We Hear That!

- NPA member **Dr. Sidney J. Stohs**, Frisco, Texas, Dean Emeritus of the Creighton University School of Pharmacy and Health Professions is the recipient of the 2019 Ragus Award by the American College of Nutrition. This award recognizes the outstanding research paper published in the Journal of the American College of Nutrition (JACN) in 2018. The paper is entitled “A Comparative Pharmacokinetic Assessment of a Novel Highly Bioavailable Curcumin Formulation with 95% Curcumin: A Randomized, Double-Blind, Crossover Study”, which appeared in print in JACN volume 37(1), January 2018. Congrats, Dr. Stohs!

- **Chris Farrell, PharmD**, will be joining his dad, Pat Farrell, at the family business - Farrell's Pharmacy, McCook. Chris becomes a third-generation pharmacist following his dad and his grandfather, Warren Farrell. Last year, Farrell Pharmacy marked its 50th anniversary. Congrats to Pat and Chris!

- **Randall Dee Rockwell**, Grand Island, passed away on September 26, 2019. He graduated from the University of Nebraska College of Pharmacy. After serving in the Navy, he worked for the Walnut Street Pharmacy, and in 1954, he became the owner of Dee’s Pharmacy Drug Stores. Dee’s daughter, Kerri Rockwell, is a pharmacist in Omaha. Our condolences to the Rockwell family!

- **Dr. Ally Dering-Anderson, PharmD**, Lincoln, was inducted into the UNMC Interprofessional Academy of Education. Congrats, Ally!

- **Andrew Meyerle**, Lincoln, celebrated is 100th birthday on October 2. Andrew graduated from the University of Nebraska College of Pharmacy. He owned Meyerle Pharmacy in McCook and later partnered with Ron Stuhmer, RP, at A&M Drug in McCook until he retired. Happy 100th Birthday, Andrew!

*Please send “We Hear That” news and photos to diane@npharm.org. You may think your news isn’t important, but M&P subscribers enjoy reading about their pharmacy friends from across the state.*

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In Case You Missed It

Your NPA member benefits include 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 and other important pharmacy news that you may have missed.

CPE Reminder
This M&P issue contains the last CPE articles published for 2019 and are due on December 12, 2019. Unless renewing for the first time, pharmacists must have completed 30 hours of CPE between January 1, 2018 and December 31, 2019 to renew their license with DHHS. Log into your NABP e-Profile and verify the accuracy of your CPE credits. It is your responsibility for the accuracy of these records.

PDMP Changes
The Nebraska PDMP is undergoing some changes and enhancements for the near future. A conversion to the nationally recognized company, NIC and their RxGov PDMP platform will occur in less than a month.

Dispensers, such as pharmacies and dispensing practitioners with a pharmacy license who send data to the PDMP, should register as Submitters now if they have not already done so. Create an account at https://nepdmrxgov.com/login. Clinicians who view the information in the PDMP will be migrated to the new system. They will not need to register if they have an existing account to the NEHII HIE or the Nebraska PDMP.

Additional information will be sent via email as the go-live date approaches. If there are any questions, contact PDMP@nehii.org (402-506-9900 ext. 1) or felica.quintana-zinn@nebraska.gov (402-471-0379).

USP Delays Official Effective Dates of New and Revised Compounding Standards
The United States Pharmacopeia is postponing the official effective dates of several new and revised standards pertaining to pharmaceutical handling until further notice while it reviews appeals to the standards. Those standards include general chapters <795> (Pharmaceutical Compounding – Nonsterile Preparations), <797> (Pharmaceutical Compounding – Sterile Preparations), and <825> (Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging).

USP new general chapter <800> (Hazardous Drugs Handling in Healthcare Settings) will remain official, but only informational and will not be applicable until the appeals process is complete.

Make a Strong Recommendation
As a health care professional, your strong recommendation is a critical factor that affects whether your patients get an influenza vaccine. Most adults believe vaccines are important, but they need a reminder from you to get vaccinated. Follow up with each patient during subsequent visits to ensure the patient received an influenza vaccine. If the patient is still unvaccinated, repeat the recommendation to try to identify and address any questions or concerns.

Preventing SIRVA
All individuals who administer vaccines should reassess their vaccine administration technique and process to ensure use of proper landmark determination and avoidance of patient shoulder injuries related to vaccine administration (SIRVA).

There have been increasing numbers of shoulder injury claims associated with vaccine administration by all providers (not just pharmacists). With pharmacists playing increasing roles in vaccine administration we need to remind practitioners regarding the use of correct vaccine administration technique and procedures. Learn more at pharmacist.com.

Phair Pricing Act of 2019
H.R. 1034, the Phair Pricing Act sponsored by Reps. Doug Collins (R-Ga.) and Vicente Gonzales (D-Texas) would address pharmacy DIR fees. Voice support for this critical legislation because it:

• directs all pharmacy DIR fees, excluding positive incentive payments, between a pharmacy and a Part D plan sponsor or PBM to be included at the point of sale
• requires PBMs and plans to provide pharmacies with claims level data on applicable pharmacy DIR fees
• ensures that pharmacies are not reimbursed less than a pharmacy’s cost of purchasing and dispensing a drug.
• directs the Secretary of Health and Human Services (HHS) to establish quality measures that apply to pharmacy operations and requires all Part D sponsors to utilize the HHS-established quality measures that are standardized and pharmacy specific

Contact your Congressional representative to voice your support!

Not receiving the Daily News Dose? Double-check your spam or junk folder or email info@npharm.org for assistance.
Elections for the 2020 NPA Board Candidates will be in November 2019. Watch your email for candidate information and voting opportunities.
2020 Community Pharmacy Scholarship

Apply at phmic.com/scholarship

• Apply October 1 - December 2, 2019
• Recipients selected will be awarded $2,500 each
• Up to $50,000 awarded annually
A common purpose unites us...

...they are better off for it.

NACDS salutes the Nebraska Pharmacists Association, and values our partnership. Our work together on policy issues is an extension of our commitment behind the counter. When we speak as one, we protect and advance the role of community pharmacy in healthcare.

We are proud to stand with you, as we stand up for those we serve.
EPINEPHRINE MDI RETURNS TO THE UNITED STATES MARKET AMID CONTROVERSY

Objectives
At the conclusion of this lesson, pharmacists and pharmacy technicians should be able to:
1. Explain why epinephrine inhalation (Primatene Mist) was removed from the market in 2011.
2. State objections for the return of epinephrine inhalation (Primatene Mist) to the market in 2019.
3. Identify key elements of education for patients who purchase epinephrine inhalation (Primatene Mist).

Introduction
In November 2018, the Food and Drug Administration (FDA) approved Primatene Mist®, an epinephrine containing metered-dose inhaler (MDI) manufactured by Amphastar Pharmaceuticals, Inc. for sale over-the-counter (OTC). The approval of Primatene Mist® was for use by patients ages 12 and above with mild intermittent asthma. With this decision, Primatene Mist® became the only FDA-approved OTC inhaler for the treatment of asthma in the United States (US). This FDA approval has proven unpopular with asthma specialists, pharmacists, and respiratory health-related societies as these entities collectively contend that this well-intentioned maneuver inadvertently places asthma patients at increased risk of suboptimal therapy and unfavorable outcomes.

Epinephrine MDIs: The Past
Early MDIs uniformly used chlorofluorocarbon (CFC) propellants to deliver inhaled medications. Because CFCs were found to contribute to ozone-layer depletion, US adoption of the Montreal Protocol in 1988 and an amendment of the Clean Air Act in 1990 called for reducing CFC-containing products by the year 2000. An “essential use protections” clause in that legislation allowed ongoing use of select CFC-containing medications until alternative delivery systems could be developed. Although albuterol manufacturers first released hydrofluoroalkane (HFA) propellants for their MDI products in 1996, epinephrine MDI manufacturers continued to use CFC propellants.1

During this same time frame, safety concerns surrounding OTC sales of epinephrine MDIs were an increasing focus of discussion. Despite statements critical of these products published by the American Medical Association (AMA) and the American College of Chest Physicians (ACCP) in 1999 and 2000 respectively,
calls for re-examination of the essential use protections for epinephrine MDI were ignored. During a series of inevitable FDA hearings in 2006, physicians and professional medical societies called for revocation of the essential use designation based on safety concerns related to OTC availability coupled with changes in the asthma guideline treatment recommendations.2

Although essential use status was revoked by the FDA, manufacturers were given through 2011 to develop a non-CFC replacement product. The cited rationale for granting an additional five-year grace period was that an estimated three million Americans were using Primatene Mist® and, of these, one million of these were using it as monotherapy.3

Because a non-CFC product was never brought forth, epinephrine MDIs were ultimately pulled from the market on December 31, 2011. Dr. Monica Kraft, President of the American Thoracic Society (ATS), testified to Congress in July of 2012 against future reintroduction of epinephrine MDIs stating, “It is my strongly held view and the view of the ATS that returning epinephrine inhaler to the US market would be ill advised. Epinephrine is NOT one of the medications that are considered safe for the treatment of asthma.”4

Two years later, Amphastar Pharmaceuticals submitted a New Drug Application (NDA) for an HFA-based epinephrine MDI. Shortly thereafter, the FDA requested public comments and convened a joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee. During this session physicians and patients alike cited safety concerns about epinephrine MDI use in asthma and the lack of a user-friendly dose counter on the proposed Primatene Mist® MDI device. Subsequently, the joint panel recommended against approval of the NDA as they felt that the risk/benefit profile was unfavorable (FDA vote of 6 FOR and 18 AGAINST) and because the safety of the device was not established (FDA vote of 7 FOR and 17 AGAINST).5

In 2018 Amphastar Pharmaceuticals submitted a new NDA for a retooled Primatene Mist® MDI which addressed the comments stemming the product’s prior rejection. Unlike the process in 2014, the FDA did not hold a public comment period, did not convene an advisory panel meeting, and did not solicit input from asthma experts or professional medical societies. Although the former commissioner of the FDA alleges that it “heard from experts and gathered new information to inform our current view,” that claim has never been substantiated. To the contrary, representatives from the ATS, the American College of Allergy Asthma and Immunology (ACAAI), the American College of Chest Physicians (ACCP), the Allergy and Asthma Network, the Asthma and Allergy Foundation of America, the National Asthma Education and Prevention Program (NAEPP), and the American Lung Association (ALA) each independently confirmed that they were not consulted prior to the FDA ruling.6 Amid this void of unbiased critical commentary, the FDA approved Primatene Mist® for OTC sales.

