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PRESIDENT'S MESSAGE

Dear MPhA Members,

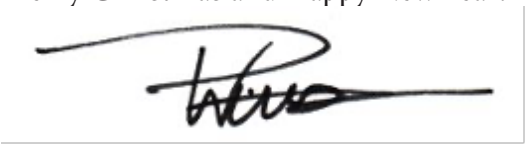
Greetings! I hope my letter finds you and yours in good health and in good spirits. This year has been a tough one, hasn't it? We have seen and experienced things never seen before, and I don't know about you, but I hope to never see some of them again. However, I am encouraged. I hope you are encouraged as well.

As we enter the holiday season, we may take time to reflect on the year that 2020 has been. We can also take time to look ahead to what 2021 may bring. As I am writing this letter, we are on the verge of seeing our first vaccine for COVID-19 being made available for administration. New therapies with monoclonal antibodies are being deployed, and tried and true therapies are being optimized. I am encouraged that the best and brightest minds in the world may be on the brink of finally getting a firm hold on the pandemic, and pharmacists and pharmacy technicians are on the forefront to make sure these interventions are successful.

As we close out 2020, we have also been busy at MPhA. Despite the challenges, MPhA has been hard at work for you this year. MPhA Committees have been meeting and working to make sure we finish 2020 strong and are poised for a successful 2021. We have also been able to find a buyer for our property and should be closing on that soon where we can redeploy and realign resources to better serve the association. MPhA certainly seems to be getting off on the right foot for 2021.

It is an honor to serve you as President of MPhA. If we can be of help to you, please to not hesitate to contact us.

Merry Christmas and Happy New Year!



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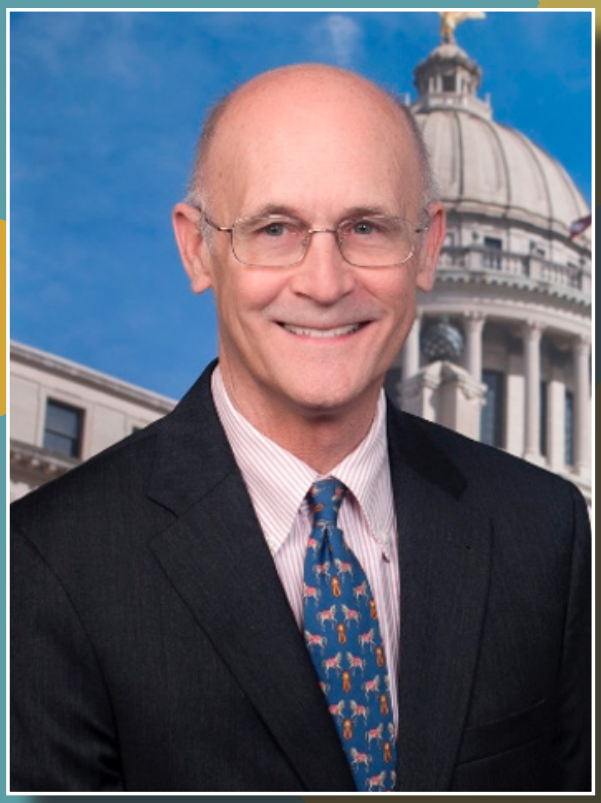

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EXECUTIVE DIRECTOR'S MESSAGE

We are in the process of selling the MPhA office building in Jackson and hopefully by the time of this printing, the contract will be signed. The Executive Committee understands that the money saved and made from the sale can be better used for our association versus maintaining the building. I can assure you that our EC is working hard to properly manage MPhA's money.

A lot of work has gone into getting the building ready for sale and it has been bitter sweet going through the attic. The old photos and journals tell the story of the evolution of pharmacy in our state. I especially enjoyed the pamphlet titled "The Plight of the Pharmacist in Filling a 3rd Party Prescription." The pamphlet details the increased amount of administrative duties, length of time for reimbursement, and need for an equitable solution.

And here we are in the same situation with the COVID vaccine. As the director of a LTC pharmacy, I was excited to hear that pharmacists are going to play a critical role in the administration of COVID vaccinations to the nursing home population. My excitement waned as more details came down from CMS. The Pfizer vaccine will most likely be the first on the market and is looking to be more than 90% effective, but it requires an ultra-low temp freezer that will maintain -94 degrees F. However, these freezers are very expensive and becoming harder to find along with the special glass for the vials and dry ice as an alternative freezing method. This will be a 2-shot vaccine given 3 weeks apart with a mountain of paperwork to be maintained for each shot. "So what, I can do this, just let me at it, by the way, what's reimbursement going to look like?" Well, the government will supply the actual vaccine, but you will be responsible for storage, handling, ancillary supplies, vaccine administration payroll, and all aspects of detailed documentation for around $17 for the first shot and $27 for the second shot. Queue the Crickets…. Pharmacists have the knowledge, ability, and desire to be involved, but we have to be reimbursed adequately. This has been the struggle for our profession, fighting to let us do it and fighting to reimburse us adequately for it. I don't see this ending in my lifetime.

This is where MPhA and you come into the picture. Thanks to your support by being a member and contributing to the Political Action Committee, we are able to monitor and act on issues affecting Pharmacy at the Capitol. Our lobbyist and I have already met with key legislative members at the capitol this fall, including our very own Rep John Read, RPh, and will continue to do so through the end of the year and during the 2021 session. The Executive Committee selected Sen Hob Bryan and Rep Sam Mims as Legislators of the Year for 2020 for their help with issues facing pharmacy including the passage of HB 708. HB 708 will go into effect January 2021 and we are currently working on a step by step guide to help pharmacists in our state report infractions by PMBs to the MS Board of Pharmacy and have that to you before the end of the year. We will be focusing legislative efforts this year on carving pharmacy out of the Medicaid MCO program and initiating a test and treat model to allow pharmacists to test for conditions such as flu and strep and then be able to treat a positive test, AND get reimbursed adequately for these services.

As always, we want to hear from you. Please feel free to reach out to me anytime with questions or concerns or ways that MPhA can be serving you better and I look forward to seeing you at Centennial Plaza in Gulfport June 3rd-5th for our 150th MPhA Annual Convention.

