2014. Quizzes cannot be carried over to another membership year.
2. If more than three questions are missed, the quiz will be returned. The quiz can be resubmitted.
3. CPE transcripts can be printed from the NPA web site at www.npharm.org.
4. CPE credits are sent to NABP by the 15th of each month. For example, M&P CPE quizzes completed in the month of August 2014, will be sent to NABP e-Profiles before September 15, 2014.
5. Pharmacy technicians may submit pharmacist/ACPE-accredited CPE activities for recertification to the Pharmacy Technician Certification Board (PTCB). However, it is the technician’s responsibility to determine whether the subject matter is acceptable for recertification. Programs relating to functions outside the scope of practice for pharmacy technicians will not be accepted by PTCB.

The Nebraska Council for Continuing Pharmacy Education (NCCPE) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This CPE home study lesson has been accredited for 1.0 contact hour or 0.10 CEU. UAN #128-000-14-015-H01-P. This lesson is a knowledge-based CPE activity targeted to pharmacists.

The authors and the Nebraska Pharmacists Association disclaim any liability to you or your patients resulting from reliance solely upon the information contained herein.

Quiz Answers may be submitted:
1. Online: www.npharm.org
2. Fax: 402-420-1406
3. Email: m&p@npharm.org
4. Mail: NPA Mortar & Pestle
6221 S 58th St, Ste A
Lincoln, NE 68516
New Therapies in Diabetes Management
Quiz #2, January/February 2014, ACPE UAN #128-000-14-015-H01-P

1. The benefits of Bydureon include:
   a. Lowest cost
   b. Once daily injection
   c. Weight loss
   d. All of the above

2. Nesina is in what anti-diabetic medication class?
   a. DPP-4 inhibitor
   b. GLP-1 agonist
   c. SGLT2 inhibitor
   d. TZD

3. Common side effects of Janumet XR include:
   a. Diarrhea
   b. Upper respiratory tract infections
   c. a and b
   d. None of the above

4. Jentadueto is the combination of:
   a. DPP-4 inhibitor/biguanide
   b. DPP-4 inhibitor/TZD
   c. TZD/sulfonylurea
   d. TZD/biguanide

5. Kazano is the combination of:
   a. Alogliptin/metformin
   b. Linagliptin/metformin
   c. Saxagliptin/metformin
   d. Sitagliptin/metformin

6. Duetact is the combination of:
   a. DPP-4 inhibitor/biguanide
   b. DPP-4 inhibitor/sulfonylurea
   c. DPP-4 inhibitor/TZD
   d. TZD/sulfonylurea

7. Side effects associated with Duetact include:
   a. Edema
   b. Hypoglycemia
   c. Weight gain
   d. All of the above

8. Oseni is the combination of:
   a. Alogliptin/pioglitazone
   b. Linagliptin/metformin
   c. Pioglitazone/glimepiride
   d. Sitagliptin/metformin ER

9. Invokana lowers blood glucose levels by:
   a. Decreasing hepatic glucose production
   b. Inhibiting DPP-4 enzyme
   c. Inhibiting SGLT2
   d. Stimulating insulin release from beta cells

10. Side effects associated with Invokana include:
    a. Female genital mycotic infections
    b. Increased urination
    c. Urinary tract infections
    d. All of the above

---

Keep the TOP portion for your records. Return the BOTTOM portion to the NPA office.
Or, take this quiz online at www.npharm.org

---

The Nebraska Mortar & Pestle 31
**Lodging**

The Cornhusker, A Marriott Hotel  
333 South 13th Street  
Lincoln, Nebraska 68508  
(402) 474-7474  

Visit [http://www.marriott.com/hotels/fact-sheet/travel/lnkfs-the-cornhusker-a-marriott-hotel/](http://www.marriott.com/hotels/fact-sheet/travel/lnkfs-the-cornhusker-a-marriott-hotel/) for hotel details. Make your lodging reservations by calling The Cornhusker at (402) 474-7474 or 866-706-7706. A block of rooms has been reserved for $109 per night (subject to state/local tax). When making lodging reservations, make them before the block expires on April 9, 2014 and be sure to tell them you are with the Nebraska Pharmacists Association’s group.

Additional lodging is available at the Country Inn & Suites By Carlson Lincoln North, 5353 N 27th Street, Lincoln, Nebraska. A block of rooms has been reserved for $89.99 per night (subject to state/local tax). Call 1-800-456-4000 or 402-476-5353 and ask for the “NPA (NE Pharmacist) Convention Block” on or before midnight of April 11, 2014. Visit [http://www.countryinns.com/lincoln-hotel-ne-68521/nelinco](http://www.countryinns.com/lincoln-hotel-ne-68521/nelinco) for hotel details.

**Parking**

The Cornhusker Hotel has on-site parking at $1.00 per hour or $9.00 per day. Valet parking is $16.00 daily.

Metered street parking is available, as well as city owned parking facilities. Visit [www.parkandgo.org](http://www.parkandgo.org) or call 402-441-7275, M-F, 8:00 am - 5:30 pm.

**Technician CPE**

Not all CPE sessions have been accredited for pharmacy technicians. This year, pharmacy technicians may attend and receive CPE credits for sessions designated for pharmacists (P). It is the technician’s responsibility to verify what credits are applicable for PTCB recertification (visit www.ptcb.org). Pharmacy technicians are encouraged to attend technician-specific CPE sessions (designated with a T at the end of the UAN). Beginning in 2015, PTCB will only accept pharmacy technician-specific CPE and will no longer accept pharmacist-specific CPE (designated with a P at the end of the UAN).

**Continuing Pharmacy Education (CPE)**

The NPA 2014 Annual Convention is sponsored by the Nebraska Council for Continuing Pharmacy Education (NCCPE). NCCPE is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). The 2014 NPA Annual Convention CPE sessions are Knowledge-based activities. Participants may earn up to 14.25 hours of CPE credits for attendance of the entire CPE session and the completion of an online evaluation for each CPE session attended. CPE credits will be awarded to participants who have provided their NABPEProfile ID # and Birth Date (month and day only). CPE credits will be sent to CPE Monitor no later than June 5, 2014. CPE Statements of Credit can be accessed at [www.MyCPEMonitor.net](http://www.MyCPEMonitor.net). For questions about CPE credits, contact NCCPE at 402-420-1500 or info@npharm.org.

**ACPE Universal Activity Numbers (UAN)**

01 = Drug Therapy  
02 = AIDS Therapy  
03 = Pharmacy Law  
04 = General Pharmacy Practice  
05 = Patient Safety

P = Pharmacist  
T = Technician

Convention center CPE rooms are often very chilly. Bring a sweater or jacket for comfort.

**Handouts**

As part of NPA’s going green and mobile efforts, speaker presentations and handouts for the convention will be posted on the NPA website at [www.npharm.org](http://www.npharm.org). Handouts may be viewed or printed before or after convention. An email will be sent with instructions no later than April 17, 2014.
FRIDAY
April 25, 2014

Friday’s Schedule At A Glance

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 am - 5:00 pm</td>
<td>Registration</td>
</tr>
<tr>
<td>7:50 am - 8:00 am</td>
<td>Welcome</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Drug Interactions</td>
</tr>
<tr>
<td>9:15 am - 10:15 am</td>
<td>Obesity &amp; Weight Control</td>
</tr>
<tr>
<td>10:30 am - 11:30 am</td>
<td>Rapid Diagnostic Testing</td>
</tr>
<tr>
<td>11:30 am - 1:00 pm</td>
<td>Exhibits &amp; Lunch</td>
</tr>
<tr>
<td>1:00 pm - 2:00 pm</td>
<td>Insomnia</td>
</tr>
<tr>
<td>2:15 pm - 3:45 pm</td>
<td>Innovative Practices</td>
</tr>
<tr>
<td>4:00 pm - 5:30 pm</td>
<td>Mortar Bowl Competition</td>
</tr>
<tr>
<td>5:30 pm - 7:00 pm</td>
<td>Dinner &amp; Team Jack, Health Care Experience</td>
</tr>
</tbody>
</table>

7:50 am – 8:00 am

WELCOME
Fred Massoomi, PharmD, RP, NPA President

8:00 am - 9:00 am

AN OVERVIEW OF DRUG INTERACTIONS: KEEPING UP
Amy Wilson, PharmD, RP, Associate Professor of Pharmacy and Director of the Creighton University Center for Drug Information & Evidence-Based Practice, Omaha

UAN: 0128-0000-14-017-L01-P 0.1 CEU/1.0 hr
Program Objectives:
1. Identify the mechanisms associated with drug interactions.
2. Explain the difference between pharmacokinetic and pharmacodynamic drug interactions.
3. Recall the clinical outcomes associated with drug interactions.
4. Describe considerations for assessing and/or managing drug interactions in practice.