The FDA has ultimately taken the position that their approval of the epinephrine MDI in 1956 provided historic precedent to compel re-approval once the dose counter concerns had been addressed.7 The fact that epinephrine’s original approval predated FDA approval of albuterol by 26 years was not addressed. Similarly, contemporary changes to asthma guidelines and increasing evidence of safety concerns were apparently not considered. The ATS and the ALA — among others — openly objected to this approval: the ATS went so far as to express “great concern” regarding the lack of public input during the FDA process.8 Furthermore, these groups predicted suboptimal disease management if patients with limited health literacy could treat their disease by relying solely on as-needed OTC meds.

**Epinephrine MDIs: The Present**

There are currently three main objections to the approval of OTC Primatene Mist®. First, current asthma guidelines uniformly recommend PRN albuterol as the preferred rescue therapy for temporary relief of asthma symptoms. This recommendation has been in place for over 50 years given that head-to-head studies establish that albuterol provides more prolonged symptom control with fewer side effects than other rescue therapies (including epinephrine).9,10 It is telling that...
inhaled epinephrine is intentionally excluded from all current asthma guidelines. The 2019 updates to the Global Initiative for Asthma (GINA) guidelines have moved completely away from recommending PRN monotherapy with short-acting agents. These guidelines now endorse the use of concurrent as-needed inhaled corticosteroids (ICS) for all patients with asthma to reduce inflammation and to reduce exacerbation risk – even in those with mild intermittent asthma. Preferred rescue therapy for patients of all asthma severity levels is now off-label use of low-dose budesonide-formoterol – an ICS with a long-acting β2 agonist that has a relatively fast onset. Ultimately, reliance on OTC drugs provides symptomatic relief without providing the medical care needed to truly establish asthma control. The asthma guidelines authored by the NAEPP specifically recommend against epinephrine for these reasons.12

Second, objections to OTC epinephrine MDIs are driven by safety concerns. Published issues include frequent misuse, exacerbation of asthma-like symptoms which are actually of cardiac origin (wheezing, cough, dyspnea), and delays in seeking effective care for uncontrolled asthma. Others express unease that populations relying on OTC therapies to treat their asthma have increased morbidity and higher rates of asthma-related deaths. The FDA contends that these safety concerns are addressed by its mandated labeling stating that the use of OTC epinephrine is limited to patients with mild asthma. In reality, such packaging is often ignored by consumers and patients with asthma often underestimate the severity of their disease.12

Third, opponents of the OTC availability of epinephrine MDIs express concern that this product perpetuates care disparities. Advocates for Primatene Mist® have argued that this medication is an affordable and convenient safety net for underinsured individuals. Although differences in drug acquisition costs are marginal – retail prices for Primatene Mist® and generic albuterol are ~$30 and ~$36 respectively – patients incur substantial costs associated with seeing a provider in order to obtain the prescription required to purchase generic albuterol. Accordingly, the uninsured and under-insured may be financially pressured to rely on OTC products. With revised guidelines now endorsing ICS for all patients with asthma, the ease of access to epinephrine comes at the expense of receiving a substandard medication and increases the likelihood of receiving inferior asthma care.

Epinephrine MDIs: The Future
To address these issues, some have suggested that Primatene Mist® be placed behind the counter, thereby requiring patients to interact with a pharmacist. It is suggested that this additional step could mitigate patient risk through providing an additional opportunity for patient education on the issues outlined herein. However, behind-the-counter sales are not overseen by the FDA and compliance with such efforts would be entirely voluntary. In January of 2019, eleven health groups (including ACAAI, ATS, and ACCP) sent a joint letter to major US retail pharmacies encouraging them to adopt this standard. To date, none of these chain pharmacies have adopted this standard.

Another possible solution – one with its own limitations and challenges – would be OTC albuterol. As with OTC epinephrine MDIs, this solution trades convenience for reduced evaluation by professionals, over-reliance on treating symptoms as opposed to establishing asthma control (e.g., missed opportunities to add ICS therapy), and increases safety concerns.

Ultimately, all clinicians share the burden of educating asthmatic patients under their care. Instructions on inhaler activation, dosing, and washing are available at https://www.primatene.com. The recommended dose is 1-2 inhalations every 4 hours, with a maximum of 8 inhalations per day. Important device-specific information includes the priming of the inhaler before each dose and the daily cleaning requirement. Pharmacists should be prepared to counsel patients who purchase Primatene Mist® on the risks of epinephrine MDI monotherapy and the recommendation that albuterol or off-label ICS/formoterol be used PRN in all asthmatics. For patients who are repeat purchasers, the pharmacist should specifically reinforce that: (1) Primatene Mist® is approved for use only in mild intermittent asthma; (2) this product does not treat the inflammation...
component of asthma; (3) asthma is not a self-treated disease and all asthmatics should seek medical care; (4) patients should seek urgent medical attention if there is no improvement in symptoms within 20 minutes of using Primatene Mist®; and (5) this product has potential drug interactions with other stimulants such as pseudoephedrine, caffeine and illicit drugs.

Providers should also familiarize themselves with patient assistance programs that may help provide affordable access to guideline-endorsed therapies and/or community resources that facilitate evaluation by asthma specialists. Finally, clinicians should be vigilant in reporting epinephrine MDI-related adverse events (drug reactions, cardiovascular events, excess emergency room visits, excess hospitalizations, etc.) to the FDA’s MedWatch program. Only with systematic monitoring of these occurrences will we confirm or refute the concerns surrounding this controversial product.

References
5. Food and Drug Administration Center for Drug Evaluation and Research. Summary Minutes of the Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pulmonary-Allergy Drugs Advisory Committee (PADAC). Silver Spring, MD. Food and Drug Administration; 2014.

Quiz Answers may be submitted:
Online: www.npharm.org
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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 2019 Membership Year must be received by December 12, 2019. 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 NABP e-Profiles at www.nabp.net.
4. CPE credits are submitted to NABP by the 15th of each month. For example, M&P CPE quizzes completed in the month of October 2019 will be sent to NABP e-Profiles before November 15, 2019.
The Epinephrine MDI Returns to the United States Market Amid Controversy

Quiz #13, September/October 2019, ACPE 0128-0000-19-046-H05-P/T

1. Why was epinephrine (Primatene Mist) discontinued several years ago?
   a. Safety concerns
   b. Chlorofluorocarbon propellants were phased out by the FDA
   c. It contained a hydrofluoroalkane propellant
   d. Lack of sales

2. Epinephrine inhalation (Primatene Mist) is currently indicated for mild intermittent asthma in what age group?
   a. Patients 4 years of age and above
   b. Patients 8 years of age and above
   c. Patients 12 years of age and above
   d. Patients 18 years of age and above

3. Primary objections to the return of epinephrine inhalation (Primatene Mist) to the market include:
   a. Current asthma guidelines recommend albuterol as preferred therapy
   b. Safety concerns of OTC epinephrine
   c. OTC status epinephrine may perpetuate health care disparities
   d. All of the above are correct

4. What strategy is recommended by national organizations for the community pharmacists to best interact with patients seeking epinephrine inhalation (Primatene Mist)?
   a. Keep the product in the fast-moving aisle at eye level
   b. Keep the product behind the counter
   c. Keep the product near the register for ease of purchase
   d. Require pharmacy personnel to alert the pharmacist of each purchase

5. What is the recommended dose of epinephrine (Primatene Mist) inhaler?
   a. 1-2 inhalations every 2 hours, max of 12 inhalations in 24 hours
   b. 1-2 inhalations every 4 hours, max of 8 inhalations in 24 hours
   c. 1-2 inhalations every 4 hours, max of 12 inhalations in 24 hours
   d. 1-2 inhalations every 6 hours, max of 8 inhalations in 24 hours

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
   If not, please explain
4. Did the lesson meet your educational/practice needs? ___ Yes ___ No
5. Comments/future topics are welcome.

The deadline for this quiz is December 12, 2019.

Keep the TOP portion for your records. Return the BOTTOM portion to the NPA office. Or, take this quiz online at www.npharm.org
Creighton Pharmacy Class of 2023

The Creighton University School of Pharmacy and Health Professions welcomed 141 pharmacy students (55 campus and 86 distance) during the 2019 Professionalism Ceremony at D.J. Sokol Arena on August 16, 2019. The professionalism ceremony emphasizes the students’ responsibility to the profession of pharmacy and provides them insight on the integration of knowledge and skills to come.

Pharmacy Alumna’s Gift Goes the Distance

Over Nelly Nigro’s 92 years, the Omaha native traveled the world many times over, making it to all seven continents and scores of countries.

But in all of her travels and in all of her experiences, this restless and fiercely independent woman never cut the tether to the place she called home—Omaha. And she never forgot about Creighton.

Before she died in the summer of 2017, Nigro, BSPha’45, bequeathed an estate gift of more than $1 million to Creighton’s School of Pharmacy and Health Professions. It is the largest gift in the school’s 114-year history.

Read more of Nigro’s story at: alumni.creighton.edu/news/pharmacy-alumnas-gift-goes-distance
To make a gift to the School of Pharmacy and Health Professions, contact Cody Fuchtman, the school’s Senior Director of Development, at CodyFuchtman@creighton.edu or 402.280.2299.

Join the School of Pharmacy and Health Professions in Vegas!
Save the date for the ASHP Midyear 2019 Clinical Meeting and Exhibition
Dec. 8–12, 2019 | Las Vegas
For more information, email spahparo@creighton.edu

To make a gift to the School of Pharmacy and Health Professions, contact Cody Fuchtman, the school’s Senior Director of Development, at CodyFuchtman@creighton.edu or 402.280.2299.

spahp.creighton.edu
The pharmacy industry has changed dramatically over the past five years. Many pharmacies are focused on just filling prescriptions. This might be ideal for patients who just want convenient access to medications. What about patients that require more care, more answers, and more time from their pharmacy? These patients need pharmacies that are members of NESP, a CPESN® Network.

Nebraska Enhanced Services Pharmacies (or NESP for short) is a network of pharmacies across the state that provide extra services such as medication optimization activities or medication delivery to help improve the health of their patients.