Thank you,
Beau Cox

A COMPARISON OF NOVEL AND LONGSTANDING POTASSIUM BINDING AGENTS

Maria Gorla, PharmD Candidate 2021, University of Mississippi School of Pharmacy
Andrew Mays, PharmD, BCNSP, CNSC, Clinical Pharmacy Specialist - Nutrition Support, University of Mississippi Medical Center

GOAL:

This continuing education activity is being provided so pharmacists and pharmacy technicians can learn or refresh their knowledge about potassium, hyperkalemia, and its management with potassium binding agents.

OBJECTIVES:

By the completion of this activity, the participant will be able to…

- recall the normal serum concentration range for potassium
- recognize signs and symptoms associated with hyperkalemia
- list three potassium binding medications used to treat hyperkalemia
- associate the brand names of potassium binders with their respective generic names

ABSTRACT

Potassium is the body's major intracellular cation, and it is required for the normal functioning of cells, nerves, and muscles. The body must maintain the potassium level in the blood within a narrow range to avoid hypokalemia or hyperkalemia. Disruptions from this range can be detrimental, causing arrythmias or even cardiac arrest. Increased potassium levels can be a result of medications, such as those acting on the RAAS, or disease states, such as chronic kidney disease. Acute hyperkalemia is emergent and requires treatment in the hospital with calcium to stabilize the heart membrane, insulin to shift potassium into the cells, and a definitive treatment such as dialysis to remove potassium from the body. The chronic elevation of serum potassium can be managed in the outpatient setting. SPS is an agent that has been used historically for the management of hyperkalemia, while patiromer and ZS-9 are newer agents used to maintain normokalaemia.

Table 1[17]

Selected Foods with High Potassium Content	
Kidney beans (1/2 cup)	357mg
Avocado (1/2 cup)	364mg
French Fries (3 oz)	470mg
Skim Milk (1 cup)	382mg
Baked Potato (1 medium)	941mg
Spinach (1/2 cup)	370-419mg
Sweet Potato (1 medium)	542mg
Banana (1 medium)	422mg

OVERVIEW

Potassium is the second most abundant cation in the body and the major intracellular cation. With only 2% of total body potassium found in the extracellular space, 98% of total body potassium is located within the cells. Potassium has a normal serum concentration of 3.5 to 5 mEq/L. Deviations above or below this range can be detrimental, as potassium contributes to many necessary physiological functions. These functions include cellular metabolism, glycogen and protein synthesis, and the regulation of electrical action potentials across cellular membranes. Potassium's role in regulating action potentials means that it has a key role in maintaining normal neuromuscular functions, including cardiac conduction.

The daily potassium requirement for most people ranges from 0.5 to 2 mEq/kg/day. Potassium can be obtained from a variety of different foods, including leafy vegetables, salmon, and bananas, to meet daily required intake. Table 1 includes some examples of foods that are high in

potassium; these foods can fulfill the daily dietary requirement for most people, but they may need to be avoided in patient populations prone to hyperkalemia.

Deficiencies in potassium can occur as a result of chronic diarrhea or vomiting, or from the use of certain medications, such as diuretics. Mild deficiencies (3 – 3.5 mEq/L serum potassium concentrations) are typically asymptomatic. Severe deficiencies (below 2.5 mEq/L serum potassium) can present with cramping, rhabdomyolysis, paralysis, and electrocardiogram changes (ST-segment depression, T-wave inversion, and sudden cardiac death).

Potassium shifting and excess retention or losses can be identified as the main reasons why serum levels are altered. Hyperkalemia can be caused by extracellular shifts of potassium, increased potassium ingestion, or impaired potassium excretion. Extracellular potassium shifts are common and can often be caused by metabolic acidosis and tissue catabolism. Metabolic acidosis causes a need for extracellular shift to maintain electroneutrality due to excess hydrogen ions being buffered intracellularly. Tissue destruction (tumor lysis syndrome, crush syndrome, rhabdomyolysis) can also cause release of potassium from cells into the extracellular fluid. Clinicians must also be aware of pseudohyperkalemia. Pseudohyperkalemia is a false elevation in serum potassium. This can be caused by trauma during venipuncture, potassium contaminated blood sample, and marked leukocytosis or thrombocytosis,[1,2]

PATHOPHYSIOLOGY

Hyperkalemia is defined as an increase in serum potassium greater than or equal to 5.5 mEq/L. Under normal circumstances, the kidneys are responsible for excreting 90% of the potassium that is consumed daily. The majority of potassium is filtered by the glomerulus and reabsorbed in the proximal tubule and the loop of Henle. The remaining potassium reaches the distal tubule. Principal cells in the renal collecting duct are responsible for secreting excess potassium from the circulation into the tubular lumen and excreting it in the urine. Secretion of potassium by the collecting duct is regulated by serum aldosterone and sodium concentration in the distal tubule. Additionally, medications commonly used in the guideline directed management of heart failure, such as ACE inhibitors, angiotensin receptor blockers, aldosterone antagonizing (potassium sparing) diuretics, and mineralocorticoid receptor antagonists, can increase the risk of hyperkalemia due to their effects on the RAAS.[1, 2, 3]

SIGNS AND SYMPTOMS

Patients with elevated potassium levels are typically asymptomatic until the serum concentration exceeds 5.5 mEq/L. When patients are symptomatic, they may experience muscle twitching, cramping, or weakness. Patients should be informed of the signs and symptoms of hyperkalemia and counseled to seek medical attention if they arise, as an increase in serum potassium can lead to electrocardiogram changes (peaked T-waves, shortened QT interval) and life-threatening arrhythmias (ventricular fibrillation, asystole).[1,2]