9:00 am – 9:15 am

BREAK

9:15 am – 10:15 am

OBESITY IN AMERICA: IS IT REALLY AN ISSUE?
Thomas Lenz, PharmD, RP, Associate Professor of Pharmacy Practice; Director, Pharmacy Distance Pathway; and Clinical Coordinator for the Cardiovascular and Diabetes Risk Reduction Programs, Creighton University School of Pharmacy & Health Professions, Omaha

UAN: 0128-0000-14-018-L04-P 0.1 CEU/1.0 hr
Program Objectives:
1. Recall the trends in obesity prevalence in the United States
2. List several risk factors associated with obesity.
3. Compare the benefits of exercise with the risk of obesity.
4. Design a weight control program.

10:30 am – 11:30 am

USE OF RAPID DIAGNOSTIC TESTS AND POINT-OF-CARE DIAGNOSTICS BY PHARMACISTS
Donald Klepser, PhD, MBA, Assistant Professor, Department of Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha; and Keith Olsen, PharmD, FCCP, FCCM, Professor of Pharmacy and Chair, Department of Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha

UAN: 0128-0000-14-019-L04-P 0.1 CEU/1.0 hr
Program Objectives:
1. Identify opportunities for pharmacists to expand the scope of their practice in the community setting through the utilization of RDTs.
2. Summarize the prevalence and impact of various infectious diseases including: influenza, Group A streptococcus, HIV, and hepatitis C in the United States.
3. Describe the current level of education of pharmacists in the United States regarding the use of RDTs.
4. Discuss specific strategies for designing and implementing a successful pharmacy-based infectious disease management program.
5. Explain how to bill for an infectious disease management program using the appropriate CPT codes.
6. Explain CLIA-waiver and the process for becoming a CLIA-waived site.
7. Recognize the procedures necessary for legal processing of CLIA-waived tests.

10:45 am – 11:30 am

INDUSTRY NETWORK MEETING
Stephanie Maciejewski, PharmD, RP, NPA Industry Network Chair, and Nebraska DUR Director, Marcia Mueting, PharmD, RP
Discussion of the Nebraska Drug Utilization (DUR) new drug products process including Prior Authorization.

11:30 am – 1:00 pm

LUNCH WITH EXHIBITORS
1:00 pm – 2:00 pm
COUNSELING ON INSOMNIA AND DRUGS FOR INSOMNIA
Allison Dering-Anderson, PharmD, RP, Clinical Assistant Professor, Department of Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha

UAN: 0128-0000-14-029-L01-P 0.1 CEU/1.0 hr

Program Objectives:
1. Evaluate a patient’s complaints of insomnia for appropriate OTC management.
2. Describe the efficacy and side effects of OTC drugs to treat insomnia.
3. Review the new dosing guidelines for zolpidem when assessing appropriateness of pharmacotherapy.
4. Counsel a patient on non-drug modalities to improve sleeplessness.

2:00 pm – 2:15 pm  Break

2:15 pm – 3:45 pm
INNOVATIVE NEBRASKA PRACTICES

UAN: 0128-0000-14-020-L04-P 0.15 CEU/1.5 hr

PRIMARY CARE CHRONIC PAIN MANAGEMENT: HAVING A PHARMACIST ON THE TEAM
Jeffrey Steffensmeier, PharmD, RP, Clinical Pharmacy Specialist, VA Nebraska Western Iowa Health Care System, Lincoln

Program Objective:
1. Describe how a pharmacist can contribute to the care of chronic pain patients.

THE DO’S AND DON’TS OF MTM
Niki Salomon, PharmD, RP, Barmore Drug Store, Lexington

Program Objectives:
1. Identify strategies for a successful MTM program
2. Describe the pitfalls of MTM.

COMPOUNDING SOLUTIONS
Lyndell White, PharmD, RP, Owner, Pharmacy Solutions, Lincoln

Program Objective:
1. Identify innovative solutions for medication delivery.

3:45 pm – 4:00 pm  Break

4:00 pm – 5:30 pm
PHARMACY MORTAR BOWL
Edward DeSimone, RP, PhD, FAPhA, Professor of Pharmacy Sciences, Creighton University School of Pharmacy & Health Professions, Omaha

UAN: 0128-0000-14-021-L04-P 0.15 CEU/1.5 hr

Through the process of answering a selected group of questions similar to those that one would experience on a national board exam the pharmacist shall be able to:
1. Identify effective self-care treatments for patients.
2. Provide information about the top 200 drugs.
3. Calculate the amount of drug or excipients needed to compound and/or dispense a prescription
4. Explain the actions a pharmacist should take based on federal or state law.
5. Answer questions concerning the relationship of this information to pharmacy practice.

5:30 pm – 7:00 pm
DINNER AND TEAM JACK: MY EXPERIENCE WITH THE HEALTH CARE SYSTEM AS A PHARMACIST AND MOTHER
Brianna Hoffman, PharmD, RP, West Holt Pharmacy, Atkinson; and Team Jack Foundation

UAN: 0128-0000-14-022-L04-P 0.10 CEU/1.0 hr

UAN: 0128-0000-14-022-L04-T 0.10 CEU/1.0 hr

Program Objectives:
1. Explain the challenges with the health care system.
2. Identify advice to pharmacists with family members who are ill.
3. Describe how pharmacists can help patients in similar situations.
Saturday’s Schedule At A Glance

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 am - 3:30 pm</td>
<td>Registration</td>
<td>Noon - 1:00 pm</td>
<td>Lunch &amp; Membership Meeting</td>
</tr>
<tr>
<td>7:50 am - 8:00 am</td>
<td>Welcome</td>
<td>1:00 pm - 2:00 pm</td>
<td>Network Breakouts</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Affordable Care Act</td>
<td>1:00 pm - 2:00 pm</td>
<td>Technician CPE</td>
</tr>
<tr>
<td>9:15 am - 10:15 am</td>
<td>Engaging in Conflict</td>
<td>2:00 pm - 3:30 pm</td>
<td>Round Table Discussions</td>
</tr>
<tr>
<td>10:30 am - Noon</td>
<td>Top 10 New Drugs</td>
<td>3:45 pm - 5:00 pm</td>
<td>Pharmacy Law</td>
</tr>
</tbody>
</table>

7:50 am – 8:00 am WELCOME
Fred Massoomi, PharmD, RP, NPA President

8:00 am - 9:00 am PHARMACY AND THE AFFORDABLE CARE ACT: WHAT WE KNOW TODAY
Clint Williams, PharmD, MBA, Senior Director of Health Care Delivery & Wellness, Blue Cross and Blue Shield of Nebraska, Omaha

UAN: 0128-0000-14-023-L01-P 0.1 CEU/1.0 hr
UAN: 0128-0000-14-023-L01-T 0.1 CEU/1.0 hr

Program Objectives:
1. Describe the ACA’s impact to benefit design and costs.
2. Explain consumerism’s role in a post-ACA world.
3. Describe the role of Pharmacy in ACO/PCMH.