**What are the benefits of being part of NESP?**

- NESP is owned by its member pharmacies
- NESP supports members as they connect with the broader patient care team
- NESP empowers members with marketing support and marketing of the network
- NESP is a clinically integrated network of community pharmacies across America who engage and negotiate together to offer value to plan sponsors and other non-PBM payers through enhanced services and lower costs

For more information on NESP, contact Staci Hubert at 402-944-3303 or Shubert.nesp@gmail.com

Visit the NESP website at: https://nebraskapharmacynetwork.com
Maintenance Therapy and Prevention of Exacerbations in COPD Patients

Abstract
Chronic obstructive pulmonary disease (COPD) is a respiratory disorder characterized by reduced expiratory flow due to irreversible airway inflammation. The strongest risk factor for developing COPD is exposure to tobacco smoke. Patients are classified based on their symptom burden and exacerbation history, which drives inhaled maintenance pharmacotherapy. In patients with frequent exacerbations (defined as two or more per year), additional therapy includes oral drugs such as roflumilast or macrolide antibiotics to prevent further exacerbations. Pharmacists are accessible health care providers who can educate patients about proper inhaler technique and adherence, help with tobacco cessation, and provide appropriate vaccines.

Objectives
At the conclusion of this lesson, pharmacists and pharmacy technicians should be able to:
1. Review diagnosis and assessment for COPD.
2. Identify therapy options for patients with COPD.
3. Explain proper administration of various inhalation devices.

Introduction
Chronic obstructive pulmonary disease (COPD) refers to a group of lung diseases, such as emphysema and chronic bronchitis, that cause respiratory problems resulting from airflow blockages. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines COPD as “a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.” In 2014, COPD was the third leading cause of death in the United States. Multiple risk factors influence disease development including exposure to air pollutants, genetics, and frequent respiratory infections, but the predominant risk factor is exposure to tobacco smoke.
Diagnosis
A presumptive diagnosis of COPD, based on a combination of symptoms and risk factors, must be confirmed by spirometry, a pulmonary function testing method. Risk factors include tobacco smoking, occupational exposure to air pollution, genetic abnormalities such as alpha-1 antitrypsin deficiency, family history of COPD, low birthweight, and childhood respiratory infections. Symptoms indicative of COPD include dyspnea, cough, excessive sputum production, wheezing, chest tightness and fatigue. Unlike asthma, COPD typically presents later in life. By spirometric measurement, a ratio of forced expiratory volume in 1 second to forced vital capacity ($FEV_1/FVC$) of $<0.7$ post bronchodilator use is diagnostic for COPD. $FEV_1/FVC$ of $<0.7$ means the patient was able to expel less than 70% of his/her lung capacity in one second. The higher this percentage, the greater lung capacity and lung health. For patients with $FEV_1/FVC$ ratio of 0.6-0.8, repeat spirometry is required to confirm the diagnosis.

Airflow Limitation Severity Classification
Following GOLD guidelines, airflow limitation is assessed through spirometry testing. A patient’s $FEV_1$, post bronchodilator use, is compared to the average $FEV_1$ of persons of the same age, height and weight. Patients are then classified as GOLD 1-4 which correlates to a range of mild to very severe (see Table 1). Although GOLD classification is a determinant of severity of the disease and mortality, it is not used to guide therapy. $FEV_1$ measurement is recommended at least once a year to track decline.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Severity</th>
<th>Spirometry</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1</td>
<td>Mild</td>
<td>$\geq 80%$ predicted $FEV_1$</td>
</tr>
<tr>
<td>GOLD 2</td>
<td>Moderate</td>
<td>$50%- &lt;80%$ predicted $FEV_1$</td>
</tr>
<tr>
<td>GOLD 3</td>
<td>Severe</td>
<td>$30%- &lt;50%$ predicted $FEV_1$</td>
</tr>
<tr>
<td>GOLD 4</td>
<td>Very Severe</td>
<td>$&lt;30%$ predicted $FEV_1$</td>
</tr>
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Symptom Assessments
Severity of symptoms is determined by using the modified Medical Research Council (mMRC) dyspnea scale or the COPD assessment test (CAT). The mMRC questionnaire assesses shortness of breath with grades of 0-4, with grade 0 being “I only get breathless with strenuous exercise” to grade 4, “I am too breathless to leave the house or I am breathless when dressing or undressing.” A comprehensive tool to assess symptoms beyond breathlessness should also be used. The CAT is an 8-question assessment tool that measures the impact of COPD symptoms on a patient’s well-being and daily life. The test includes questions on a scale of 0-5 to assess severity of COPD symptoms such as cough, mucus in the chest, and shortness of breath. Table 2 lists the categories evaluated by the CAT. The CAT is easy for patients to complete and scores range from 0-40. The higher the score, the greater the impact of COPD on the patient, and the GOLD guidelines use scores of at least 10 or more to stage patients.

Exacerbation Risk
COPD exacerbations are defined as an acute worsening of respiratory symptoms that result in additional therapy. Exacerbation severity determines the therapy used to treat the patient. Frequent exacerbations are defined as two or more exacerbations per year and the best way to predict future exacerbation frequency is to assess the history of previous exacerbations, including their frequency and severity. Exacerbation rates are increased in patients with progressively worsening airflow leading to an increase in the incidence of hospitalizations and death. Exacerbation rates also correlate with disease severity, such as GOLD 3 (severe, $FEV_1$ 30-<50\% of predicted) and GOLD 4 (very severe, $FEV_1$ < 30\% predicted) classifications.
The ABCD classification, which is based on symptoms and exacerbations, is what guides treatment selection. GOLD has created and refined an assessment tool to classify patients into four different therapeutic treatment groups (Groups A-D). The ABCD Assessment is shown in Table 3. Pharmacotherapy selection is based on evaluation of morbidity factors such as symptom burden and frequencies of moderate and severe exacerbations. Thus, the ABCD assessment combines results from a patient’s mMRC and CAT assessments and a detailed exacerbation history to determine appropriate therapeutic options. Short-acting beta-agonists (SABAs) either alone or in combination with short-acting muscarinic antagonists (SAMAs) are recommended for acute management. Bronchodilator therapy with long-acting beta-agonists (LABAs) and/or long-acting muscarinic antagonists (LAMAs) is used as monotherapy or in combination for maintenance treatment for chronic stable COPD. Inhaled corticosteroids are reserved for patients requiring additional treatment for chronic disease, despite LAMA and LABA therapy, or in patients with asthma and COPD overlap. Symptom-driven maintenance reliever therapy (SMART), which is used in asthma has been recently studied in COPD. This therapy combines inhaled corticosteroid (ICS) and a fast-acting LABA (e.g., formoterol) in a single inhaler for use as both maintenance therapy and symptom relief. Evidence results are pending regarding SMART therapy for COPD patients. SMART therapy may be seen in future guidelines based on results of risks and exacerbation outcomes.

### Treatment

#### Non-pharmacologic Therapy

A significant aspect in treating COPD is to emphasize the importance of smoking cessation, physical activity, adequate sleep, and healthy diet. These factors may be addressed in a formal pulmonary rehabilitation program, especially for patients with severe symptoms and high risk for exacerbation. For patients with moderate-severe symptoms (GOLD Groups B and D), it is essential for the patient to learn how to self-manage breathlessness. Patients with moderate-severe exacerbation histories (GOLD Groups C and D) should avoid aggravating factors, monitor and manage worsening symptoms, and maintain a good relationship with a healthcare professional. GOLD Group D patients would benefit from a discussion regarding palliative strategies and advance care directives. Finally, long-term oxygen therapy may be indicated in stable patients with low oxygen saturation with re-evaluation for necessity of therapy every 60-90 days.

### Table 3 | Initial Pharmacological Management of COPD

<table>
<thead>
<tr>
<th>Exacerbations</th>
<th>Group C</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 moderate exacerbations or 1 leading to a hospitalization</td>
<td>LAMA</td>
<td>LAMA + LABA*&lt;br&gt;OR&lt;br&gt;LAMA + LABA*&lt;br&gt;(Consider if highly symptomatic (e.g., CAT &gt; 20)&lt;br&gt;OR&lt;br&gt;ICS + LABA (Consider if eos 300)&lt;br&gt;*Consider triple therapy if patient is using LABA/LAMA with further exacerbations, or if eos&gt;100 cells/ul</td>
</tr>
<tr>
<td>0 or 1 moderate exacerbations (not leading to hospital admission)</td>
<td>Group A&lt;br&gt;Bronchodilator (Albuterol preferred over ipratropium/albuterol (Combivent))</td>
<td>Group B&lt;br&gt;Long Acting Bronchodilator (LABA or LAMA)</td>
</tr>
<tr>
<td>mMRC 0-1 CAT &lt;10</td>
<td>mMRC 2 CAT 10</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** eos = blood eosinophil count in cells per microliter; mMRC = modified Medical Research Council dyspnea questionnaire; CAT = COPD assessment test; LAMA = long-acting muscarinic antagonist; LABA = long-acting beta-agonist; ICS = Inhaled corticosteroid
first class of bronchodilator the way to decrease the risk of lower respiratory tract infections.1,5 Patients between the ages of 19-64 should receive the pneumococcal polysaccharide vaccine (PPSV23) at the time of diagnosis. Then at age 65 years, the pneumococcal 13-valent conjugate vaccine (PCV13) should be given, if not previously received, followed at least one year later with another dose of PPSV23. There should be at least 5 years between the two PPSV23 doses. If a patient is diagnosed with COPD after the age of 65 years and has not received any pneumococcal vaccines, they should follow the normal recommendations for that age group and receive one dose of PCV13 and then one year later a dose of PPSV23.5

**GOLD Group A (mild-moderate symptoms and exacerbation history)**

First-line maintenance therapy for patients classified as GOLD Group A is a short or long-acting bronchodilator. These include beta agonists and muscarinic antagonists. Both work by relaxing smooth muscle. SABAs, albuterol and levalbuterol, are available as metered-dose inhalers and nebulizer solutions. In COPD patients, albuterol and levalbuterol are typically recommended in dosing intervals of every 4-6 hours and every 6-8 hours, respectively.6 Ipratropium is a SAMA available as a metered-dose inhaler or a nebulizer solution and is typically dosed three to four times daily. Inhaled bronchodilators seem to be well tolerated by most patients and the adverse effects are dose related.1 Beta agonists may cause hypokalemia, sinus tachycardia and, rarely, rhythm disturbances in predisposed patients. Initially, some patients may develop skeletal muscle tremors, but these typically subside as tolerance develops. Other adverse effects include anxiety, headache, insomnia, nervousness, and restlessness. Muscarinic antagonists are poorly absorbed systemically and are considered safe. Commonly reported adverse effects include dry mouth, dry eyes, metallic taste, and prostatic symptoms. However, patients taking systemic anticholinergic drugs may experience increased systemic anticholinergic effects when taking inhaled muscarinic antagonists. Initial inhalation therapy is based on patient preference and response. If the patient does not show optimal response to the first class of bronchodilator the alternative bronchodilator class may be tried.1 Available SABAs and SAMAs are listed in Table 4.