TREATMENT

Acute alterations in potassium levels are typically managed in the in-patient setting; however, patients with diseases that lead to a chronically elevated serum potassium are evaluated and treated in ambulatory care settings. Providers caring for patients with chronic diseases such as diabetes, heart failure, and chronic kidney disease with persistent hyperkalemia have to balance the use of guideline-directed therapy with demonstrated mortality and morbidity benefits because many of the agents used in these disease states can contribute to an elevated potassium concentration. In some patients, hyperkalemia can be managed with a low potassium diet or by altering the doses of current medications. In others, the use of a potassium binding agent may be warranted to achieve normokalaemia. The addition of a potassium binding agent to a patient's regimen may allow them to have more freedom in their diet or to achieve appropriate doses of guideline directed therapies.[3]

ACUTE TREATMENT OF HYPERKALEMIA

The emergent treatment of hyperkalemia should be focused on cardiac stability and shifting or elimination of potassium from the extracellular space. Intravenous calcium should be initially administered for symptomatic patients with ECG changes, but it is often given in patients with significant hyperkalemia (> 6 mEq/L). IV calcium will antagonize the effects of potassium on the myocardium. The remaining treatments for hyperkalemia cause intracellular shift of potassium. This shift is

produced from the administration of insulin, dextrose, and sodium bicarbonate. Patients who are already hyperglycemic do not need dextrose administration. This initial treatment regimen will give the provider time to determine the cause of hyperkalemia and how to appropriately treat the cause. Hemodialysis remains the best treatment for the removal of potassium from the extracellular space. Please see Table 2 for the dose and administration of medications for the treatment of acute hyperkalemia.[1,2]

Table 2. Treatment for Hyperkalemia[1,2]

Medication	Dose	Onset	Duration
Calcium gluconate	1 – 2 grams IV over 5 – 10 minutes	1 – 2 minutes	10 – 30 minutes
Sodium bicarbonate	50 – 100 mEq IV over 2 – 5 minutes	30 minutes	2 – 6 hours
Regular insulin	10 units IV	15 – 45 minutes	2 – 6 hours
Dextrose (D50%)	50 mL IV over 5 minutes	30 minutes	2 – 6 hours

COMPARISON OF POTASSIUM BINDING AGENTS

SPS

Sodium polystyrene sulfonate (Kionex®; SPS®) is an older agent that has been used to treat hyperkalemia. It was best known as the brand name Kayexalate®, but that brand was discontinued by the manufacturer. The term SPS is used as an abbreviation for sodium polysterene sulfonate, but SPS is also an available branded generic of the agent. We will use the abbreviation SPS, but this should in no way be considered an endorsement of the branded SPS® over any other available generic product. While one or two doses of SPS may be utilized to lower potassium levels, it is not routinely used for long-term control. SPS is a non-selective agent that binds calcium and magnesium in addition to potassium, which can cause electrolyte disturbances. Intestinal necrosis and severe gastrointestinal events, such as bleeding, ischemic colitis, and perforation, have been reported with this drug, particularly when in a suspension including sorbitol. A 20-gram dose of SPS contains 15 grams of sorbitol; the sorbitol content of other agents are included in Table 3. The risk for adverse gastrointestinal events appears to increase in patients with renal insufficiency and failure, which is a common patient population that is likely utilizing a potassium binding agent. Additionally, it should be noted that a 15-gram dose of SPS contains 1500 mg (65 mEq) of sodium. This large sodium load may cause fluid retention and overload, something that is of significant concern in patients with heart failure, another patient population that may routinely require a potassium binding agent. If a patient is prescribed SPS, SPS should be separated from other medications by at least three hours.[4,5]

The average daily dose is 15 to 60 grams, administered as a 15-gram dose one to four times daily. SPS is supplied as a powder for suspension or as a premixed suspension. Each gram of powder requires 3 to 4 mL of water for reconstitution and the solution should be ingested within 24 hours of reconstitution.[4,5]

SPS was approved by the FDA in 1958, which was four years before the Kefauver-Harris Drug Amendments were passed to assure drug efficacy and safety. For this reason, trial data for SPS is limited and affects the willingness of clinicians to use SPS as a first-line treatment for hyperkalemia. In 2014, a study was completed to evaluate the efficacy of SPS in the treatment of mild hyperkalemia. SPS when compared to placebo, demonstrated superiority in reducing serum potassium over 7 days in patients with mild hyperkalemia and CKD with a mean difference between groups of 1.04 mEq/L ($P<0.001$). While a higher proportion of patients in the SPS group attained normokalaemia at the end of treatment when compared to those in the placebo group, the difference was not statistically significant (73% vs. 38%; $P= 0.07$). There was an increased incidence of gastrointestinal side effects in the treatment group, however, there were no cases of colonic necrosis observed in this trial.[6]

PATIROMER

Patiromer (Veltassa®) is a novel agent used as treatment for hyperkalemia. It is a non-absorbed, cation exchange polymer that binds potassium in the gastrointestinal tract and increases fecal potassium excretion. Patiromer is more selective than SPS, but it does bind magnesium in addition to

potassium. For this reason, patients can develop hypomagnesemia while taking patiromer. This was reported in 5.3% of patients treated with patiromer in the trials used for FDA approval. It should be noted that some of these trials reported hypomagnesaemia based on investigator's assessment, not necessarily on laboratory values. In one 4-week trial using a lower limit of normal magnesium concentration of 1.8 mg/dL, 24.5% of the patiromer treated patients had a concentration < 1.8 mg/dL. Serum magnesium should be monitored while on this medication, and magnesium supplementation may be required. Apart from electrolyte disturbances, the most commonly reported adverse effect of this medication was constipation. Although it was originally recommended to separate patiromer from other drugs by 6 hours, newer studies indicate that patiromer can be administered 3 hours before or 3 hours after other medications. While it is recommended that all drugs be separated from patiromer, the most notable drugs that interact with this medication include metformin, levothyroxine, and ciprofloxacin.[7,8]

The initial dose of patiromer is 8.4 grams by mouth once daily. This dose can be adjusted as needed to a maximum dose of 25.2 grams daily to reach the desired potassium concentration. The dose should be adjusted after an interval of at least one week by an increment of 8.4 grams. Patiromer is available as a powder for reconstitution that should be stored in the refrigerator before use. Each dose can be mixed with 1/3 cup of water. Half the water can be poured into a glass followed by the patiromer powder. After stirring these components, the rest of the water can be added and stirred. The reconstituted solution will be cloudy. The mixture should be swallowed immediately after