9:00 am – 9:15 am BREAK

9:15 am - 10:15 am ENGAGING IN CONFLICT APPROPRIATELY AND EFFECTIVELY
Bryan Hanson, Assistant Director of the Werner Institute, Creighton University, Omaha

UAN: 0128-0000-14-017-L01-P 0.1 CEU/1.0 hr
UAN: 0128-0000-14-017-L01-T 0.1 CEU/1.0 hr

Program Objectives:
1. Explain the difference between conflict engagement and conflict resolution.
2. Describe the negotiation approaches that affect team cohesion in the workplace.
3. Identify the most appropriate approach to conflict, based on the situation.
4. Describe a process for engaging in conflict through active listening.
5. Explain the importance of responding to conflict consciously, rather than reactively.

10:15 am – 10:30 am BREAK

10:30 am – Noon TOP 10 NEW DRUGS
Creighton University School of Pharmacy & Health Professions PharmD Candidates: Jocelyn Calado; Laura Cotiguala; Megan Derba; Megan Wehrer; and Kevin Welch. University of Nebraska College of Pharmacy PharmD Candidates: Kelsey Bryant; Sloane Hartzell; Yimei Huang; Justin Lane; and Jenalee Schwab.

UAN: 0128-0000-14-023-L01-P 0.15 CEU/1.5 hr
UAN: 0128-0000-14-023-L01-T 0.15 CEU/1.5 hr

Program Objectives:
1. Identify the top ten new drugs.
2. Describe each drug’s role in therapy.

Noon – 1:00 pm LUNCH & MEMBERSHIP MEETING

1:00 pm – 2:00 pm NETWORK BREAKOUT SESSIONS
Academia/Specialty Practice Network
Independent Network
Hospital/Health-System Network
Long-Term Care Network

1:00 pm – 2:00 pm PHARMACY TECHNICIAN CPE
What’s Your Policy? A Comparison of Pharmacy Methods and Discussion of Best Practices with Sterile Compounding, Labeling Medications, and Look-Alike/Sound-Alike Names
Elina Pierce, MSP, CPhT, Program Chair/Instructor, Southeast Community College, Lincoln Campus; and Sara Steele, PharmD, RP

UAN: 0128-0000-14-028-L01-T 0.1 CEU/1.0 hr

Program Objectives:
1. Identify potential errors made with sterile compounding, medication labeling, and look-alike/sound-alike names.
2. Discuss risk reduction strategies with regard to sterile compounding, medication labeling, and look-alike/sound-alike names.
3. Explain best practices in high risk areas of pharmacy and propose process changes to improve medication safety.
2:00 pm – 3:30 pm

**ROUND TABLE DISCUSSIONS**

**UAN: 0128-0000-14-026-L04-P** 0.15 CEU/1.5 hr

**UAN: 0128-0000-14-026-L04-T** 0.15 CEU/1.5 hr

**MEDICAL MARIJUANA**

Allison Dering-Anderson, PharmD, RP, Clinical Assistant Professor, Department of Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha

Program Objective:
1. Discuss the pros and cons of legalizing medical marijuana in Nebraska.

**E-PRESCRIBING**

Joni Cover, JD, Executive Vice President, Nebraska Pharmacists Association, Lincoln

Program Objective:
1. Identify the successes and challenges of e-prescribing in Nebraska.

**340B DRUGS: A DISCUSSION ABOUT THE IMPACT ON PHARMACY**

Linda Myers-Bock, PharmD, MBA, Columbus

Program Objective:
1. Examine the pros and cons of 340B involvement for pharmacies and hospitals.

**CPOE - COMPUTERIZED PHYSICIAN ORDER ENTRY**

Keith Berg, PharmD, RP, Director of Pharmacy, Community Memorial Hospital, Syracuse

Program Objective:
1. Review the success and challenges of implementing CPOE.

3:30 pm – 3:45 pm

**BREAK**

3:45 pm – 5:00 pm

**PHARMACY LAW**

Charles Krobot, PharmD, RP, Associate Dean for Student Affairs, and Assistant Professor, Department of Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy, Omaha; and Joni Cover, JD, Executive Vice President, Nebraska Pharmacists Association, Lincoln

Program Objectives:
1. Explain the importance of practicing pharmacy within the law.
2. Describe how recent revisions in statutes and regulations impact the practice of pharmacy.
3. Identify changes in Federal law.
**Registration Information**

**PHARMACIST REGISTRATION**

Option 1 - Full Registration (Friday & Saturday)
Includes up to 14.25 hours of continuing pharmacy education; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors; and evening meal.

Option 2 - Friday Only Registration
Includes up to 8 hours of continuing pharmacy education; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors, and evening meal.

Option 3 - Saturday Only Registration
Includes up to 6.25 hours of continuing pharmacy education; access to handouts online; morning and afternoon refreshment breaks; and lunch.

**TECHNICIAN REGISTRATION**

Option 1 - Full Registration (Friday & Saturday)
Includes up to 7 hours of continuing pharmacy education and 8.25 hours of technician continuing education; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors; and evening meal.

Option 2 - Friday Only Registration
Includes up to 7 hours of continuing pharmacy education and 1 hour of technician continuing education; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors, and evening meal.

Option 3 - Saturday Only Registration
Includes up to 7.25 hours of technician continuing education; access to handouts online; morning and afternoon refreshment breaks; and lunch.

**STUDENT REGISTRATION**

Option 1 - Full Registration (Friday & Saturday)
Includes access to all continuing pharmacy education sessions; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors; and evening meal.

Option 2 - Friday Only Registration
Includes access to Friday’s continuing pharmacy educations; access to handouts online; morning and afternoon refreshment breaks; lunch with exhibitors, and evening meal.

Option 3 - Saturday Only Registration
Includes access to Saturday’s continuing pharmacy education sessions; access to handouts online; morning and afternoon refreshment breaks; and lunch.

**TECHNICIAN REGISTRATION**

**SPouse/GUEST REGISTRATION**

Full Registration (Friday & Saturday)
Includes access to all continuing pharmacy education sessions; morning and afternoon refreshment breaks; lunch with exhibitors, and evening meal.

Friday Only Registration
Includes access to Friday’s continuing pharmacy education sessions; morning and afternoon refreshment breaks; lunch with exhibitors, and evening meal.

Saturday Only Registration
Includes access to Saturday’s continuing pharmacy education sessions; morning and afternoon refreshment breaks; and lunch.

**TICKETED EVENTS**

Option 4 - Event Registration Only
Registration for Friday’s Lunch with Exhibitors; Friday’s dinner program; and Saturday’s lunch; may be purchased as stand alone items. They do **not** include access to any continuing education sessions, refreshment breaks; or program handouts.

**CANCELATION & REFUND POLICY**

Cancelled registrations must be in writing. Cancellations received on or before April 10, 2014, will receive a refund in the amount paid less a 25% administrative fee. Cancellations received between April 11 and April 22, 2014 will receive a refund in the amount paid less a 50% administrative fee. No refunds will be made after April 23, 2014.

**CANceLLAtioN & refUNd PoLicY**

Cancelled registrations must be in writing. Cancellations received on or before April 10, 2014, will receive a refund in the amount paid less a 25% administrative fee. Cancellations received between April 11 and April 22, 2014 will receive a refund in the amount paid less a 50% administrative fee. No refunds will be made after April 23, 2014.
PHARMACIST

Name __________________________________________ Phone Number _______________________

Badge Name __________________________________ Email Address _______________________

Mailing Address ________________________________ CPE e-Profile # ______________________

City/State/Zip __________________________________ Birthdate (MM/DD) ___________________

Spouse/Guest Name (If applicable) ____________________________

<table>
<thead>
<tr>
<th>Option 1 - Full Registration (Friday &amp; Saturday)</th>
<th>EARLY BIRD On or Before 04/07/2014</th>
<th>On or After 04/08/2014</th>
<th>Registration Sub Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPA Member</td>
<td>$215</td>
<td>$255</td>
<td>$________</td>
</tr>
<tr>
<td>Non NPA Member</td>
<td>$290</td>
<td>$330</td>
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| Option 2 - Friday Only Registration             |                                   |                        |                        |
| NPA Member                                      | $140                              | $180                   | $________               |
| Non NPA Member                                  | $215                              | $255                   | $________               |
| Spouse/Guest                                    | $75                               | $100                   | $________               |

| Option 3 - Saturday Only Registration           |                                   |                        |                        |
| NPA Member                                      | $95                               | $135                   | $________               |
| Non NPA Member                                  | $170                              | $210                   | $________               |
| Spouse/Guest                                    | $50                               | $90                    | $________               |

| Option 4 - Event Registration Only              |                                   |                        |                        |
| Friday Lunch & Exhibits                         | $45                               | $55                    | $________               |
| Friday Evening Meal                             | $40                               | $50                    | $________               |
| Saturday Lunch                                  | $35                               | $45                    | $________               |