**GOLD Group B (moderate-severe symptoms and mild-moderate exacerbation history)**

Maintenance therapy recommended for patients in GOLD Group B is a long-acting bronchodilator. Available LABAs and LAMAs are listed in Table 5 and Table 6, respectively, along with the dosing intervals. There is no evidence to recommend one class over another in this group of patients and the agent selected should be dependent on the patient’s perception of symptom relief. If a patient does not experience relief with monotherapy, a second bronchodilator is recommended. If dual therapy does not optimize symptom relief, it is plausible to step back down to monotherapy. In patients who present with severe breathlessness, two bronchodilators may be considered for initial therapy.1

**GOLD Group C (mild-moderate symptoms and moderate-severe exacerbation history)**

For patients in GOLD Group C, maintenance therapy with a single long-acting inhaler is recommended. Head to head trials have shown LAMAs to be superior to LABAs in exacerbation prevention; therefore, use of a LAMA is recommended. If the patient experiences persistent exacerbations, ICS or LABA may be added.1

**GOLD Group D (moderate-severe symptoms and exacerbation history)**

First-line maintenance therapy for most GOLD Group D patients is a LAMA; however, a LAMA/LABA combination may be considered for patients with severe symptoms, including a CAT score of at least 20. If patients experience frequent exacerbations, have advancing disease or present with wheezing, therapy may be changed to a LABA/LAMA/ICS combination. (See Table 7 for available combination products.) Patients with pneumonia or lack of results with ICS may consider de-escalation of the ICS.1 Continued exacerbations may be treated with roflumilast or a macrolide antibiotic. Roflumilast is to be used in patients with FEV1 <50% and chronic bronchitis, while azithromycin is to be used in former smokers. Blood eosinophil counts are
Table 4 | SABA/SAMA Inhalation Products

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Products</th>
<th>Dosage Form</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol</td>
<td>Ventolin HFA, Proventil HFA, ProAir HFA, and Generic</td>
<td>Inhalation aerosol</td>
<td>1-2 actuations four to six times daily</td>
</tr>
<tr>
<td></td>
<td>Accuneb and Generic</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized three to four times daily</td>
</tr>
<tr>
<td></td>
<td>ProAir RespiClick</td>
<td>Inhalation powder</td>
<td>1-2 inhalations four to six times daily</td>
</tr>
<tr>
<td>Levalbuterol</td>
<td>Xopenex HFA and Generic</td>
<td>Inhalation aerosol</td>
<td>2 actuations four to six times daily</td>
</tr>
<tr>
<td></td>
<td>Xopenex and Generic</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized three times daily</td>
</tr>
<tr>
<td>Ipratropium</td>
<td>Atovent HFA</td>
<td>Inhalation aerosol</td>
<td>2 actuations three to four times daily</td>
</tr>
<tr>
<td></td>
<td>Ipratropium</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized three to four times daily</td>
</tr>
<tr>
<td>Albuterol, Ipratropium</td>
<td>DuoNeb and Generic</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized four times daily</td>
</tr>
<tr>
<td></td>
<td>Combivent Respimat</td>
<td>Soft Mist inhaler</td>
<td>1 actuation four times daily</td>
</tr>
</tbody>
</table>

Table 5 | LAMA Inhalation Products

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Product</th>
<th>Dosage Form</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aclidinium</td>
<td>Tudorza Pressair</td>
<td>Dry powder for inhalation</td>
<td>1 Inhalation twice daily</td>
</tr>
<tr>
<td>Glycopyrrolate</td>
<td>Seebri Neohaler Lonhala Magnair</td>
<td>Dry powder for inhalation Nebulizer solution for inhalation</td>
<td>Inhale contents of one capsule twice daily 1 vial nebulized twice daily</td>
</tr>
<tr>
<td>Revefenacin</td>
<td>Yupelri</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized once daily</td>
</tr>
<tr>
<td>Tiotropium</td>
<td>Spiriva HandiHaler Spiriva Respimat</td>
<td>Dry powder for inhalation Soft Mist inhaler</td>
<td>2 inhalations of one capsule once daily 2 actuations once daily</td>
</tr>
<tr>
<td>Umeclidinium</td>
<td>Incruse Elipta</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation once daily</td>
</tr>
</tbody>
</table>

Table 6 | LABA Inhalation Products

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Products</th>
<th>Dosage Form</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arformoterol</td>
<td>Brovana</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized twice daily</td>
</tr>
<tr>
<td>Formoterol</td>
<td>Perforomist</td>
<td>Nebulizer solution for inhalation</td>
<td>1 vial nebulized twice daily</td>
</tr>
<tr>
<td>Indacaterol</td>
<td>Arcapta Neohaler</td>
<td>Dry powder for inhalation</td>
<td>Inhalate contents of one capsule once daily</td>
</tr>
<tr>
<td>Olodaterol</td>
<td>Striverdi Respimat</td>
<td>Soft Mist inhaler</td>
<td>2 actuations once daily</td>
</tr>
<tr>
<td>Salmeterol</td>
<td>Serevent Diskus</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation twice daily</td>
</tr>
</tbody>
</table>

Another way to assess a patient’s risk of exacerbations. Elevated blood eosinophil levels are associated with an increased risk of exacerbations in patients with a history of COPD exacerbations. Interleukin-5 (IL-5) antagonists, currently approved for use in asthma patients, are being studied in COPD patients with elevated eosinophil counts with promising results but are not yet approved for COPD.

**Maintenance Management of Dyspnea and Exacerbations**

When a patient is in the maintenance phase of managing dyspnea and exacerbations, the following items need to be reviewed and assessed prior to adjusting medications: dyspnea symptoms and exacerbation risk, adherence to both pharmacological and nonpharmacological interventions, and proper technique when using inhalers.
Table 7 | Inhalation Combination Products

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Combination Type</th>
<th>Product</th>
<th>Dosage Form</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formoterol, Aclidinium</td>
<td>LABA/LAMA</td>
<td>Duaklir Pressair</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation twice daily</td>
</tr>
<tr>
<td>Formoterol, Budesonide</td>
<td>LABA/ICS</td>
<td>Symbicort</td>
<td>Inhalation aerosol</td>
<td>2 actuations twice daily</td>
</tr>
<tr>
<td>Formoterol, Glycopyrrolate</td>
<td>LABA/LAMA</td>
<td>Bevespi Aerosphere</td>
<td>Inhalation aerosol</td>
<td>2 actuations twice daily</td>
</tr>
<tr>
<td>Formoterol, Mometasone</td>
<td>LABA/ICS</td>
<td>Dulera*</td>
<td>Inhalation aerosol</td>
<td>2 actuations twice daily</td>
</tr>
<tr>
<td>Indacaterol, Glycopyrrolate</td>
<td>LABA/LAMA</td>
<td>Utibron Neohaler</td>
<td>Dry powder for inhalation</td>
<td>Inhalate contents of one capsule twice daily</td>
</tr>
<tr>
<td>Olodaterol, Tiotropium</td>
<td>LABA/LAMA</td>
<td>Stiolto Respimat</td>
<td>Soft Mist inhaler</td>
<td>2 actuations once daily</td>
</tr>
<tr>
<td>Salmeterol, Fluticasone</td>
<td>LABA/ICS</td>
<td>Advair Diskus and Generic</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation twice daily</td>
</tr>
<tr>
<td>Vиландерол, Flутикасон</td>
<td>LABA/ICS</td>
<td>Breo Ellipta</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation once daily</td>
</tr>
<tr>
<td>Vиландерол, Умеclidиниум</td>
<td>LABA/LAMA</td>
<td>Anoro Ellipta</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation once daily</td>
</tr>
<tr>
<td>Vиландерол, Умеclidиниум, Flутикасон</td>
<td>LABA/LAMA/ICS</td>
<td>Trelegy Ellipta</td>
<td>Dry powder for inhalation</td>
<td>1 inhalation once daily</td>
</tr>
</tbody>
</table>

*Off Label

Patients taking a LABA who experience persistent breathlessness or exercise limitation should use two bronchodilators. Patients being treated with a LABA/ICS combination with persistent breathlessness or exercise limitation may add a LAMA or the ICS may be replaced with a LAMA. Table 8 contains recommendations for patients that have persistent exacerbations while being treated.

Nebulizer treatment is also used at home for patients to treat dyspnea. A new nebulized formulation of glycopyrrrolate (Lonhala Magnair) was approved by the FDA for the long-term maintenance treatment of airflow obstruction in patients with COPD. Glycopyrrolate must be used with its proprietary nebulizer. Revefenacin (Yupelri), a long-acting anticholinergic nebulization solution, was approved in November 2018. Two, 12-week clinical trials were used for the FDA-approval of revefenacin nebulization solution for the maintenance treatment of COPD. The primary endpoint of the trials was change from baseline trough FEV1 at day 85. Revefenacin increased FEV1 more than placebo in both studies with a mean difference of 146 mL and 147 mL, in trials 1 and 2, respectively. Changes were considered statistically and clinically significant. FDA review suggests a greater clinical benefit in patients with very severe COPD. Revefenacin may be used in a standard jet nebulizer.

Roflumilast (Daliresp) is a phosphodiesterase-4 (PDE4) inhibitor. PDE4 is an enzyme that is expressed in inflammatory cells. Therefore, roflumilast reduces inflammation in patients with COPD leading to decreased exacerbations. Roflumilast therapy is initiated at 250 µg by mouth once daily for 4 weeks. This subtherapeutic dose allows for development of tolerance to gastrointestinal adverse effects, at which time the dose is increased to the optimal dose of 500 µg once daily. In clinical trials, roflumilast treatment resulted in a significantly lower risk of moderate to severe COPD exacerbations with the greatest impact seen in patients with more severe disease. Adverse reactions observed in
Tables 8, 10, 11, and 12 cover important counseling points for different types of inhalers, including common problems that patients experience. Pharmacists can offer counseling using the teach-back method, where patients can demonstrate their ability to use the inhaler properly.