Table 3.[6,10]

Comparison of Potassium Binding Agents			
	SPS (Kionex®; SPS®)	**Patiromer (Veltassa®)**	**ZS-9 (Lokelma®)**
Selectivity for Potassium	Nonselective; also binds magnesium and calcium	Selective; also binds magnesium	Highly selective; also binds ammonium
Initial Dosing	15g one to four times daily	8.4g once daily with food	10g three times daily for 48 hours for initial treatment
Maintenance Dosing	Not recommended for maintenance	Adjust as needed by 8.4g increments to maximum of 25.2g daily	5-10g once daily with food; adjust as needed by 5g to maximum 15g daily
Dosage Forms	Powder for suspension available in 454g jar; premade oral suspension in 16 oz bottle and 60 mL jar	Single-use packets containing 8.4g, 16.8g, or 25.2g. Available as single packets, in boxes of 4, or boxes of 30.	Single-use packets containing 5g or 10g. Available as single packets or in boxes of 30
Sorbitol Content	~20 g per 60 mL of commercially prepared suspension	4 g per 8.4 g dose	NO sorbitol content
Common Adverse Effects	Nausea, vomiting, constipation, hypernatremia, hypocalcemia, hypomagnesemia, hypokalemia, sodium retention	Constipation, diarrhea, abdominal discomfort, hypomagnesemia	Edema, hypokalemia
Miscellaneous Pearls	Can be given as enema	Store in refrigerator	
Pharmacokinetics	Onset: 2 to 6 hours Duration: 6 to 24 hours	Onset: 7 to 48 hours Duration: 12 to 24 hours	Onset: 1 to 6 hours Duration: 4 to 12 hours
Price (AWP)	$22 per 15g/60 mL	$36 per 8.4 gram packet	$27 per 5 gram packet

reconstitution. If powder remains in the glass, add more water, stir, and drink immediately.[7,8]

Patiromer was studied in hyperkalemic patients with CKD on stable doses of at least one renin-angiotensin-aldosterone system inhibitor in the OPAL-HK trial. In patients with a baseline potassium of 5.1 to <5.5 mEq/L, the serum potassium was reduced by 0.65 + 0.05 mEq/L after 4 weeks of treatment. In patients with a baseline potassium of 5.5 to <6.5 mEq/L, the serum potassium was reduced by 1.23 + 0.04 mEq/L after 4 weeks of treatment. During the 4-week treatment period, 60% of patients had a recurrence of hyperkalemia with a potassium level greater than 5.5 mmol/L in the placebo group, while only 15% in the patiromer group had a recurrence of hyperkalemia. The continued use of patiromer was evaluated in patients with CKD and type 2 diabetes mellitus on RAAS inhibitor therapy in the AMETHYST-DN trial. In this study, a statistically significant decrease of serum potassium was maintained for 52 weeks with a reduction in the recurrence of hyperkalemia in patients that received patiromer when compared to those receiving placebo.[9,10]

ZS-9

Sodium zirconium cyclosilicate (Lokelma®; ZS-9) is another novel agent used for the management of potassium levels. ZS-9 is a non-absorbed zirconium silicate that binds potassium in exchange for hydrogen and sodium. ZS-9 is selective for potassium, even in the presence of calcium and magnesium. Each 5-gram dose of ZS-9 contains 400mg of sodium, which has the ability to lead to edema in patients treated with ZS-9. In clinical trials, edema was generally mild to moderate in severity and was more frequently seen in patients treated with 15-gram doses. For this reason, patients who should restrict sodium intake or are prone to fluid overload should be educated on and monitor for signs of edema. This is especially significant in patients with chronic kidney disease and heart failure who are likely using this medication for the control of hyperkalemia. ZS-9 can transiently increase gastric pH and have an effect on the absorption of drugs that exhibit pH-dependent solubility. For this reason, medications should be administered 2 hours before or 2 hours after ZS-9. Notable drug interactions for this medication include clopidogrel, dabigatran, and warfarin. [11,12]

The initial dose of ZS-9 is 10 grams three times daily for 48 hours, after which the dosing is 10 grams once daily. The dose can be adjusted to obtain desired potassium levels after an interval of at least one week by increments of 5 grams. Maintenance dosing ranges from 5 grams every other day to 15 grams daily. Patients should empty the contents of the dose packet into at least 45mL of water, stir well, and drink immediately. If powder remains in the glass, more water can be added, and the mixture should be stirred and ingested immediately. [11,12]

In the initial approval study, ZS-9, when compared to placebo, was associated with a decrease in serum potassium levels within 48 hours. The mean reduction after the first 10 g dose was 0.11 mmol/L. The mean reduction in potassium level was greater on day 2, with a mean reduction of 1.1 mmol/L in patients with a potassium level of greater than 5.5 mEq/L. ZS-9 lead to a significant decrease in serum potassium levels when compared to placebo without a significant difference in the safety profile. The HARMONIZE trial demonstrated that ZS-9 was able to reduce serum potassium levels to normokalaemia within 24 hours in 84% of patients and within 48 hours in 98% of patients. The HARMONIZE trial extended past the initial 48 hours for 28 days of treatment, and the serum potassium was significantly reduced for all doses of SZ-9 when compared to placebo with 80%, 90%, and 94% of patients maintaining normokalaemia with 5g, 10g, and 15g doses respectively. In a 12-month phase 3 study, 88% of patients were able to maintain a mean serum potassium value <5.1 mmol/L and 99% of participants were able to maintain a mean serum potassium of <5.5 mmol/L. In this study, 87% of patients on RAAS inhibitors at baseline were able to continue therapy or have their dose increased and maintain normokalaemia. In RAAS inhibitor naïve patients, 14% were able to initiate a RAAS inhibitor and maintain normokalaemia.[13,14,15]

When the new drug application was submitted to the FDA for approval, ZS-9 was rejected twice due to concerns about the manufacturing process. It should be noted that this rejection did not require the submission of any new clinical data, as the concern was related to a pre-approval manufacturing inspection, rather than issues with safety or efficacy.[16]

CONCLUSION

Potassium is an intracellular cation that is involved in many processes in the body. Drugs and disease states that influence the RAAS can lead to hyperkalemia. Hyperkalemia limits the treatment of many patients with disease states such as heart failure, CKD, and diabetes. Novel potassium binding agents may allow patients to achieve appropriate doses of guideline directed therapies that exert their action on the RAAS; the presence of an elevated serum potassium concentration does not need to limit treatment options in these patients. Veltassa® and Lokelma® are agents that have been studied for this purpose as their use over extended periods of time is considered safer and better tolerated than SPS. Please see for a comparison of potassium binding agents.