Donations                                        | NebPharmPAC                        | $________               |
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The Nebraska Mortar & Pestle 39
## PHARMACY TECHNICIAN

**Name**  
_______________________________  
**Phone Number**  
______________________  

**Badge Name**  
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**Email Address**  
______________________  

**Mailing Address**  
_______________________________  
**CPE e-Profile #**  
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**City/State/Zip**  
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**Birthdate**  
(MMDD)  
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**Spouse/Guest Name (If applicable)**  
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On or After 04/08/2014  
Registration Sub Totals

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### Donations

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### Handout Booklet

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  Check #____________

- **Credit Card #**  
  Exp. Date ____/_____  
  Security Code ______  

- Please send receipt.

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**Fax**  
402-420-1406

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40  January/February 2014
**STUDENT PHARMACIST**

<table>
<thead>
<tr>
<th>Name</th>
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Signature ____________________________  Please send receipt.

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**Registration Total** $______

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Cataracts and Glaucoma

This CPE lesson was written by Nam Phuong T. Tran, PharmD Candidate, Lake Erie College of Osteopathic Medicine, School of Pharmacy, who has no financial or conflict of interest disclosures.

Objectives
At the conclusion of this lesson, participants should be able to:
1. Describe the pathophysiology of cataracts and glaucoma.
2. List risk factors for cataracts and glaucoma.
3. Explain the surgery procedures for cataracts.
4. Review the pharmacologic management of post-cataract surgery and primary open-angle glaucoma.

CATARACTS

Background
A cataract is the clouding of the eye’s lens causing loss of vision. According to the World Health Organization (WHO), cataracts are the leading cause of blindness worldwide.1 It is estimated that 51% of world blindness is caused by cataracts. In the United States, 22 million people age 40 and older are affected by cataracts. It is estimated that the number of people with cataracts will reach 30.1 million by the year 2020.2 A cataract can occur in either or both eyes, but cannot spread from one eye to the other.3

Normally, the lens focuses light on the retina. As we age, the lens hardens, cannot focus at close distance and may become cloudy. A cloudy lens prevents light from focusing sharply on the retina.4

There are different types of cataracts, including nuclear, cortical, posterior subcapsular, or any combination of these three. Nuclear cataracts are the most common type of cataracts that progress slowly with the lens becoming brown and opaque later in life. "Nuclear" refers to the gradual clouding of the central portion of the lens called the nucleus. A cortical cataract can be central or peripheral with white opacities that develop in the cortex of a lens where patients may complain of glare. Posterior subcapsular (PSC) cataracts are found more often in younger patients compared to nuclear or cortical cataracts for older patients. The term "subcapsular" is used because it forms beneath the lens capsule. A PSC cataract often interferes with reading and causes glare or "halo" effect around lights.4

Risk Factors
Everyone is at risk of developing cataracts because age is the single greatest risk factor. Other risk factors include exposure to sunlight (UV light), smoking, diabetes, injury to the eye, family history of cataracts, radiation exposure, previous intraocular surgery, and other eye problems such as glaucoma.4

Table 1 lists medications that are associated with cataracts. Long-term use of oral or inhaled steroids is a well-known cause of cataracts.4 It is interesting to note that the use of statin drugs may be linked with a lower frequency of nuclear cataracts. Statins have been shown to increase antioxidants in the body, and thus prevent damage to the eye. According to "Recent statin use and cataract surgery", a case-control study: long term use of statins was protective against cataract formation in patients that were 50-64 years of age with dyslipidemia, while short term use was associated with an increased risk of cataract surgery. Statins have not been studied as preventative medications for cataracts and additional studies are needed to understand the difference between short and long term use of statins.5 Moreover, there are conflicting studies published about the association of statins and cataracts, thus patients and health care providers should carefully consider the risks versus the benefits of statin use, especially for primary prevention.

Signs/Symptoms and Diagnosis
The most common symptom associated with cataracts is decreased visual acuity that often results in painless blurring of vision, colors appear faded, glare and sensitivity to bright lights, difficulty reading due to reduced black-white contrast, and poor night vision. The cloudiness in the eye caused by a cataract may affect only a small part of the eye’s lens, and the patient may be unaware of any vision loss at first. As

<table>
<thead>
<tr>
<th>Well-known causes of cataracts</th>
<th>• Corticosteroids (topical, systemic, or inhaled oral but not nasal)</th>
</tr>
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<tbody>
<tr>
<td>Associated with cataracts</td>
<td>• Antipsychotics such as Seroquel* (quetiapine), Thorazine* (chlorpromazine)</td>
</tr>
<tr>
<td></td>
<td>• Glaucome medication such as Phospholine Iodine* (echotiohiophate iodide) for open-angle glaucoma</td>
</tr>
<tr>
<td></td>
<td>• Psoralens</td>
</tr>
<tr>
<td>Weakly associated with cataracts</td>
<td>• Allopurinol</td>
</tr>
<tr>
<td></td>
<td>• Amiodarone</td>
</tr>
<tr>
<td></td>
<td>• Potassium-sparing diuretics (but not other diuretics)</td>
</tr>
<tr>
<td></td>
<td>• Tamoxifen</td>
</tr>
<tr>
<td></td>
<td>• Tetracycline</td>
</tr>
<tr>
<td></td>
<td>• Thyroid hormone</td>
</tr>
<tr>
<td></td>
<td>• Tricyclic antidepressants (amitriptyline and imipramine)</td>
</tr>
<tr>
<td>Potentially reduces the risk for nuclear cataracts</td>
<td>• Statins</td>
</tr>
</tbody>
</table>

Table 1. Cataracts Associated Medications4-5
Table 2. Post-Cataract Surgery Medications

<table>
<thead>
<tr>
<th>Class</th>
<th>Medications</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corticosteroids</td>
<td>• Durezol™ (difluprednate 0.05%)</td>
<td>• Reduce swelling, but can pose a risk for increased pressure in the eye</td>
</tr>
<tr>
<td></td>
<td>• Lotemax™ (loteprednol 0.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pred Forte™ &amp; Omnipel® (prenisolone 1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Vexol™ (rimexolone 1%)</td>
<td></td>
</tr>
<tr>
<td>Nonsteroidal anti-inflammatory drugs (NSAIDs)</td>
<td>• Acuvail™ &amp; Acular® (ketorolac 0.45, 0.5%)</td>
<td>• Reduce swelling, pain, and do not have the same risks as steroids</td>
</tr>
<tr>
<td></td>
<td>• Bromday™ &amp; Xibrom® (bromfenac 0.09%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ilvetro™ &amp; Nevanac® (nepafenac 0.3%, 0.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Naproxen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Prolensa™ (bromfenac 0.07%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Voltaren™ (diclofenac 0.1%)</td>
<td></td>
</tr>
<tr>
<td>Topical antibiotics</td>
<td>• Azasite™ (azithromycin)</td>
<td>• Prevent infection and bacterial growth</td>
</tr>
<tr>
<td></td>
<td>• Ciloxan™ (ciprofloxacin)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ocuflox™ (ofloxacin)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Vigamox® (moxifloxacin)</td>
<td></td>
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<tr>
<td></td>
<td>• Zymaxida™ (gatifloxacin)</td>
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the cataract grows larger, it clouds more of the lens and distorts the light from passing through the lens leading to more noticeable symptoms. The cataract grows larger, it clouds more of the lens and distorts the light from passing through the lens leading to more noticeable symptoms. The cataract grows larger, it clouds more of the lens and distorts the light from passing through the lens leading to more noticeable symptoms. The cataract grows larger, it clouds more of the lens and distorts the light from passing through the lens leading to more noticeable symptoms.