**Summary**

After a diagnosis of COPD is made, pharmacotherapy is based on individual symptom burden and exacerbation history. Initial therapy is guided by the GOLD Guidelines ABCD assessment. If inhalation therapy is not enough to prevent exacerbations, roflumilast or a macrolide antibiotic may be considered. Pharmacists have the ability to make a strong impact on COPD management. Patient education regarding proper inhaler technique and the importance of adherence to the overall preventive and treatment regimens are critical to the management of COPD symptoms. Pharmacists may also play an important role in reviewing, assessing, and recommending pharmacologic therapy and monitoring for potential drug-drug interactions in patients with COPD. Pharmacists can recognize exacerbation symptoms such as increased sputum, dyspnea and breathlessness. Tobacco cessation counseling is also important and crucial for prevention of COPD progression. Lastly, pharmacists can recommend immunizations for patients with COPD including PPSV23, PCV13, and influenza vaccines.

---

**Table 8 | Recommendations for Persistent Exacerbations while on Treatment**

<table>
<thead>
<tr>
<th>Current Treatment</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>LABA Monotherapy</td>
<td>• Escalation to LABA/LAMA or LABA/ICS</td>
</tr>
<tr>
<td>LABA/LAMA therapy</td>
<td>• Escalation to LABA/LAMA/ICS</td>
</tr>
<tr>
<td></td>
<td>• Add roflumilast or azithromycin if eosinophil count &gt; 100 cells/µL</td>
</tr>
<tr>
<td>LABA/ICS therapy</td>
<td>• Escalation to LABA/LAMA/ICS or switch to LABA/LAMA</td>
</tr>
<tr>
<td>LABA/LAMA/ICS</td>
<td>• Consider adding roflumilast</td>
</tr>
<tr>
<td></td>
<td>• Consider adding macrolide</td>
</tr>
<tr>
<td></td>
<td>• Consider stopping ICS</td>
</tr>
</tbody>
</table>

---

clinical trials included various psychiatric effects (5.9%), weight loss (7.5%), and diarrhea (9.5%). It is recommended to monitor behavior and weight changes. Roflumilast is contraindicated in patients with moderate to severe liver disease, defined as a Child-Pugh score of B or C.

Macrolide antibiotics have been studied in COPD patients with frequent exacerbations. In a meta-analysis that assessed the efficacy of azithromycin, erythromycin, and clarithromycin in reducing exacerbations. It was found that macrolide prophylaxis treatment for 3 months did not significantly reduce exacerbations, but prophylactic treatment for 6 to 12 months with erythromycin or azithromycin significantly reduced the number of exacerbations. There are no safety or efficacy data beyond one year, so it is not recommended to give macrolides as prophylaxis for more than one year. In a large clinical trial, azithromycin 250 mg once daily was compared to placebo to determine the difference in the timing to the first exacerbation and the frequency of exacerbations. Patients taking azithromycin were found to have a significant increase in time to first exacerbation compared to placebo (266 days and 174 days, respectively) and a significantly decreased frequency of exacerbations per patient per year compared to placebo (1.48 and 1.83, respectively). This trial did identify significant differences in adverse events compared to placebo, including increased hearing decrements (25% vs. 20%) and resistance to macrolides (81 vs. 41%) in a sub-group of patients who were not colonized with select respiratory pathogens at the time of study enrollment. Monitor patients taking azithromycin concurrently with other drugs known to cause QT prolongation.

**Inhaler Counseling**

Inhaler adherence and technique are crucial in receiving the benefit of these medications, and poor technique and adherence are often the cause of frequent exacerbations. Inhaler therapy with consistent patient education is crucial for preventing COPD exacerbations and improving patients’ quality of life. It can be confusing for patients to own three different types of inhalers, which all require different directions. Characteristics of different types of inhalers are shown in Table 9.
Table 10  |  Metered Dose Inhaler Counseling Points

<table>
<thead>
<tr>
<th>Priming</th>
<th>Inhaler Use</th>
<th>Tips</th>
<th>Spacer</th>
<th>Cleaning</th>
<th>Common problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priming is preparing an inhaler for use before its first use or if it hasn’t been used for a period of time. Priming directions differ for MDIs so follow manufacturer instructions.</td>
<td>Remove cap from mouthpiece and inspect for obstruction.</td>
<td>Keep chin up and the inhaler upright (not aimed at the roof of the mouth or tongue).</td>
<td>A spacer/holding chamber is a device that is placed between the MDI and mouth.</td>
<td>The HFA solution may build up in or around the small hole where it exits the mouthpiece so the mouthpiece should be cleaned periodically.</td>
<td>Holding the inhaler in the wrong position.</td>
</tr>
<tr>
<td></td>
<td>Check dose counter (if device has one).</td>
<td>If using a corticosteroid MDI, rinse mouth with water and spit after inhaling the last dose to reduce the risk of side-effects.</td>
<td>A spacer/holding chamber can improve the delivery of the inhaler to the lungs. The spacer/holding chamber helps coordinate the timing of activating the MDI and breathing in.</td>
<td>Take the metal canister out of the mouthpiece.</td>
<td>Not breathing in at the same time as pressing the canister.</td>
</tr>
<tr>
<td></td>
<td>Shake well.</td>
<td></td>
<td></td>
<td>Wash the mouthpiece weekly with warm soapy water and rinse.</td>
<td>Not breathing in deeply enough.</td>
</tr>
<tr>
<td></td>
<td>Breathe in and out gently (away from inhaler).</td>
<td></td>
<td></td>
<td>Air dry.</td>
<td>Not holding breath long enough.</td>
</tr>
<tr>
<td></td>
<td>Put mouthpiece between teeth (without biting) and close lips to form good seal.</td>
<td></td>
<td></td>
<td>Put the metal canister back into the mouthpiece when completely dry.</td>
<td>Taking 2 puffs of albuterol/levalbuterol without waiting 30 - 60 seconds between doses or not shaking the inhaler in between doses.</td>
</tr>
</tbody>
</table>
### Table 11 | Dry Powder Inhaler Counseling Points

<table>
<thead>
<tr>
<th>Inhaler Use</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Check dose counter. (Do not shake at any time.)</td>
<td></td>
</tr>
<tr>
<td>• Open inhaler to expose the mouthpiece.</td>
<td></td>
</tr>
<tr>
<td>• Most DPIs, with the exception of the Elliptas, have an additional step to prepare the dose.</td>
<td></td>
</tr>
<tr>
<td>• Hold the inhaler flat and level.</td>
<td></td>
</tr>
<tr>
<td>• Breathe in and out gently (away from inhaler).</td>
<td></td>
</tr>
<tr>
<td>• Put mouthpiece in mouth and close lips to form a good seal (Do not block air vent on Elliptas).</td>
<td></td>
</tr>
<tr>
<td>• Breathe in quickly and deeply (Slowly and deeply with Elliptas).</td>
<td></td>
</tr>
<tr>
<td>• Hold breath for 10 seconds or as long as comfortable.</td>
<td></td>
</tr>
<tr>
<td>• While holding breath, remove inhaler from mouth.</td>
<td></td>
</tr>
<tr>
<td>• Breathe out gently (away from inhaler).</td>
<td></td>
</tr>
<tr>
<td>• Close the inhaler.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tips</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Do not open the mouthpiece until ready to inhale the dose; if the mouthpiece is closed, the dose is lost.</td>
<td></td>
</tr>
<tr>
<td>• Always close the cover after use.</td>
<td></td>
</tr>
<tr>
<td>• If using an inhaler with a corticosteroid, rinse mouth with water and spit after inhaling the last dose to reduce the risk of side-effects.</td>
<td></td>
</tr>
<tr>
<td>• With the exception of the Spiriva Handihaler (which is washed after each use) DPIs are never washed. The mouthpiece should be wiped periodically with a dry cloth or tissue.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Common Problems</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Shaking the inhaler.</td>
<td></td>
</tr>
<tr>
<td>• Opening and closing.</td>
<td></td>
</tr>
<tr>
<td>• the mouthpiece without inhaling a dose.</td>
<td></td>
</tr>
<tr>
<td>• Leaving the mouthpiece open.</td>
<td></td>
</tr>
<tr>
<td>• Covering vent on Elliptas with hands.</td>
<td></td>
</tr>
<tr>
<td>• Not closing the cover after inhaling.</td>
<td></td>
</tr>
</tbody>
</table>

### Table 12 | Soft Mist Inhaler Counseling Points

Emphasize to the patient T.O.P (Turn, Open, Press) to avoid inadvertent spraying of medication towards the patient’s face.

<table>
<thead>
<tr>
<th>Priming</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hold the inhaler upright with the cap closed.</td>
<td></td>
</tr>
<tr>
<td>• Turn the clear base in the direction of the white arrows on the label until it clicks.</td>
<td></td>
</tr>
<tr>
<td>• Flip the open.</td>
<td></td>
</tr>
<tr>
<td>• Point the inhaler toward the ground</td>
<td></td>
</tr>
<tr>
<td>• Press the dark gray button.</td>
<td></td>
</tr>
<tr>
<td>• Repeat the above steps until a mist is visible (It will look like a vapor).</td>
<td></td>
</tr>
<tr>
<td>• If the inhaler is new and has never been used repeat the above steps 3-4 times.</td>
<td></td>
</tr>
<tr>
<td>• If the inhaler has not been used for 3 days spray one additional time after the mist is seen.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inhaler Use</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hold the inhaler upright with the cap closed.</td>
<td></td>
</tr>
<tr>
<td>• Turn the clear base in the direction of the white arrows on the label until it clicks.</td>
<td></td>
</tr>
<tr>
<td>• Flip the cap open.</td>
<td></td>
</tr>
<tr>
<td>• Breathe in and out fully away from the inhaler.</td>
<td></td>
</tr>
<tr>
<td>• Close lips around the end of the mouthpiece without covering the holes on the side of the mouthpiece.</td>
<td></td>
</tr>
<tr>
<td>• While taking in a slow deep breath press the dark gray button and continue to breathe in slowly until lungs are full.</td>
<td></td>
</tr>
<tr>
<td>• Hold breath for 10 seconds or as long as comfortable and exhale.</td>
<td></td>
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<td>• If the provider has prescribed more than one inhalation of an inhaler containing albuterol, wait 30 seconds and repeat above.</td>
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<td>• Close the cap.</td>
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<td>• Clean the mouthpiece, including the metal part inside the mouthpiece, with a damp cloth or tissue only, at least once a week.</td>
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The Nebraska Pharmacists Association disclaims any liability to you or your patients resulting from reliance solely upon the information contained herein.