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CONTINUING EDUCATION

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A Comparison of Novel and Longstanding Potassium Binding Agents

INSTRUCTIONS: After reading the continuing education article, photocopy or detach this page. Take the quiz below. A grade of 70 percent or better is required to earn 2.0 hours of continuing education credit. This is a free service for MPhA members. Email submit or scan your answers into info@mspharm.org to have your quizzes graded and certificate emailed back to you. If mailing, please include self-addressed stamped envelope.
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1. What is the normal range of potassium in the body?
   a. 3.5 to 5 mEq/L b. 8 to 10 mEq/L
   c. 1 to 3 mEq/L d. 10 to 15 mEq/L
2. At what concentration is a patient considered "hyperkalemic"
   a. >4.5 mEq/L b. >3.0 mEq/L
   c. >5.5 mEq/L d. >6.0 mEq/L
3. Which of the following drug classes is NOT commonly associated with hyperkalemia?
   a. ACE inhibitors b. NSAIDs
   c. ARBs d. Beta Blockers
4. Hyperkalemia can be caused by all of the following EXCEPT:
   a. extracellular shifts of potassium
   b. impaired potassium excretion
   c. increased potassium ingestion
   d. increased potassium excretion
5. The majority of potassium is found in the _____ space.
   a. Extracellular b. Intracellular
   c. Interstitial d. Intracranial
6. The _____ is/are responsible for the majority of potassium excretion.
   a. Liver b. Kidneys
   c. Sweat d. Gastrointestinal Tract
7. Sodium polystyrene sulfonate is the generic name for
   a. Veltassa® b. Lokelma®
   c. Patiromer d. Kionex®
8. Veltassa® is the brand name for
   a. Patiromer
   b. Sodium polystyrene sulfonate
   c. Sodium zirconium cyclosilicate
   d. Sevelamer carbonate
9. Which of the following has notable drug interactions with drugs having pH dependent solubility, such as metformin, levothyroxine, and ciprofloxacin?
   a. Patiromer
   b. Sodium zirconium cysilicate
   c. Sodium polystyrene sulfonate
   d. Sevelamer carbonate
10. Of the following which agent has the greatest risk of intestinal necrosis?
    a. Patiromer
    b. Sodium zirconium cysilicate
    c. Sodium polystyrene sulfonate
    d. Sevelamer carbonate
11. Which of the following agents has hypomagnesemia as its most common side effect?
    a. Patiromer
    b. Sodium zirconium cysilicate
    c. Sodium polystyrene sulfonate
    d. Sevelamer carbonate
12. Which agent notes significant interactions with anticoagulants including warfarin, dabigatran, and clopidogrel?
    a. Patiromer
    b. Sodium zirconium cysilicate
    c. Sodium polystyrene sulfonate
    d. sevelamer carbonate
13. Which agent below is the least expensive?
    a. Patiromer
    b. Sodium zirconium cysilicate
    c. Sodium polystyrene sulfonate
    d. Veltassa®
14. Which food has the highest potassium content per serving?
    a. Baked potato b. Sweet potato
    c. Avocado d. Banana
15. Which agent must be stored in the refrigerator prior to reconstitution?
    a. Patiromer
    b. Sodium zirconium cysilicate
    c. Sodium polystyrene sulfonate
    d. sevelamer carbonate
16. Lokelma® should be administered at least _____ apart from other drugs.
    a. 1 hour b. 2 hours
    c. 3 hours d. 4 hours

Medical Marijuana (Cannabis) in Mississippi

Cliff Osbon, RPh • Chair, Government Affairs Committee • November 10, 2020

On Tuesday, November 3, 2020, 74% of Mississippians that went to the polls voted to legalize medical marijuana in our state. There were two competing ballot initiatives to choose from, as well. The majority of voters selected Initiative 65. Mississippi now becomes the 35th state to legalize medical marijuana, following neighbors like Arkansas and Louisiana, who have already done so.

Initiative 65 was a ballot initiative, begun outside of the legislature, by citizens of Mississippi who wanted to make medical marijuana legal in our state. In accordance with our Constitution, a required number of certified signatures had to be received from each of the congressional districts on a petition. Over 228,000 registered voters signed that petition and had their signatures certified by their county officials.

The legislature had offered a competing ballot initiative, 65A, but voters favored 65. At the time I am writing this article, there is a court case pending in Madison County, where the City of Madison has opposed this ballot initiative and the court is set to resolve this matter soon.

By Initiative 65, the Mississippi Department of Health is defined as the regulatory authority for medical marijuana. They now have until mid-2021 to create and finalize any regulations necessary to define how this program will operate. In late summer 2021, the Department of Health must begin to award licenses to companies or individuals who with to grow, test or dispense medical marijuana. Additionally, companies that wish to work with marijuana flower and create other dosage forms such as creams, edibles or other items must be licensed.

As of yet, we do not know the specifics of how the Department of Health (DOH) will license each entity but we do know that in every state where medical marijuana has been legalized, testing requirements have been put into place. These typically include testing for potency to ensure dose accuracy, testing for contamination by heavy metals or pesticides and sometime other tests.

Also, in late 2021, the DOH will begin to issue medical marijuana cards to qualifying patients. To qualify, a patient must visit a Mississippi licensed physician and have a confirmed diagnosis that is included in the 22 approved disease states. These include seizure disorders, ALS, PTSD, cancer and some chronic pain among other conditions. Once the physician has certified the patient's diagnosis, the patient will be able to apply to the DOH, pay a fee of up to $50.00 and obtain a medical marijuana purchase card that is valid for one year. Each year, they will have to repeat this certification process and they must present the card and ID to make a purchase at a dispensary.