Cataracts are simple to diagnose by an ophthalmologist or an optometrist during a routine eye examination. A cataract is detected through a comprehensive evaluation that includes patient history, acuity test, glare exam, dilated eye exam, intraocular pressure (IOP) measurement, and other supplemental tests.

**Treatment**

Surgery is the only way to remove cataracts. Most cataract surgeries are called phacoemulsification or phaco. Patients should be advised about the risks of surgery, as well as the advantages. Surgery is usually performed on an outpatient basis and only local or topical anesthesia is needed. The procedure involves the following steps:

1. A microscopic incision is made close to the edge of the cornea by the surgeon.
2. A tiny, high-frequency ultrasound probe is inserted and used to break up the clouded lens into smaller fragments.
3. The clouded, broken-up, natural lens is removed with suction.
4. An artificial lens is inserted. The new intraocular lens (IOL) replaces the natural cloudy lens.
5. The IOL is placed behind the iris (posterior chamber lens) or in front of iris (anterior chamber lens). The posterior chamber lenses are the choice for almost all patients today. In addition, multifocal IOL lenses are available options instead single-focus IOL lenses to allow both near and distance vision after surgery and reduce the need for reading glasses.

6. The surgeon closes the incision in the eye (a stitch may or may not be needed), and a protective shield or bandage is placed over the eye for protection in the early stages of the cataract surgery recovery.

Other types of surgeries include femtosecond laser-assisted cataract surgery and extracapsular cataract extraction (ECCE). In laser-assisted cataract surgery, a surgeon uses computer-controlled laser technology instead of handheld instruments during the key steps of the procedure. Laser surgery is fairly new and not offered by all cataract surgeons, and not all patients are candidates compared to the phaco.

ECCE is used more in rare cases where patients have multiple conditions or with advanced cataracts that cannot be broken up by ultrasound. This procedure requires several stitches and may take as long as eight weeks to heal.

**Risks of Cataracts Surgery**

Most cataract surgical procedures are performed without complications, although there are always some risks involved such as infection, bleeding, double vision, and lid dropiness. The patient is expected to have minimal to no pain following the surgery. There can be mild irritation for a few days as the eye is healing. The clarity of vision will be noticeable by the next day, and within the first month, the eye should fully recover.

The use of eye drops is necessary for 3-6 weeks following surgery to reduce the risk of infection and/or inflammation in the eye.

Table 2 lists the medications that are used after cataract surgery. The three different drug class medications are corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and topical antibiotics. These medications help fight infection, inflammation, pain, and swelling.

**New NSAID Option:**

**Prolensa™ (bromfenac ophthalmic solution)**

**Indication and Use**

Prolensa (bromfenac ophthalmic solution) was approved by the FDA on April 5, 2013 for the treatment of postoperative infection and reduction of ocular pain following cataract surgery formulated as a different concentration than other available bromfenac products.

**Dosing and Availability**

Prolensa is available as topical ophthalmic solution: bromfenac 0.07% in 1.6 ml and 3 ml bottles. Patients are instructed to instill one drop into the affected eye daily beginning one day prior to surgery, the day of surgery, and continuing for two weeks postoperatively. There are no adequate and well-controlled studies in pregnant women and patients under 18 years old. Therefore, Prolensa is not recommended for use in children or during pregnancy. For patients with hepatic and renal impairment,
Mechanism of Action
Bromfenac is a nonsteroidal anti-inflammatory drug (NSAID). It inhibits cyclooxygenase (COX) 1 and 2, which results in decreased formation of prostaglandin precursors. In animal studies, prostaglandins produce disruption of the blood-aqueous humor barrier, leukocytosis, vasodilation, increased vascular permeability, and increased intraocular pressure (fluid pressure inside the eye).8

Adverse Drug Events
In clinical trials, the safety of the 0.07% bromfenac formulation was evaluated in 222 patients and compared to 218 patients who received placebo. Several adverse reactions were reported in 3% to 8% of patients including eye pain, anterior chamber inflammation, foreign body sensation, photophobia, and blurred vision. Compared to other ophthalmic NSAIDs, the safety profile of bromfenac is consistent.7,8

Warning, Precautions, and Contraindications
Prolensa contains sodium sulfite and may cause allergic reactions in susceptible patients. All NSAIDs may slow or delay healing, and there is a potential cross-sensitivity with aspirin. There is potential for keratitis and corneal erosion, ulceration and perforation, and may increase bleeding time.8

Prolensa contains the preservative benzalkonium chloride. Benzalkonium chloride may be absorbed by soft contact lenses, so lenses must be removed prior to instillation of Prolensa. Patients must wait at least 10 minutes to reinset the lens.8

There are no contraindications for this product listed in the manufacturer’s prescribing information.8

Drug-Drug Interaction
There are no known significant interactions with Prolensa. Caution must be taken in patients taking concomitant drugs that prolong bleeding time such as aspirin.8

Place in Therapy
There are many NSAIDs on the market to treat postoperative pain and inflammation. An NSAID is part of a three-drug combination: an antimicrobial, a topical steroid and a topical NSAID for post-op treatment of cataracts. Compliance and cost are two factors in choosing an NSAID. Prolensa might be more costly than diclofenac or ketorolac, but patients may be more compliant with once daily dosing with Prolensa, rather than twice a day or four times a day with other NSAIDs.

Glaucoma
Background
Glaucoma is the second most common cause of blindness nationally and globally. In 2010, it was estimated that there were 2.4 million people diagnosed with open-angle glaucoma in the United States. As the proportion of elders in the U.S. continues to rise, this number is expected to increase to 3.4 million by the year 2020. There are two common types of glaucoma: open-angle glaucoma and closed-angle (angle closure) glaucoma.9 Primary open-angle glaucoma (POAG) accounts for most cases of glaucoma and is the focus for this lesson.

Glaucoma is a group of ocular disorders that damage the optic nerve, causing optic neuropathy.10 Optic nerve damage results in a progressive loss of retinal ganglion cell axons, loss of optic nerve tissue, and blindness. Glaucoma patients typically lose peripheral vision and may lose all vision if not treated.11 Once vision is lost, it is not recoverable.

Pathophysiology and Risk Factors
In a healthy eye, a clear fluid called aqueous humor circulates around the lens, through the pupil, to the anterior chamber. To maintain a healthy eye pressure, the eye continuously produces a small amount of aqueous humor and an equal amount of this fluid flows out of the anterior chamber through a microscopic drain called trabecular meshwork in the iridocorneal angle.11 In glaucoma patients, the aqueous humor in the eye does not flow to the iridocorneal angle properly, and there is a buildup of fluid in the front of the eye. Fluid pressure in the eye increases and the extra force on the optic nerve causes a phenomenon called optic-nerve cupping, which damages the nerve fibers resulting in the loss of the visual field.11

Elevated intraocular pressure (IOP) is the most common risk factor for the development of glaucoma; however, some patients have progressive, glaucomatous nerve damage despite having IOPs in the normal range (typically 10 to 21 mmHg). This form of the disease is called normal or low-tension glaucoma. Generally, the higher the IOP, the greater the risk for developing glaucoma. Elevated IOP is the only modifiable risk factor for glaucoma. Advanced age, African American race, family history, myopia, hypertension, and microvascular disease are other risk factors for glaucoma.10-12

Glaucoma is an eye disorder where many pharmacists become involved especially from a prescription drug perspective. There are some medications that can increase intraocular pressure including antihistamines, anticholinergics, chronic corticosteroids, ß-agonists, and topiramate. These medications should be avoided in patients with glaucoma.13

Signs/Symptoms and Diagnosis
Symptoms of glaucoma do not develop until bilateral visual field loss has already occurred. The diagnosis of open-angle glaucoma is based on the presence of characteristic optic disk changes and visual field loss, with or without an increased IOP. Patients may complain about the presence of blind spots, reduced peripheral vision, cloudiness in eyes, and changes in color perception.12