Quiz Answers may be submitted:

Online:  www.npharm.org
Fax:  402-420-1406
Email:  m&p@npharm.org
Mail:  Nebraska Mortar & Pestle
6221 S 58th St, Ste A
Lincoln, NE 68516

References
Maintenance Therapy and Prevention of Exacerbations in COPD Patients

Quiz #14, September/October 2019, ACPE 0128-0000-19-045-H01-P/T

1. All of the following statements about chronic obstructive pulmonary disease (COPD) are true, EXCEPT:
   a. Cigarette smokers are the only patients who develop COPD.
   b. COPD is a disease characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities.
   c. People with COPD should stop smoking to slow disease progression.
   d. Symptoms of COPD include dyspnea, cough, and excessive sputum production.

2. The ABCD classification, which guides COPD treatment selection, is based on what?
   a. Chest x-ray
   b. Sputum cytology
   c. Symptoms and exacerbations
   d. White blood cell count

3. JT, a 62-year-old male patient with a past medical history of type II diabetes mellitus, hypertension, arthritis and chronic obstructive pulmonary disease (COPD). He is classified as “Group B”. Which of the following medication classes is/are initially recommended for the management of this patient’s stable COPD?
   a. Long-acting beta-agonist (LABA) and an inhaled corticosteroid (ICS).
   b. Long-acting beta-agonist (LABA) or long-acting muscarinic antagonist (LAMA).
   c. Short-acting beta-agonist (SABA).
   d. Short-acting muscarinic antagonist (SAMA).

4. JT has arthritis and will need an inhaler that does not require dexterity or coordination. What would be the most appropriate to recommend for him?
   a. Advair Diskus
   b. ProAir RespiClick
   c. Spiriva Respimat
   d. Ventolin HFA

5. The physician is concerned that JT may have compliance issues. He would prefer an inhaler with a once daily dosing regimen and consults you. Which of the following would you recommend?
   a. Aclidinium
   b. Formoterol
   c. Glycopyrrolate
   d. Tiotropium

6. Roflumilast may be used for the prevention of COPD exacerbations in chronic bronchitis patients with severe chronic obstructive pulmonary disease (COPD). How is roflumilast dosed?
   a. 10 µg twice daily for 2 weeks, then increase to 20 µg twice daily
   b. 75 µg three times daily for 1 week, then increase to 150 µg three times daily
   c. 120 µg four times daily for 6 weeks, then increase to 240 µg four times daily
   d. 250 µg once daily for 4 weeks, then increase to 500 µg once daily

7. Which type of inhaler is not compatible with a spacer device?
   a. Dry powder inhaler
   b. Metered dose inhaler
   c. Soft mist inhaler
   d. All inhalers can be used with a spacer device

8. How often should you counsel a patient to clean the plastic mouthpiece of an MDI?
   a. At least once per week
   b. Every two weeks
   c. Once per month
   d. The HFA inhalers are dry powers and you should never allow moisture to come into contact with them

9. Which vaccination should be recommended to a 62-year-old patient at the time of diagnosis?
   a. Pneumococcal conjugate vaccine (PCV13)
   b. Pneumococcal polysaccharide vaccine (PPSV23)
   c. Both PCV13 and PPSV23
   d. No vaccine is needed because the patient is not 65-years-old

10. What may be added to the medication regimen of a Group D COPD patient who is experiencing frequent exacerbations?
    a. Azithromycin
    b. Cefdinir
    c. Doxycycline
    d. Levofloxacin

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
   If not, please explain ________________________________
4. Did the lesson meet your educational/practice needs? ___ Yes ___ No
5. Comments/future topics are welcome. ________________________________
UNMC enrollment exceeds 4,000 for first time

Student enrollment at UNMC set a record high for the 19th straight year with 4,055 students enrolled for the 2019-2020 school year, an increase of 85 students or 2.1% over last year’s record of 3,970.

“This is a significant year for UNMC. For the first time in our history, we have enrolled more than 4,000 students, our 19th consecutive year of enrollment increase, and more than a 50% increase from where we were in 2000,” said Dele Davies, M.D., UNMC senior vice chancellor for academic affairs and dean for graduate studies. “It’s truly a reflection of our continued commitment to provide the highest quality programs to address the demand for highly skilled health care providers and scientists in our state and beyond.”

During UNMC’s 19 years of continued growth, it has added several new and critically needed programs, including, this year, the first class of master’s degree in genetics counseling and a new master’s in health administration. “Our genetics counseling program in particular is a good example of responding to a major community need due to the increasing and anticipated future explosion in genetics testing and the need for skilled counselors to help interpret the data and provide useful and empathetic advice to patients and their families,” Dr. Davies said.

The genetics counseling program was borne from a partnership between the UNMC Munroe-Meyer Institute, the UNMC College of Allied Health Professions, UNMC’s hospital partner, Nebraska Medicine, and a number of community partners including Children’s Hospital & Medical Center, Methodist Health System, Blue Cross Blue Shield of Nebraska and Boys Town National Research Hospital.

The College of Pharmacy admitted 55 new students with an average GPA of 3.6. Of these new students, 67% are Nebraska residents, with 68% of those coming from rural areas. The new students bring the total enrollment in the four-year program to 238 students.

College of Pharmacy welcomes new faculty members, Sean Avedissian & Paul Trippier

Sean Avedissian, Ph.D. joins the College of Pharmacy as an Assistant Professor. Dr. Avedissian lectures in infectious diseases and pharmacokinetics. Dr. Avedissian’s primary research interests are related to the pharmacokinetic modeling of antibiotics/antivirals in special populations (HIV, critically-ill). His recent research has focused on developing pharmacokinetic models in clinical and pre-clinical environments.

Paul Trippier, Ph.D. joined the College of Pharmacy in July 2019. Dr. Trippier lectures in Medicinal Chemistry and Drug Discovery. His research focuses on small molecule drug discovery for cancer and neurodegenerative diseases. Discoveries in the Trippier lab have led to the identification of the most potent and selective Aldo-Keto reductase 1C3 (AKR1C3) inhibitor which shows significant effect to counter drug resistance in prostate cancer and leukemia.

Biopharmaceutical Research & Development Symposium doubles as a tribute to Courtney Fletcher, Pharm.D.

When they attend scientific conferences, former fellows of Courtney Fletcher, Pharm.D., dean emeritus of the College of Pharmacy, find each other. They are proud members of an exclusive club and “a pretty tight group,” said Anthony Podany, Pharm.D., assistant professor of pharmacy practice and science.

But now, the “band is getting back together” at UNMC. The College of Pharmacy’s sixth annual Biopharmaceutical Research and Development Symposium doubled as a tribute to Dr. Fletcher and his career of pioneering work in the field of infectious diseases. The symposium was held Sept. 4-5 in the Sorrell Center’s Truhlsen Events Center.

The slate included speakers from both academia and industry -- but several of the headliners were mentees of Dr. Fletcher, who have since gone on to impressive careers in their own right.

Dr. Fletcher’s longtime collaborators, Timothy Schacker, M.D., of the University of Minnesota, Charlie Flexner, M.D., of Johns Hopkins and Susan Swindells, M.B.B.S., one of UNMC’s top scientists, also presented.
The UNMC College of Pharmacy Annual White Coat Ceremony took place on August 21 at the Michael F. Sorrell Events Center with a reception following in the UNMC Center for Drug Discovery and Lozier Center for Pharmacy Sciences and Education building.

Fifty-five students received their professional white laboratory jackets, provided by friends of the College of Pharmacy and the University of Nebraska Foundation, and took the pledge of professionalism.

Dean Keith Olsen, Pharm.D. welcomed the students. Associate Dean for Academic Affairs, Don Klepser, Ph.D., delivered the keynote presentation on “What Do You Want To Do With Your Life?”

Anthony Donovan, P4, also shared his reflections as a Pharmacy student.

Dr. Don Klepser and Associate Dean for Student Affairs, Christopher Shaffer, Pharm.D., welcomed the class of 2023 to the Ceremony and assisted with the presentation of the white coats to the students.

The College of Pharmacy Open House followed where new students and their families and friends were invited to mingle with faculty, students and staff.
Nebraska Pharmacists Association and SoFi have teamed up to help you take down student debt—with student loan benefits, exclusively for NPA members, family and friends.

### Why refinance student loans with SoFi?

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<td>Members save thousands when they refinance.</td>
<td>Low variable and fixed rate options may reduce your interest rate.</td>
<td>You can consolidate and refinance both federal and private loans.</td>
<td>No application/origination fees or prepayment penalties—ever.</td>
<td>Exclusive networking events, financial workshops, and more.</td>
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### How to apply:

1. Find your rate at sofi.com/NPA.
2. If approved, select your rate and term.
4. Celebrate your savings.

### Claim your 0.125%¹ discount toward your student loans at SoFi.com/NPA.

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¹Additional terms and conditions apply. If you apply and are approved, the interest rate shown in the Final Disclosure Statement will include an additional 0.125% rate discount because of your involvement with a SoFi partner company at the time of loan origination. Offer good for new customers only. Cannot be combined with other rate discounts, with the exception of the 0.25% AutoPay rate discount. SoFi reserves the right to change or terminate the Rate Discount Program to unenrolled participants at any time with or without notice.

²To check the rates and terms you may qualify for, SoFi conducts a soft credit pull that will not affect your credit score. A hard credit pull, which may impact your credit score, is required if you apply for a SoFi product after being pre-qualified.
Objective
At the conclusion of this lesson, pharmacists and pharmacy technicians should be able to:

1. Identify changes to Nebraska law that impact the practice of pharmacy.

The 106th Legislature – First Session adjourned on May 31, 2019. During this 90-day Session, several legislative bills passed which changed Nebraska law that impact pharmacy practice and drug laws. The 2019 Nebraska Law Review article will provide an overview of law changes that are important for pharmacists and pharmacy technicians to know and understand.