While only about one in four voters opposed medical marijuana, they may be pleased to learn that Initiative 65 has some restrictions that they may appreciate. Dispensaries and licensed facilities may not be located closer than 500 feet to a pre-existing church, school or licensed child-care center. Additionally, municipalities may impose zoning ordinances to determine where these facilities may be located (though they cannot be more restrictive than ordinances that determine where businesses like community pharmacies can be located).

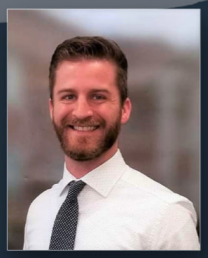
The Mississippi Board of Pharmacy took a public position on this matter, seeking to ensure that Mississippi, like some other states, requires that dispensaries make a consulting pharmacist available to patients purchasing medical marijuana. In other states with similar requirements, like Arkansas, the pharmacist is not an employee of the dispensary, but is an independent consultant.

The Mississippi Pharmacists Association also took a public position on this matter. MPhA urged the FDA, DEA and State of Mississippi work together to resolve any legal and regulatory conflicts that might surround this matter. Additionally, MPhA urged regulatory authorities to continue to seek more clinical research into medical marijuana, provide education for health care practitioners about medical marijuana and seek to ensure that pharmacists are involved in managing the care of patients receiving medical marijuana, similar to the position taken by the Board of Pharmacy.

MPhA will continue to monitor this important topic as the DOH creates the regs that define how this program will function and we will update our members as this information becomes available.

New Practitioner Spotlight

Michael Bounds, Pharm D



Hometown or Current Residence: Pontotoc, MS

Pharmacy School & Graduation Year:
University of Mississippi 2018

Current Job Position
Assistant Professor of Pharmacy Practice, William Carey University School of Pharmacy

Practice Site: Singing River Health System, Infectious Diseases

Hobbies / Interests: Traveling, playing music, reading

Why did you join the Mississippi Pharmacists Association (MPhA)?
Pharmacy is a small world, and in Mississippi it's even smaller. It's important that we stay connected to one another and combine our efforts to make positive changes for our profession within our state. The Mississippi Pharmacists Association and Mississippi Society of Health System Pharmacists organizations are the best platforms we have for doing just that.

What is your favorite part of your job?
The best part about my job is the variety. As a clinical faculty member, I get to spend some days as a teacher, some as an administrator, and some as a clinical pharmacist. Often times I'm wearing all three hats at once. The variety keeps me from getting too fatigued by one particular work schedule.

Interested in being featured? Answer our Questionnaire Here: https://bit.ly/388poMQ

Practitioner Spotlight

Shanna Whitwell, Pharm D

Auburn Harrison School of Pharmacy, 2011
Pharmacy Manager at Baptist Family Pharmacy
Hobbies: Reading and spending time with my 3 kids

We are the most accessible healthcare professionals. We have the ability to help impact the education and understanding of patient's health issues.

New Practitioner Spotlight

Ashton Smith, Pharm D

Hometown: Jackson, MS
Current Residence: Richland, MS
Pharmacy School: University of Mississippi School of Pharmacy, 2019
Current Job Title: Public Health Pharmacist at the Mississippi State Department of Health Pharmacy
Hobbies: Time with family, attending sporting events, interior decorating, baking

Why did you join the Mississippi Pharmacists Association (MPhA)?
To connect with other pharmacists around the state and keep up-to-date with what is new in the pharmacy world!

How do new practitioners make an impact on the pharmacy profession and healthcare in Mississippi?
New practitioners enter the field with a clear mindset and abundant opportunity to introduce innovative practices into the profession of pharmacy.

What advice would you give yourself if you were to be a new graduate again?
Enjoy every opportunity to learn something new- even if it does not relate to your specific job. Keep an open mind!

New Practitioner Spotlight

Jordan Marie Ballou, PharmD BCACP

Hometown: Morehead City, NC
Current Residence: Oxford, MS
Pharmacy School: Campbell University, 2015
Current Job Position & Practice Site: Clinical Assistant Professor of Pharmacy Practice, University of Mississippi
Practice Site: Tyson Drugs, Holly Springs, MS
Hobbies / Interests: Reading, Music, Boating

Why did you join the Mississippi Pharmacists Association (MPhA)?
When I was in pharmacy school, it was instilled in me that finding your "organization home" was something for everyone. For me, that became APhA and subsequently MPhA. I just feel like the state level is where we can really let our voices be heard and make changes that improve the profession of pharmacy.

What challenges have you encountered in the transition from student to resident and/or practitioner?
Networking was the difficult part for me. I had moved to a new state and didn't know anyone. MPhA really helped me to meet other practitioners from across the state in a variety of practice areas.

Interested in being featured? Answer our Questionnaire Here: https://bit.ly/388poMQ

Practitioner Spotlight

Jennifer Duncan, RPh

University of Tennessee Health Science Center, 1988
General Manager, Omnicare of Jackson
Hobbies: Reading, writing, & theatre

" We are incredibly important, often overlooked resources to both patients and other members of the healthcare team. When we are actively involved in patient care, we support better outcomes and more effective use of limited healthcare dollars. "

PRACTITONER SPOTLIGHT

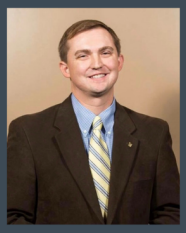
Kimberly, Allen, Pharm D.

University of Mississippi School of Pharmacy, 2017
Current Residence: Jackson, MS
Job Title & Practice Site: Walgreens - Pharmacy Manager & MTM Lead
Hobbies / Interests: watching Ole Miss sports, running, traveling

Pharmacists play an invaluable role in healthcare in the state, working with other healthcare providers to provide and increase access to high-quality care. Pharmacists continue to be leaders in providing medication-related services. As the scope of pharmacy continues to grow and change, pharmacists in the state are playing more of a role in preventative health services and individualized patient care.