Treatment
The goal of drug therapy in patients with glaucoma is to preserve visual function by reducing the IOP to a level at which no further optic nerve damage occurs. The initial goal is to achieve at least a 25% reduction in IOP, as suggested by evidence from the Early Manifest Glaucoma Trial and Collaborative Initial Glaucoma Treatment Study.12 Additional lowering may be necessary based upon the baseline IOP, the
Table 3. Prostaglandin Analogss\textsuperscript{12,14-15}

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>Normal Dosing</th>
<th>Contraindications</th>
<th>Main Side Effects</th>
<th>Major Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bimatoprost</td>
<td>Lumigan\textsuperscript{*}</td>
<td>1 drop HS</td>
<td>• Hypersensitivity</td>
<td>• Brown discoloration of the iris (not reversible), eyelid pigmentation (may be reversible)</td>
<td>• No significant interaction</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Xalatan\textsuperscript{*}</td>
<td>1 drop HS</td>
<td></td>
<td>• Macular edema</td>
<td></td>
</tr>
<tr>
<td>Tafluprost</td>
<td>Zioptan\textsuperscript{TM}</td>
<td>1 drop HS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travoprost</td>
<td>Travatan Z\textsuperscript{*}</td>
<td>1 drop HS</td>
<td></td>
<td></td>
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</tbody>
</table>

Prostaglandin analogs

Prostaglandin analogs are considered first-line therapy for POAG unless there are concerns about cost, side effects, intolerance, or patient’s noncompliance.\textsuperscript{13} They can be used as monotherapy or in combination with other classes. If a patient does not tolerate or does not respond with a decrease in IOP, an alternative medication should be used. If a patient partially responds to an agent (some decrease in IOP, but not at goal), addition of another medication should be considered.\textsuperscript{12}

Table 3 lists prostaglandin analog medications. These medications are usually dosed once daily in the evening and are most effective to reduce IOP, typically by 25-33%.\textsuperscript{12} Prostaglandin analogs reduce the IOP by increasing the outflow of aqueous humor. Bimatoprost is generally regarded as the most efficacious of the prostaglandin analogue ophthalmic class. Pigmentation of the eye and eyelid along with lengthening of eyelashes are the most common adverse effects.\textsuperscript{13}

Table 4. Topical Beta Blockers\textsuperscript{10,12,15}

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>Normal Dosing</th>
<th>Contraindications</th>
<th>Main Side Effects</th>
<th>Major Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betaxolol ((\beta)-selective)</td>
<td>Betoptic-S\textsuperscript{*}</td>
<td>1 drop BID</td>
<td>• Heart block</td>
<td>\textit{Local Effects}</td>
<td>• Digoxin, verapamil, diltiazem, or clonidine = (\uparrow) risk of bradycardia, or heart block</td>
</tr>
<tr>
<td>Carteolol</td>
<td>Ocupress\textsuperscript{*}</td>
<td>1 drop BID</td>
<td>• Bradycardia</td>
<td>• Stinging</td>
<td>• Oral (\beta)-blockers = (\uparrow) risk of systemic side effects.</td>
</tr>
<tr>
<td>Levobunolol</td>
<td>Betagan\textsuperscript{*}</td>
<td>1 drop QD or 1 drop BID</td>
<td>• Severe chronic obstructive pulmonary disease/asthma</td>
<td>• Burning</td>
<td></td>
</tr>
<tr>
<td>Metipranolol</td>
<td>OptiPranolol\textsuperscript{*}</td>
<td>1 drop BID</td>
<td></td>
<td>• Xerostomia</td>
<td></td>
</tr>
<tr>
<td>Timolol</td>
<td>Timoptic\textsuperscript{<em>} Betimol\textsuperscript{</em>} Istalol\textsuperscript{*}</td>
<td>1 drop QD or 1 drop BID Gel: 1 drop QD</td>
<td></td>
<td>• Blurred vision</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Tearing</td>
<td></td>
</tr>
</tbody>
</table>

Beta-Blockers

Table 4 lists the topical beta blockers to treat POAG. These beta blockers lower IOP by 20-25% by decreasing the aqueous humor production with once- or twice-daily dosing.\textsuperscript{10} Topical beta blockers are used after the prostaglandin analgols as initial therapy due to systemic effects such as bradycardia, fatigue, dizziness, heart failure exacerbation, and bronchospasm. Additive systemic effects occur when these topical beta blockers are used concurrently with oral beta blockers. All of these beta blockers are nonselective, except for betaxolol, which is \(\beta\)_1 selective. Beta blockers may be available at a lower cost as generic formulations.\textsuperscript{12}

Carbonic Anhydrase Inhibitors (CAIs)

Table 5 lists the carbonic anhydrase inhibitor (CAI) medications. They are generally used in patients already being treated with a prostaglandin analog. These topical medications are used to lower IOP by 15-20% by decreasing the aqueous humor production with three times a day
dosing. Acetazolamide is an oral and IV carbonic anhydrase inhibitor that may be used in patients refractory to maximal doses of topical therapy. This class of drugs is associated with a higher risk of side effects. These carbonic anhydrase inhibitors are contraindicated in patients with a sulfa allergy or renal dysfunction.

**Alpha 2 Agonists** Table 6 lists the alpha 2 agonist medications. Brimonidine is more commonly used than apraclonidine. Brimonidine may increase outflow of aqueous humor, as well as decrease aqueous humor production. Apraclonidine is primarily used for prevention and treatment of postsurgical intraocular pressure (IOP) elevation. Although ocular side effects are less common with brimonidine than with apraclonidine, systemic side effects such as xerostomia, orthostatic hypotension, dizziness, and fatigue are more common with brimonidine. Alpha 2 agonists should be used with caution in patients with cardiovascular disease, orthostatic hypotension, depression, and renal or hepatic dysfunction. These medications have similar structure to clonidine, an alpha 2 agonist hypotensive agent. Their systemic side effects are similar to clonidine.

**Cholinergic Agonists** Table 7 lists the direct-acting cholinergic agonists: pilocarpine and carbachol. The mechanism of action of cholinergic agonists is to increase outflow of aqueous humor to decrease the IOP. Cholinergic agonists are used as last-line therapies for POAG because of adverse events and reduced efficacy compared with newer agents. Pilocarpine is more commonly used than carbachol, and comes in five different concentrations. Pilocarpine concentrations greater than 4% may be associated with increased risk of systemic side effects such as increased urinary frequency, sweating, bronchospasm, and bradycardia.

**Fixed-Combination Medications** When monotherapy cannot lower IOP to target goal, patients with glaucoma will require treatment with multiple drugs. Fixed-combination products offer many advantages in the treatment of POAG. These advantages include greater reductions in IOP than monotherapy, improved adherence, and convenience. Other
advantages of fixed-combination products include eliminating the need to instill two separate medications 5 to 10 minutes apart to prevent a washout effect from the second medication, improving safety and tolerability by limiting the exposure to the benzalkonium chloride (BAK) preservative, and cost savings for the patient by potentially eliminating a co-pay for one of the medications. Combination medications may unfortunately also have additive side effects.

Table 8 lists the three combination medications to treat POAG. Currently Cosopt® and Combigan® are the two topical medication combinations containing beta blocker components (see Table 8). Beta blockers have many adverse effects that some patients cannot tolerate.

### Indication and Use
Simbrinza was approved by the FDA on April 19, 2013 for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

### Mechanism of Action
Simbrinza combines brinzolamide (carbonic anhydrase inhibitor) and brimonidine (alpha 2 agonist) into a single multidose bottle. Brinzolamide works in the ciliary processes and retina of the eye. Brimonidine lowers IOP by decreasing bicarbonate ions with subsequent reduction in sodium and fluid transport, resulting in a decrease in aqueous humor secretion. Brimonidine has a dual mechanism of action: to lower IOP by decreasing the production of aqueous humor and by increasing uveoscleral outflow.

### Adverse Drug Events
During clinical trials, the most common adverse reactions were blurred vision, eye irritation, dysgeusia (unpleasant taste), dry mouth, eyelid edema, and eye allergy.