Certified Pharmacy Technician Validation
LB 74 changed the practice of certified pharmacy technicians working within the confines of a hospital in Nebraska allowing tech-check-tech within the workflow. The basis for the law changes were the successful pilot projects, as permitted by the Nebraska Board of Pharmacy, at several Nebraska hospitals. Certified pharmacy technicians may validate the work of another certified pharmacy technician in the process of preparing medications for administration within the hospital. The validation process must include the use of bar code technology, radio frequency identification, or other similar technology to ensure the accuracy of the medications. The medications being validated by certified pharmacy technicians must be prepackaged by the manufacturer or prepackaged and verified by a pharmacist. All of these activities must be outlined in policies and procedures established by the hospital’s pharmacist in charge.

Because the law now refers to “validation” of the work between certified pharmacy technicians, a definition of validation was added to the Pharmacy Practice Act. Validation means the action of a certified pharmacy technician checking the accuracy and completeness of the acts, tasks, or functions undertaken by another certified pharmacy technician as provided in 38-2891.01. Additionally, the definition of supervision was updated to recognize the certified pharmacy technician validation process. Supervision means the personal guidance and direction by a pharmacist of the performance by a pharmacy technician of authorized activities or functions subject to (1) verification by such pharmacist or (2) validation by a certified pharmacy technician subject to section 38-2891.01. Supervision of a pharmacy technician may occur by means of a real-time audiovisual communication system. Pharmacists and pharmacy technicians must remember that the ratio of pharmacists to pharmacy technicians did not change. The effective date for LB 74 was September 1, 2019.

This continuing pharmacy education lesson was written by Joni Cover, JD, Chief Executive Officer, Nebraska Pharmacists Association, who does not have any conflicts of interest, nor does she have any financial relationships with a commercial interest related to this continuing pharmacy education activity.
Waiver of Certain Credentialing Fees

Several bills have been introduced over the past few years that would waive fees and requirements for certain individuals governed by the Uniform Credentialing Act. This year, the Nebraska Legislature passed LB 112, a bill to waive certain fees for low-income individuals, military families, and young workers. LB 112 also defined low-income individual (Low-income individual means an individual enrolled in a state or federal public assistance program, including, but not limited to, the medical assistance program established pursuant to the Medical Assistance Act, the federal Supplemental Nutrition Assistance Program, or the federal Temporary Assistance for Needy Families program, or whose household adjusted gross income is below one hundred thirty percent of the federal income poverty guideline or a higher threshold to be set by the Licensure Unit of the Division of Public Health of the Department of Health and Human Services.), military families (Military families means active duty service members in the armed services of the United States, military spouses, honorably discharged veterans of the armed services of the United States, spouses of such honorably discharged veterans, and unremarried surviving spouses of deceased service members of the armed services of the United States.), and young worker (Young worker means (1) for an initial credential under the Cosmetology, Electrology, Esthetics, Nail Technology, and Body Art Practice Act, except for a body art license, an applicant who is between the ages of seventeen and twenty-five years or (2) for an initial credential issued under any other provision of the Uniform Credentialing Act, including a body art license, an applicant who is between the ages of eighteen and twenty-five years.). New language was added that states that all fees for initial credentials under the Uniform Credentialing Act for low-income individuals, military families, and young workers shall be waived except the actual cost of the fingerprinting and criminal background check for an initial license under section 38-131. Low-income individuals must meet income guidelines set forth in the definition found in Neb. Rev. Stat. Sec. 38-117.01. The young worker definition applies to the initial credential (the first time a license or registration in a specific profession is issued) and the person is between the ages of eighteen and twenty-five years old. Student pharmacists, pharmacy technicians, those in the military, and first time licensees will be impacted by this new law. The effective date of this legislation is January 1, 2020.

Pharmacy Benefit Manager (PBM) Transparency

Transparency in the payment model for pharmacies from insurers and their pharmacy benefit managers continues to be an issue in Nebraska and across the country. LB 316 was passed by the Nebraska Legislature as a small step in the long process of regulating PBMs. Nebraska law now prohibits “gag clauses” and says that pharmacists and contracted pharmacies are not prohibited from, will not be penalized for or removed from a network or plan for sharing costs, price, or copayments of prescription drugs with insured patients or their caregivers. The law also states that an insurer that offers a health plan with prescription drug coverage shall not require the patient to pay more at the point of sale than the lesser amount of the copay, deductible, coinsurance, or cash. These provisions were designed to support those in federal law pertaining to gag clauses and claw backs. The law also includes a definition section for the terms contained in the law. An important point to remember is that any changes to Nebraska law with regard to regulation of PBMs will only apply to those governed by Nebraska insurance laws (no Medicare plans, TriCare plans, etc.). With the emergency clause added to the bill, the law became effective when signed by Governor Ricketts on April 24, 2019.

Medication Synchronization

Medicare authorized medication synchronization by pharmacists as a way for patients to pick up their medications at a pharmacy on the same day, with the goal of improving adherence, and pay the pharmacists an additional fee to synchronize the medications for the patient. Some third-party payers outside of Medicare recognize the value of this service, and pay pharmacists the extra dispensing fee to synchronize a patient’s medications, but other payers do not. LB 442 was introduced to require payors to reimburse pharmacists for the extra dispensing fee for the medication synchronization of medications in Nebraska.

As defined in Neb. Rev. Stat. Sec. 44-7,108, synchronizing the patient’s medications means the coordination of medications of a patient who has been prescribed two or more medications for one or more chronic conditions so that the patient’s medications are refilled on the same schedule for a given time period. The new law allows for a prorated daily cost-sharing rate (ie: dispensing fee) for a partial supply of medications in order to synchronize a patient’s medications if the prescriber or pharmacist determines the synchronization is in the best interest of the patient and the patient requests the medication synchronization. Medications eligible to be synchronized and paid for are those that are part of the patient’s drug plan, have met the prior authorization criteria or utilization management criteria (if needed), are for a chronic illness, in formulations that can be safely split into short-fill periods to achieve the synchronization, and are not schedule II controlled substances. Pharmacists are allowed to override the insurance/PBM denial code if a message is received that a prescription is being refilled too soon for purposes of medication synchronization. Nebraska’s new medication synchronization law became effective September 1, 2019.
Prescription Drug Monitoring Program (PDMP)
Changing the information pharmacies are required to report to the Prescription Drug Monitoring Program (PDMP) has become an annual legislative initiative. 2019 was no exception with the introduction and passage of LB 556. Nebraska law was changed to include new reporting requirements for prescription drug data to the PDMP. All dispensers must now report the following:

- Name of the prescriber and the drug quantity and days’ supply; and
- Drug strength; and
- National Drug Code (NDC) of the prescription; and
- Prescription number (no longer the number of authorized refills; and
- Date the prescription is filled; and
- Date the prescription is issued; and
- Name and address of the pharmacy from which the drug was dispensed; and
- Patient identifier (military ID number, driver’s license number, state identifier card number, other valid government-issued ID number, insurance ID number, pharmacy software-generated patient-specific identifier, or other identifier associated specifically with the patient); and
- Name and address of the pharmacy
- Date the prescription is issued; and
- Date the prescription is filled; and
- Number of authorized refills; and
- Prescription number (no longer reporting the name) of the drug; and
- National Drug Code (NDC) of the drug; and
- Drug strength; and
- Drug quantity and days’ supply; and
- Name of prescriber and the prescriber’s NPI or DEA number (for prescriptions for controlled substances).23

Because of federal and state law changes, the number of individuals and entities that have access to information in the NeHII system expanded.26 Patients, specific individuals within the Medicaid programs, managed care organizations, and other state PDMP/HIEs now have certain authority to receive certain data.27 Since Nebraska does not allow law enforcement to have access, law enforcement in other states will not have access.

LB 556 updated the requirements for prescribers with regard to education of patients when prescribing Schedule II controlled substances and other opiates.28 The law changed to allow any member of the health care team (including pharmacists) who is under the direct supervision or in consultation with the prescriber to provide the education to patients to, unless already counseled within the previous 60 days, counsel a patient younger than 18 years of age before issuing an initial prescription with any medication in Schedule II or any opiate about:

- the risks of addiction and overdose,
- why the medication is necessary,
- alternative treatments.

The law does not apply to hospice, cancer, or palliative care patients, and removed the requirement for additional counseling upon issuance of the third prescription.29 All of the changes contained in LB 556 became effective on May 1, 2019.

Telehealth
Telehealth is such an important tool in providing health care in Nebraska. The Nebraska Legislature passed LB 29 which expanded the list of health care providers that can utilize telehealth in establishing a provider-patient relationship.30 Pharmacists are included in the list of credential holders (as provided in the Uniform Credentialing Act) that are allowed to establish a provider-patient relationship.31 While the law is vague as to how it can be utilized, the possibilities are many with regard to pharmacists and patient care.

Health Care Quality Improvement Act
The Nebraska Health Care Quality Improvement Act provides protection for those individuals who participate in peer review activities which evaluate the quality and efficiency of health care providers and to protect the confidentiality of peer review records.32 LB 119 was adopted by the Nebraska Legislature to update and improve the Act, adding professional health care service entities to the list of those protected under this Act.35 A professional health care service entity is defined as an entity which is organized for purposes of rendering professional services pursuant to the Nebraska Professional Corporation Act, the Nebraska Uniform Limited Liability Company Act, or the Uniform Partnership Act of 1998 and which renders health care services through individuals credentialed under the Uniform Credentialing Act.36 With the change in the law, an officer, director, employee or member of a professional health care service entity shall be provided immunity from liability for activities within the scope of a peer review committee. Peer reviews conducted by a member of the professional health care service entity are confidential.37

Expeditied Partner Therapy
Nebraska law recognizes expedited partner therapy, whereby a patient visits a prescriber and gets a prescription for a sexually transmitted disease and the prescriber can prescribe for that patient’s partner(s) without the partner(s) being examined by that prescriber.32 The expedited partner therapy pertains to patients diagnosed with chlamydia, gonorrhea, or trichomoniasis (which was added with the passage of LB 62).31 Pharmacists may receive prescriptions for the patients and their partners, but the prescriptions for the partners will include the partners’ names.
Hemp
The Nebraska Legislature established a hemp farming program under the guidance and direction of the Nebraska Department of Agriculture.\(^{38}\) As a growing industry, hemp farming operations are now permitted, within the established rules of state and federal law. LB 657 added a definition of hemp which means the plant Cannabis sativa L. and any part of such plant, including the viable seeds of such plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.\(^{39}\) The Nebraska law definition of hemp mirrors the definition of hemp in federal law.\(^{40}\) Nebraska law states that hemp is considered an agricultural commodity, and is not a considered a controlled substance under the Uniform Controlled Substances Act.\(^{41}\)

Does the passage of LB 657 make it legal to sell CBD in Nebraska? The answer is unclear. The Department of Justice made the following statement: "The Agriculture Improvement Act of 2018, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude “hemp”—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it."\(^{42}\) The FDA has sent warning letters to companies that market their CBD products, for humans or animals, with claims to prevent, diagnose, treat, or cure serious diseases or as food additives. Depending on the county in Nebraska, county attorneys may or may not decide to prosecute businesses that sell CBD. Until such time as the state or federal laws are clarified, pharmacists are advised to seek legal advice on whether to sell CBD.