Practitioner Spotlight

Jonethan Morris, Pharm D



Current Residence: Biggersville, MS
Pharmacy School: University of Mississippi School of Pharmacy, 2011
Current Job Title: Pharmacy Manager at Walgreens # 1913 in Corinth
Hobbies: Spending time with my girls, Camping, Boating, Hunting, Hay farming, raising ducks, chickens, and horses

Pharmacists impact healthcare in MS by increasing awareness to state legislators. We also have the ability to improve health outcomes in the community by being a trusted, reliable, and available healthcare source.

Being able to improve health outcomes for family and friends in my community motivates me to get up to work every morning!

Practitioner Spotlight

ANN FRANKLIN, PHARM D

Current Residence: Cleveland, MS
Pharmacy School: University of MS, 2012
Pharmacy Manager at Walgreens
Hobbies/Interests: Spending time with my boys, exploring new places, lactation consulting, volunteering

MPha is the voice of pharmacists in Mississippi. If we all unite as pharmacists in our state, we can help drive the changes that we all want to see in our profession.

Pharmacists are the most accessible healthcare provider. Our underinsured have access to us at no charge, seven days a week to recommend care or over the counter medications to treat problems that might have cost them their electric bill money at the doctors office. Pharmacists ability to immunize not only protects patients from preventable disease, but frees time up for other healthcare workers to assess chronic illness.

PRACTITIONER SPOTLIGHT

I CAN DISTINCTLY REMEMBER ONE TIME ANSWERING A CALL WITH A FRANTIC NEW MOM ON THE OTHER END. HER FIRST WORDS AFTER INTRODUCING MYSELF, "THANK GOD IT'S YOU TONIGHT! YOU ARE ALWAYS THE MOST HELPFUL!" THAT STUCK WITH ME AND HAS BEEN MY MOTIVATION. WE ARE THE ONES PEOPLE SEEK OUT. BEING THAT PERSON HAS ALWAYS BEEN MY FAVORITE PART.

UNIVERSITY OF MISSISSIPPI, 2012
PHARMACIST AT COVENANT PHARMACY
HOBBIES / INTERESTS: TRAVELING (SPECIFICALLY TO DISNEY), COOKING WITH MY HUSBAND, BAKING, READING, COMMUNITY THEATRE

EMILY BOND, PHARM D.

Practitioner Spotlight

Current Residence: Madison, MS
Pharmacy School: University of Mississippi Class of 2007
Current Job Title: Clinical Services Pharmacist and Residency Program Director, Walgreens Area 88
Hobbies / Interests: Traveling - Volleyball & Tennis - Running - Reading - Being outside with my family

I believe it's important to be involved because we are the future of pharmacy. Change will not happen spontaneously. We must work to advance our practice and we cannot do it alone. Working with others will not only advance pharmacy services as a whole across the state (hopefully) but also allows you to personally meet and learn from those you would not normally have crossed paths with in your current practice setting.

Olivia Strain, Pharm D

Practitioner Spotlight

Your voice needs to be heard, and united voices are heard much better! Pharmacy desperately needs everyone's help in dealing with today's problems, opportunities and obstacles.

Randy Calvert, RPh

Director of Pharmacy- Mississippi Sports Medicine and Orthopedic Center/ Surgery Center
Madison, MS
University of MS, 1980

PRACTITONER SPOTLIGHT

Beau Cox, Pharm D

Brandon, MS
University of MS, 2005
Tara Pharmacy-Executive Director | MPhA-Executive Director
Hobbies / Interests: Politics. Hunting. Fishing.

Why should others join MPhA?
Networking. Legislative advocacy. Education.

I feel that pharmacists really make a difference in the health of the public and it encourages me to fight to expand what pharmacists are able to do and get reimbursed for it.

Brandon, MS
University of MS SOP, 1985
Executive Director, MS Board of Pharmacy
Hobbies / Interests: Spending time with my 7 grandchildren!

Our ultimate mission at the Board of Pharmacy is to have the safety of the citizens of MS as our primary goal. I enjoy the global position that I am in to deal with all aspects of this safety, whether it be licensing, compliance, prescription monitoring, or the Pharmacy Benefit Managers. These are very broad categories and I never have a day that is the same as the day before. There is always something new to learn.

It is important to be a part and to contribute whenever possible to our profession. The organization is only as strong as its membership. There needs to be a unified front from all pharmacists to get new laws passed that would help the profession do what we do best - serve our patients.

SUSAN MCCOY
PRACTITONER SPOTLIGHT

Practitioner Spotlight

Peyton L Herrington, Pharm D

Current Residence: Flowood, MS

Pharmacy School: University of Mississippi School of Pharmacy, 2006

Current Job: Specialty Pharmacist at the Adult Special Care Clinic at UMMC

Hobbies: Camping, Biking, Swimming, and Teaching my kids science and reading

MPhA is a group that can allow us to gather individual pharmacists voices into a louder chorus which works for the advancement of pharmacy in our state. This will in turn lead to more positive health outcomes for the citizens of MS. We have multiple state pharmacy associations and we must find a way to foster cooperation and common goals between our representative organizations so we can have the best shot at voicing the ways that pharmacy can improve the health of citizens in our state.

Practitioner Spotlight

Wilma Johnson Wilbanks

University of Mississippi, 1981
Staff pharmacist at Walgreens
in Cleveland

Why should others join MPhA? Why is it important to be a member of your state association?
MPhA represents all pharmacists, and our collective voice is louder and more effective than those of individuals. It is crucial for pharmacists to join together so that the profession is represented when healthcare decisions are made legislatively. Pharmacy must have a seat at the table, and joining MPhA makes that possible.

How do pharmacists impact healthcare in Mississippi?
Mississippi is one of the most medically under-served parts of the country, and empowering pharmacists to provide healthcare services, in addition to filling prescriptions, benefits the citizens of our great state. If one just examines the immunization statistics since pharmacists began immunizing, it is very clear that pharmacy services move the needle significantly for patients in the areas of greatest need.