### Warning, Precautions, and Contraindications
Simbrinza is a sulfonamide and should be avoided in patients with a sulfonamide allergy. Although administered ocularly, systemic absorption may occur and could result in hypersensitivity or serious reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, aplastic anemia, agranulocytosis, and other blood dyscrasias.

Caution should be taken when using Simbrinza in patients with low endothelial cell counts, depression, severe hepatic impairment, severe cardiovascular disease, orthostatic hypotension, cerebral or coronary insufficiency, Raynaud’s phenomenon, or thromboangitis obliterans.

Simbrinza is contraindicated in neonates and infants under the age of 2 years and for patients who have hypersensitivity to any component of this drug. Simbrinza is not recommended for use in patients with severe renal impairment (CrCl <30 mL/min) and acute angle-closure glaucoma, since the drug was not studied in these patients.

### Drug-Drug Interaction
The concomitant use of Simbrinza with an oral carbonic anhydrase inhibitor is not recommended. Patients should be cautious when using Simbrinza with antihypertensives, cardiac glycosides,

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**Table 7. Direct-acting Cholinergic Agonists**

<table>
<thead>
<tr>
<th>MOA: ↓ IOP</th>
<th>by ↑ outflow of aqueous humor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic</td>
<td>Brand</td>
</tr>
<tr>
<td>Carbachol</td>
<td></td>
</tr>
<tr>
<td>Pilocarpine</td>
<td></td>
</tr>
</tbody>
</table>

**Table 8. Combination Medications**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand</th>
<th>Dose</th>
<th>Pharmacologic Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brinzolamide/Timolol</td>
<td>Combigan®</td>
<td>1 drop BID</td>
<td>β2 agonist/ Beta blocker</td>
</tr>
<tr>
<td>Brinzolamide/Brimonidine</td>
<td>Simbrinza™</td>
<td>1 drop TID</td>
<td>Carbonic anhydrase inhibitor/ β2 agonist</td>
</tr>
<tr>
<td>Dorzolamide/Timolol</td>
<td>• Cosopt*</td>
<td>1 drop BID</td>
<td>Carbonic anhydrase inhibitor/Beta blocker</td>
</tr>
<tr>
<td></td>
<td>• Cosopt* PF</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**New Treatment Option**

Simbrinza (brinzolamide/brimonidine) was approved because there was a great need for a beta-blocker-free fixed combination, and Simbrinza meets that need. Previously, there were two fixed-combination medications containing beta blocker components (see Table 8). Beta blockers have many adverse effects that some patients cannot tolerate.

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**Continuing Pharmacy Education Lesson #3**

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**The Nebraska Mortar & Pestle 47**
tricyclic antidepressants, and monoamine oxidase inhibitors. The concomitant use of high-dose salicylates may produce acid-base and electrolyte alterations. Simbrinza™ may be potentiated by CNS depressants such as alcohol, opiates, barbiturates, sedatives, and anesthetics.19

Dosing and Availability
Simbrinza is available in an ophthalmic suspension of 8 mL in a 10 mL bottle. The suspension contains 10 mg/mL brinzolamide (1.0%) and 2 mg/mL brimonidine tartrate (0.2%). The solution must be shaken well before use and 1 drop should be instilled in the affected eye three times daily. If more than one topical medication is required, instillation should be separated by 5 to 10 minutes to provide optimal ocular contact.20

Place in Therapy
Simbrinza is used as adjunctive therapy after the patient has failed prostaglandin analogs, beta blockers, and CAI. Simbrinza may be the next choice after a prostaglandin analog, since the efficacy is comparable to fixed combinations that contain a beta-blocker such as Cosopt® or Combigan®; therefore, a beta-blocker is not needed to achieve a similar efficacy. This is a good news for patients who cannot take beta-blockers, such as those with restrictive airway disease and those with slow heart rates.20 Simbrinza and other fixed combinations are used as first-line therapy when patients with IOP of 40 to 50 mmHg and need a rapid IOP reduction along with a prostaglandin analog. Simbrinza should also be used initially in patients with unilateral glaucoma, such as pseudoexfoliation, since prostaglandin analogs may cause unilateral eyelash changes and hyperemia.19

Conclusion
Cataracts and glaucoma are the two leading ophthalmic diseases worldwide that cause blindness. There are no medications that reduce or eliminate the need for cataract surgery. Surgery is the only method to restore vision for patients with cataracts. For glaucoma, eye drops can help to reduce intraocular pressure. Vision loss cannot be reversed in glaucoma patients. Pharmacists may positively impact outcomes by providing education about cataracts and glaucoma to patients. Patients need to know the proper use of prescribed medications, common side effects, proper aseptic technique to use with eye drops, and appropriate intervals between drops. Pharmacists may need to identify patient factors to increase treatment compliance, and develop strategies to help patients overcome obstacles for successful management of cataracts and glaucoma.

References
Cataracts and Glaucoma Quiz #3, January/February, UAN #128-000-14-016-H01-P

1. Cataracts affect which part of the eye?
   a. Cornea  c. Retina
   b. Lens  d. Vitreous

2. What are the risk factors for getting cataracts?
   a. Diabetes
   b. Long-term steroid use
   c. Smoking
   d. All of the above

3. Cataract surgery utilizes which of the following techniques?
   a. Infrared light
   b. Radiation
   c. Ultrasound
   d. Ultraviolet light

4. What is the active ingredient in Prolensa?
   a. bromfenac
   b. diclofenac
   c. ketorolac
   d. nepafenac

5. Which of the following is true about cataracts?
   a. Cataract surgeries are called phacoemulsification or phaco.
   b. Cataracts are the second most common cause of blindness globally.
   c. Contact lenses do not need to be removed prior to instillation of Prolensa.
   d. Vision loss cannot be reversed in cataract patients.

6. What is the only modifiable risk factor for glaucoma?
   a. Advanced Age
   b. African American
   c. Elevated IOP
   d. Family history of glaucoma

7. What are the symptoms of primary open angle glaucoma?
   a. Blurred vision
   b. Halo around lights
   c. Ocular pain
   d. None, until bilateral visual field loss occurs.

8. Which glaucoma medication may increase the outflow of aqueous humor?
   a. Brimonidine
   b. Brinzolamide
   c. Latanoprost
   d. Timolol

9. How long should the patients wait between instillation of eye drops when using more than one medication?
   a. 2 minutes
   b. 3 minutes
   c. 4 minutes
   d. 5 minutes

10. The components in Simbrinza are:
    a. Brimonidine and timolol
    b. Brinzolamide and brimonidine
    c. Dorzolamide and timolol
    d. Latanoprost and brimonidine

Keep the TOP portion for your records. Return the BOTTOM portion to the NPA office.
Or, take this quiz online at www.npharm.org

The Nebraska Mortar & Pestle 49

CPE Home Study Evaluation
1. Rate this lesson: (Excellent) 5 4 3 2 1 (Poor)
2. Did this lesson meet each of its objectives? ___ Yes ___ No
3. Was the content without commercial bias? ___ Yes ___ No
4. Did the lesson meet your educational/practice needs? ___ Yes ___ No
5. Comments/future topics are welcome.__________________________

The deadline for this quiz is December 8, 2014
How New Compounding, Track-and-Trace Law May Affect Pharmacists

President Barack Obama signed the Drug Quality and Security Act (H.R. 3204) into law on November 27. What are the practical implications for most pharmacists of the new compounding and track-and-trace legislation?

The short answer is that the compounding part of the legislation, which became effective upon enactment, may affect more pharmacists than initially anticipated. The track-and-trace part of the legislation will affect all pharmacists to some extent, according to Michael Ghobrial, PharmD, JD, APhA Associate Director of Health Policy.

Of course, the language in the legislation is not the last word. FDA has to decide how to implement it through the regulatory process. Traditional community pharmacies are “probably” not going to be affected by the compounding part of the law “unless we get more stringent regulation from the FDA,” said Lee Rosebush, PharmD, JD, MBA, MS, Counsel at the BakerHostetler law firm in Washington, DC. “While we got by with 3204, we may not necessarily get by with the regulations proposed by FDA.”