Conclusion
Knowing about and understanding the law changes that impact pharmacy practice in Nebraska each year is important for pharmacists and pharmacy technicians.

References
\(^{1}\) LB 74 or 38-2891.01
\(^{2}\) Neb. Rev. Stat. Sec. 38-2891.01
\(^{4}\) Neb. Rev. Stat. Sec. 38-2846.01
\(^{5}\) Neb. Rev. Stat. Sec. 38-2845
\(^{6}\) Neb. Rev. Stat. Sec. 38-2866.01
\(^{7}\) LB 112, 106th Legislature, 1st Session, 2019
\(^{8}\) Neb. Rev. Stat. Sec. 38-117-01
\(^{9}\) Neb. Rev. Stat. Sec. 38-117-02
\(^{10}\) Neb. Rev. Stat. Sec. 38-120-03
\(^{11}\) Neb. Rev. Stat. Sec. 38-155(3)
\(^{12}\) Neb. Rev. Stat. Sec. 38-120-03
\(^{13}\) LB 316, 106th Legislature, 1st Session, 2019
\(^{14}\) Neb. Rev. Stat. Sec. 71-248(4)(2)
\(^{15}\) Neb. Rev. Stat. Sec. 71-248(4)(2)
\(^{16}\) Neb. Rev. Stat. Sec. 71-248(1)
\(^{18}\) LB 442, 106th Legislature, 1st Session, 2019
\(^{19}\) Neb. Rev. Stat. Sec. 44-7108(6)
\(^{20}\) Neb. Rev. Stat. Sec. 44-7108(6)
\(^{21}\) Neb. Rev. Stat. Sec. 44-7108(3) & (4)
\(^{22}\) Neb. Rev. Stat. Sec. 44-7108(2)
\(^{23}\) Neb. Rev. Stat. Sec. 71-2145
\(^{24}\) Neb. Rev. Stat. Sec. 71-2145
\(^{25}\) Neb. Rev. Stat. Sec. 71-2145
\(^{26}\) Neb. Rev. Stat. Sec. 71-2145
\(^{27}\) LB 556, 106th Legislature, 1st Session, 2019
\(^{29}\) LB 29, 106th Legislature, 1st Session, 2019
\(^{30}\) Neb. Rev. Stat. Sec. 38-1143
\(^{31}\) Neb. Rev. Stat. Sec. 71-503.02
\(^{32}\) LB 62, 106th Legislature, 1st Session, 2019
\(^{33}\) Neb. Rev. Stat. Sec. 71-7905
\(^{34}\) LB 119, 106th Legislature, 1st Session, 2019
\(^{35}\) Neb. Rev. Stat. Sec. 71-7910.01
\(^{36}\) Neb. Rev. Stat. Sec. 71-7910.01
\(^{37}\) LB 657, 106th Legislature, 1st Session, 2019
\(^{38}\) Neb. Rev. Stat. Sec. 2-503(11)
\(^{39}\) AMA, 7 U.S.C. 1621 et seq.
\(^{40}\) Neb. Rev. Stat. Sec. 28-401

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Quiz Answers may be submitted:

Online: www.npharm.org
Fax: 402-420-1406
Email: m&p@npharm.org
Mail: Nebraska Mortar & Pestle
6221 S 58th St, Ste A
Lincoln, NE 68516

Quiz #15 is the LAST M&P CPE lesson for 2019. All of the 2019 M&P CPE lessons and quizzes have been published. All 2019 M&P CPE quizzes are due December 12, 2019. No carry overs. No exceptions.
1. Certified Pharmacy Technician validation (tech-check-tech) can occur:
   a. in a community pharmacy.
   b. in a long-term care pharmacy.
   c. in a hospital for inpatient administration.
   d. all of the above.

2. If medications are repackaged in a hospital, before the medications are stocked into an automated medication system,
   a. they can be validated by two certified pharmacy technicians.
   b. they must be checked by a pharmacist.
   c. they can be verified by two licensed health care professionals.
   d. they must be checked by a nurse and a certified pharmacy technician.

3. Nebraska’s law was changed to allow waiver of initial credentialing fees for certain individuals. Those individuals include:
   a. Young workers
   b. Low income
   c. Military families
   d. All of the above

4. To which insurance plan does LB 316 apply?
   a. Medicare Advantage Plans
   b. Medicare Part D
   c. Nebraska Medicaid plans, including the MCOs
   d. Tricare

5. Upon the request of a patient, a pharmacist may synchronize:
   a. amoxicillin
   b. oxycodone
   c. albuterol inhaler
   d. atorvastatin

6. Acceptable patient identifiers for the PDMP include:
   a. Driver’s license
   b. State identifier card number
   c. Insurance identification number
   d. All of the above

7. The expedited partner therapy pertains to patients diagnosed with:
   a. Chlamydia
   b. Gonorrhea
   c. Trichomoniasis
   d. Any of the above

8. For purposes of the Health Care Quality Improvement Act, a professional health care service entity may be an entity licensed under the:
   a. Nebraska Professional Corporation Act
   b. Nebraska Uniform Limited Liability Company Act
   c. Uniform Partnership Act
   d. All of the above

9. As defined in Nebraska, hemp that contains 0.3% dry weight THC is considered:
   a. A controlled substance
   b. A legend drug
   c. An agricultural commodity
   d. Marijuana

10. Which of these CBD products are legal to sell in Nebraska?
    a. Hemp-based gummy bears labeled to treat anxiety
    b. CBD oil labeled for topical use to cure dry skin (Hemp-based dry weight of not more than 0.3% THC)
    c. Epidiolex with a valid prescription
    d. Hemp extract for coffee to treat dry eyes

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

**Where do you practice?**
I practice at Cardinal Health Nuclear and Precision Health Solutions.

**Where did you attend pharmacy school?**
I graduated from the University of Nebraska Medical Center College of Pharmacy.

**Why did you choose to pursue a career in nuclear pharmacy?**
I became a pharmacist due to my strong interest in science. I started my career as a pharmacy intern at Great Plains Radiopharmacy in Omaha, and I was offered a job when I graduated. In 1992, Great Plains Radiopharmacy opened a pharmacy in Lincoln, Nebraska, and I moved to become a manager at the new location. Over time, the company changed owners to Syncor and then Cardinal Health. Now I manage a pharmacy in the nation’s largest radiopharmaceutical network comprised of over 130 Cardinal Health nuclear pharmacies preparing and distributing more than 12 million radiopharmaceuticals across the United State every year. It’s exciting to be a part of that work.

**What is your favorite part of your position?**
I enjoy helping providers by routinely consulting on patient care and best practices while also managing through the challenges of transporting radiopharmaceuticals across a large geographic area that stretches as far as North Platte. Our product is constantly decaying. It’s like transporting a melting ice cube. We make and deliver the dose based on the decay factor, the scheduled procedure time—down to the minute and the unique requirements of each individual patient. Every minute counts. The product must be used the same day it’s made and prepared, despite unforeseen circumstances like weather conditions. It certainly makes every day interesting.

**What is your favorite part about being an NPA member?**
I have enjoyed the connections I have made through events hosted by the NPA. I have been able to stay up to date on my continuing education credits, and changes to Nebraska Law. It’s a great source of information! Our work is so precise, it’s good to have an established network of experts.

**What advice would you give someone looking to move into a management position?**
I would recommend that they develop their interpersonal skills. To be successful in leading a group of people you need to be able to get others to buy into what they are doing and understand the impact they have on the team.

**Is there an NPA member who’s work needs to be recognized?**

Please contact NPA Project Coordinator, Sarah Hunter, at 402-420-1500 or sarah@npharm.org. We want to hear from you!
2020 Membership

Member Information

Name ____________________________________________

Address _________________________________________

City ___________________________________ State ______ Zip _____________

Phone __________________________ Cell Phone _________________________

Email ________________________________

NABT e-Profile ID # ________________________________ Birth Date (MMDD) ____________

☐ Paperless Option I will access the M&P journal from the NPA website. Please send all communications to my email address.

☐ Mail Option I would like to receive the M&P journal by mail. My NPA Daily News Dose will be sent to my email address.

☐ Check this box if you are interested in serving on an NPA Task Force, Committee, or the Board of Directors.

Membership (Check one)

☐ Active License Pharmacist $200

☐ 1st Year Pharmacist $95 (2019 Graduate)

☐ 2nd Year Pharmacist $145 (2018 Graduate)

☐ Inactive Licensed Pharmacist $100 (Does not include CPE)

☐ Student Pharmacist $15

☐ Friends of Pharmacy $100*

☐ Pharmacy Technician $65**

*Membership is electronic only. No printed communication will be mailed. 2020 membership year runs January 1–December 31.

Donations

☐ *NebPharmPAC $________________________

☐ Foundation $________________________ (Tax Deductible)

*Contributions to the NPA or NebPharmPAC are not tax deductible as charitable contributions for income tax purposes. They may be tax deductible as ordinary and necessary business expenses subject to restrictions imposed as a result of association lobbying activities. The NPA estimates that the nondeductible portion of your 2020 dues used for lobbying is 18%.

Payment

☐ Check (Payable to the Nebraska Pharmacists Association)

Check #____________________ for $ _____________________

☐ Credit Card ☐ AmEx ☐ MC ☐ Visa ☐ DISC

# ______________________

Amount $ ____________________

Exp. Date _____/______ Sec. Code __________

Signature ________________________________

Specialty Practice Interest Network

(Flip all that apply)

Select a network that expresses your interest, not necessarily your work setting. The network you choose is not binding and can be changed at any time. Network preferences are used to tailor NPA communications to your area of interest.

☐ New Practitioner ☐ Independent ☐ Hospital/Health-System

☐ Academia/Specialty Practice

☐ Chain ☐ Industry ☐ Long-Term Care

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Fax 402-420-1406

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Questions?

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