Practitioner Spotlight

What motivates you to get up for work every morning?
As a pharmacy owner, the challenge to make my team better every day motivates me

How do pharmacists impact healthcare in Mississippi?
We're the most easily accessible health care provider, always on the frontline

BOB LOMENICK
POTTS CAMP, MS
OWNER, TYSON DRUGS INC.
UNIVERSITY OF MS, 1977

Joining MPhA is a great way to network with colleagues across the state and to keep in touch as well as keep up to date on current Pharmacy topics local and nationwide.

Mollie Spencer, Pharm D

Pharmacy School: University of MS, Pharmacy School Class of 2011
Current: Owner and PIC at Community Pharmacy
Hobbies / Interests: Art and running after my little boys

Practitioner Spotlight

PRACTITIONER SPOTLIGHT

Cliff Osbon

Consultant, Fort Miro Professional Services, LLC.
University of Louisiana-Monroe, 1984

Hobbies: Backpacking, Day Hiking, Working Out, Boating, Reading, Live Music, Travel, Spending Time in NOLA French Quarter at our apartment there, SEC Football

As a pharmacy business consultant, I guide other businesses to operate efficiently and profitably, allowing them to grow and to continue to serve others.

We are the most accessible and most accessed healthcare provider.
We have a very high level of public trust.

AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

CORRESPONDING RESPONSIBILITY

The opioid crisis, and the multitude of court cases around the country that followed from it, have placed additional scrutiny on the duty of Corresponding Responsibility for pharmacists. This concept is not new. The regulation has been in effect for many years. The regulation states;

> "*A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.*"[1] (emphasis added)

Recent activity in the Multi District Litigation (MDL) court in Ohio[2] focused on Corresponding Responsibility. Judge Dan Polster issued an order on August 6, 2020 denying the pharmacy defendants' motion to dismiss the complaint against them. The pharmacy defendants' motion to dismiss asserted that the duty of Corresponding Responsibility falls on the pharmacist, not on the pharmacy. Therefore, the pharmacies had no duty to take any action during the opioid crisis. The judge disagreed and denied the motion.

The judge then went on in his ruling to outline what steps the pharmacies should have taken and the information that should have been provided to their staffs. His opinion was very detailed and involved data mining and data analytics. The pharmacy defendants filed a motion to reconsider on August 25, 2020 because they believed the requirements outlined by the judge were excessive and beyond the requirements imposed by statute

1 21 C.F.R. Section 1306.04(a)

2 https://www.ohnd.uscourts.gov/sites/ohnd/files/MDL2804_2709.pdf

and DEA regulations. The motion to reconsider was denied on September 22, 2020. However, the judge did acknowledge that his previous order was not intended to prescribe the actions that the pharmacy defendants should have taken. The question of whether the actions they did take were sufficient under the law is a question of fact for the jury to decide.

The Corresponding Responsibility regulation does specifically cite pharmacists. However, the assertion by the pharmacy defendants to say that they have no duty here seems to be an extreme position. Pharmacies are registrants too. As registrants under the Controlled Substances Act, pharmacies also have a duty to prevent abuse and diversion of controlled substances. The Administrator of the DEA has the authority to suspend or revoke a pharmacy's registration if it appears to create a danger to the public health or safety to allow the pharmacy to continue. While the Corresponding Responsibility regulation refers to pharmacists, it seems unrealistic to leave the dispensing pharmacist unsupported in the performance of their duty. The judge's initial ruling also seems to be an extreme position. As is many times the case, the best solution is somewhere in the middle.

Pharmacy owners need to be clear with their staff about diversion and addiction prevention. Establishing a culture of judicious and sensible dispensing of controlled substances starts with owners and managers of the pharmacy. Owners who concentrate on volume will get less discernment from their staff pharmacists as the staff will likely feel pressure to fill all controlled substance prescriptions. The DEA believes that the law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. The pharmacist is making a real-time decision with the conflicting pressures of prevention of diversion or addiction and patient care. It seems unreasonable that the pharmacy has no duty in this situation. Yes, the pharmacist is on the frontline and has to make the decision, but the pharmacy and its owner create the environment where this decision must be made. The pharmacists can't make these decisions in a vacuum. Discussion with the prescriber will probably be necessary. Perhaps discussions with the patient will also be necessary. The pharmacist can then use this information in conjunction with their professional knowledge, experience and judgment.

Another portion of the filings in this case discussed the pharmacy's duty to train their staff pharmacists to properly handle prescriptions for opioids and to establish policies and procedures to prevent their pharmacies from facilitating the diversion of opioids. While this duty is not explicitly spelled out in the DEA regulations, it seems to be implied in the pharmacy's duty to protect public health and safety. The judge's initial ruling went into a lot of detail on what he thought was acceptable and went far beyond what someone could easily infer from the regulations. The judge stepped back from this initial position when he denied the motion for reconsideration.

What can we learn from this case? There will be a continued focus on the doctrine of Corresponding Responsibility going forward. The law continues to evolve and yesterday's solution will not be sufficient for tomorrow. Pharmacists have an independent duty to the patient and are not merely order takers for the physician. Following the physician's orders is no longer a sufficient defense when a patient is harmed by a prescription when the pharmacist could have intervened. The pharmacy needs to create a team atmosphere and assist their pharmacists as they make these important patient care decisions.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Mississippi Pharmacists Association

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Your membership matters to pharmacy in Mississippi

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Today's date: _____ /_____ /_____

Name:

_____
LAST FIRST INITIAL

Mailing address:

_____
STREET ADDRESS APT/SUITE

_____
CITY STATE ZIP

Primary phone: (_____) _____ - _____

Email: _____

Birthday: _____ /_____ /_____

Area of Profession:

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☐ Clinical/Health System ☐ Technician

☐ Consultant ☐ Industry ☐ Student

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Employer: _____

Employer City/State: _____

Work phone: (_____) _____ - _____

Work Email: _____

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Dues and Contributions:

☐ Student	$0
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☐ Pharmacy Technician	$50/year
☐ Joint Pharmacist (husband/wife)	$200/year
☐ Pharmacist – retired and over 65	$75/year
☐ Non-pharmacist/Associate	$100/year

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341 Edgewood Terrace Dr. • Jackson, MS 39206
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