Compounding: Practical Impact

Under the new law, traditional pharmacies are still regulated by state boards of pharmacy. Compounding pharmacies are still regulated by state boards of pharmacy, Ghobrial said. But now compounding pharmacies that voluntarily elect to be “outsourcing facilities” are regulated by both state boards of pharmacy and FDA.

“Here’s the big question everybody’s going to be asking: If [registration with FDA] is voluntary, why would you want to have the FDA breathing down your neck? And the answer to that is brilliant,” Ghobrial said. “People will sign up because their product is less likely to be sold if they’re not an FDA-ovenseen outsourcing facility.”

Traditional pharmacies that do sterile compounding based on specific, individualized prescriptions have no reason to register with FDA, emphasized Rosebush. Pharmacies that are going to supply office use medication, however, have to do the registration. “You’re going to see a business model determination,” Rosebush said. “You’re going to see entities say, ‘Well, is the $15,000 user fee and the cGMP [current Good Manufacturing Practices] compliance worth moving into this new business model?’”

Rosebush has “several clients who are large compounding pharmacies,” he said. “I do have some that are willing to register with the FDA and are currently pursuing compliance policies that use cGMPs and USP [U.S. Pharmacopeia] <797> standards. We eagerly await the publication of regulations in this area.” He added, “Some of my clients do not feel that they will have to register with the FDA and are not planning on registering with the FDA.”

Many in the industry don’t think that cGMPs (which are aimed at manufacturers) will be applied across the board to compounding pharmacies, according to Rosebush. “They can’t do it. It’s impossible,” he said. “I think you’ll see some new cGMPs put forth for compounding pharmacies, and I think those cGMPs will adopt certain aspects of <797>.”

Track and Trace: Practical Impact

“Track and trace affects all pharmacists, but it’s really not that difficult,” Ghobrial said. As of January 1, 2015, the manufacturers and the wholesale distributors “can’t ship anything out unless it has a transaction history” in the form of paper documentation for each individual unit of a drug; if there’s a hiccup or if, say, the paperwork gets lost somehow, pharmacies can still accept the product until July 1, 2015. Starting on that date, following the 6-month grace period, pharmacists have to reject products without an accompanying transaction history.

When pharmacists get the product in from the distributor, they need to take the transaction history paperwork, put it in a drawer, and keep it for 6 years.

Along the same lines, one pharmacy can transfer a drug to another pharmacy to fulfill a specific patient need without needing an accompanying transaction history—but if a pharmacy just wants to lessen their inventory because there’s too much money on their shelves, as of July 1, 2015, the drugs need to be sent back to the distributor with a transaction history. “Say they do want to lighten their inventory a year later,” Ghobrial said. “They go back into their drawer, pull out the transaction history, maybe write a line item saying it was at my pharmacy on such-and-such a date, and they can ship it. So it’s not like they have to do all this investigation and research. All the information should be in their drawer.”

As of the bill being signed, the pharmacist is required to investigate a product that he or she finds to be suspicious, quarantine it, dispose of it, and give appropriate notice to FDA. But FDA has 7 years to implement regulations for exactly what pharmacists should do in a rigorous investigation process, Ghobrial continued. “After you do all the transaction history, have all the documents where...
you transfer ownership, make sure that you receive the drug with the proper documentation, store the documentation away for 6 years—[the next step] is to investigate” suspicious drugs (drugs that are counterfeit, tampered, or adultered).

“My read is that the duty begins when” pharmacists see a suspicious product, Ghobrial said. “The duty's not to find it. The duty is to set it aside once they do find it, and contact the FDA.”

Also through FDA rulemaking, in 10 years, track and trace will be implemented electronically with technology that is not specified in the law—but which could be bar codes and/or RFID (radio-frequency identification), for example. “You have to assume that not all pharmacies have a scanner and the software and the hardware to visualize what would be in the bar code,” Ghobrial said. “In 10 years, I think that's what they'd want to do.”

The intent of Congress was that the track-and-trace legislation will curb counterfeit drugs entering the supply chain, Ghobrial said. The new law will not “stop all diversion,” Rosebush said. But “it’s a good step moving forward.”

FDA Issues Pharmacy Compounding Draft Guidance

H ot on the heels of the Drug Quality and Security Act (H.R. 3204) being signed into law, FDA issued three draft industry guidances reflecting the agency’s current thinking on the compounding part of the new compounding and track-and-trace legislation before implementation begins. According to APhA’s analysis of the draft guidance of particular interest to most pharmacists, “Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act,” more pharmacists than initially anticipated may be affected if FDA’s thinking informs its future regulations.

“When we think of compounders, we think of brick-and-mortar pharmacies mixing lotions,” said Michael H Ghobrial, PharmD, JD, APhA Associate Director of Health Policy. “FDA has said their enforcement regarding traditional compounding in these settings is going to be very similar to what was in place before the passage of H.R. 3204. This guidance could have a significant effect on compounders of sterile products, especially if the guidance is translated into regulations in the future.”

The current guidance does provide some clarity to compounders, according to Jillanne Schulte, JD, APhA Director of Regulatory Affairs. “Guidance is advice,” but does not have the force of law, she emphasized. “It’s a safe harbor. If you’re complying with the guidance, it’s unlikely that you’re going to be in any enforcement danger.” Will future compounding regulations substantially mirror this guidance? “I think [FDA] thought they were offering some clarity,” said Schulte. APhA will comment on this draft guidance and may comment on the other two draft guidances that cover compounding pharmacies that voluntarily register with FDA as outsourcing facilities. Comments on the draft guidances were due 02/03/2014.

**Sterile Compounding**

The draft guidance suggests that compounding under section 503A of the Food, Drug, and Cosmetic Act be done in accordance with U.S. Pharmacopeia (USP) chapters <795> and <797>. Compliance with USP <795> for nonsterile compounding would not pose a significant cost or implementation burden to pharmacies. Compliance with USP <797> for sterile compounding, however, could generate implementation costs for some pharmacies, according to APhA.

“A lot of traditional pharmacy compounding is not sterile. But if they are compounding sterile products and they cannot comply with <797>, then [if the draft guidance becomes law], they would have to get themselves up to standard,” according to Schulte.

Should the draft guidance become law, any potential new expenses for sterile compounders would fall into the categories of facility design; environmental testing; personnel training and competency testing; and maintaining sterility, purity, and stability of dispensed and distributed compounding sterile products. That last item, which would put the duty on the compounding pharmacy to ensure that the product remains in accordance with all the <797> requirements until it gets to the patient, sets up sterile compounders for “potential liability,” Ghobrial said.

**More Potential Changes**

Compounding pharmacies located in states that do not have a memorandum of understanding (MOU) in place between FDA and their state could not ship more than 5% of their prescription volume of compounded products outside of the state. This limitation, known as the 5% rule, would not go into effect until 90 days after FDA finalizes a new MOU through rulemaking with comments from stakeholders. FDA has not yet begun this process. An MOU can be thought of as a short contract or an agreement that compounders will comply with certain rules they’re distributing compounded drugs, Schulte said. MOUs would vary from state to state.

One pharmacist who would feel an impact is Cheri Garvin, BSPharm, owner and CEO of Leesburg Pharmacy and the Compounding Center in Leesburg, VA—the only accredited compounding pharmacy in the Washington, DC, metro region. “One of my concerns as a practitioner is that I do not know how my state will respond to the request for the MOU. Because I am in a border town very close to Maryland and very close to DC, if this MOU were not in place, I would be limited to dispensing less than 5% of my prescriptions across state lines,” Garvin said. “That would really affect us.”

The draft guidance also indicates that FDA will regulate the bulk substances drug list but will not enforce that list until the regulations are finalized. FDA is seeking nominations for the Pharmacy Compounding Advisory Committee, which will oversee some of the rulemaking. “Another thing we’re waiting on with this guidance is additional information regarding ‘office-use’ and also repackaging and how it’s going to be treated under the law,” said Schulte. That information is being drafted by FDA.
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