MISSOURI BOARD OF PHARMACY

NEWSLETTER

JUNE 2024

TABLE OF CONTENTS

CONGRATULATIONS

The Missouri Board of Pharmacy has been awarded the 2024 Fred T. Mahaffey award from the National Association of Boards of Pharmacy (NABP) for its outstanding contributions to:

(1) the protection of the public health and welfare through the enforcement of state and federal laws and regulations, and

(2) the advancement of the objectives and goals of NABP.

Thank you to all current and former Board members and Board staff for their dedication and commitment to the public and the state of Missouri.

Vice-President Christian Tadrus (on right) accepting NABP's 2024 Fred T. Mahaffey Award.

UPCOMING BOARD MEETINGS

JUNE	JULY	AUGUST	SEPTEMBER
12	10-11	14	11
Virtual	Jefferson City, MO	Virtual	Virtual

BOP ANNUAL REPORT

The Board's 2023 Annual Report is available online. Here are some interesting statistics as of June 30, 2023:

LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,344 (+3.5%)
Drug Distributor Manufacturer Registrants	100 (+4.16%)
Drug Outsourcers	47 (+9.3%)
Intern Pharmacists	1,264 (-28%)
Pharmacists (active and inactive)	11,833 (-2.9%)
Pharmacists (temporary)	11 (- 15%)
Pharmacies (instate, non-resident and temporary)	2,842 (+8%)
Pharmacy Technicians	20,100 (+.44%)
Third-Party Logistics Provider (licensed & temporary)	241 (+17.5%)
TOTAL	**37,782 (-1.2%)**

- New license applications decreased by 6.5%, with a 10.9% decrease in new pharmacist applicants, 28% decrease in intern pharmacists and 8.5% decrease for pharmacy technicians.
- The 28% decrease in intern pharmacists corresponds with the 16% nationwide decline in pharmacy school enrollment reported by the American Association of Colleges of Pharmacy in FY22.
- 11,549 active pharmacists and 284 inactive pharmacists were licensed by the Board at end of FY23. 7,008 pharmacists reported a Missouri address.
- Total licensed pharmacies included 1,443 resident, 1,324 non-resident, & 75 temporary pharmacies.
- 73 Missouri located pharmacies closed business in FY 23, impacting 19 Missouri counties (does not include change of ownership closures). Currently, two (2) Missouri counties do not have a licensed pharmacy (Schuyler, Knox).
- 1,034 inspections were conducted with violations noted in 66.2% of inspections.
- 285 investigations were completed (+8.7% increase).
- 507 complaints were received/opened. Top complaint categories were: License Application Cases, Disciplinary Action in Other States, Improper/Unauthorized Dispensing, and Improper Controls/Security.

- The Board issued final disposition on 624 complaints/cases (includes complaints from prior fiscal years disposed of in FY 23). Approximately 11% were resolved with discipline; 89% were resolved without discipline (e.g., no further action/ administrative letter)

- 32 total disciplinary actions were taken, representing a 49.5% decrease since FY 2019.

Review the full FY23 Annual Report on the Board's website.

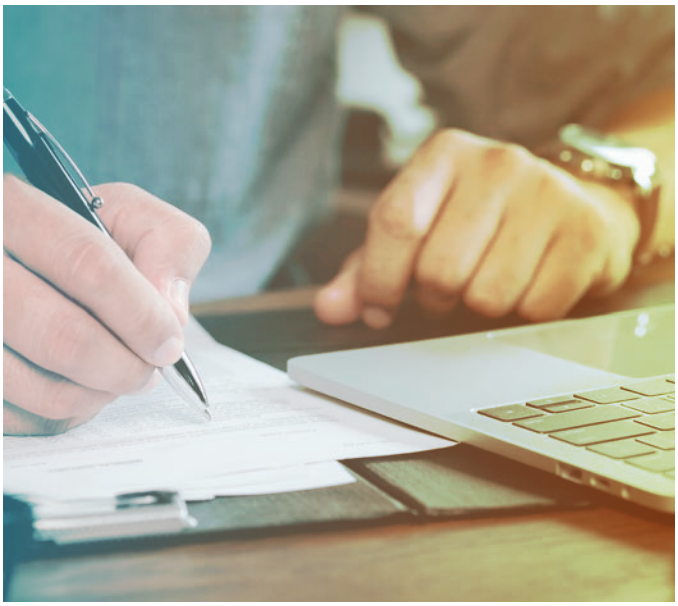
DON'T FORGET YOUR CE

Pharmacist renewals will be open soon! Renewals will be e-mailed to your e-mail address of record around August 1, 2024, and must be completed/submitted before October 31st. E-mail address changes can be submitted online at https://info.mo.gov/pr-forms/pharmacy/pharmacists-coa.php

Pharmacists are required to have thirty (30) hours of continuing education (CE) to renew. CE must have been earned between November 1, 2022, and October 31, 2024 and must be completed before you renew. Up to a $1,000 delinquency fee will apply for late/delinquent CE.

See rule 20 CSR 2220-7.080 for complete CE requirements; A CE chart is also available in the Missouri Pharmacist Practice Guide **(Section B.3).**

**New pharmacist licenses issued by the Board on or after November 1, 2023 are exempt from CE for the 2024 renewal period.



E-ALERTS

Sign up on the Board's website to receive e-alerts on Board news, compliance updates and licensing changes.

BOARD NOTIFICATIONS

The Board continues to observe compliance issues regarding late Board notifications. A summary of common notification violations is listed below. ***This list is not exhaustive; other notification requirements apply that are not listed below.*** Interested individuals should review the Missouri Pharmacy Practice Act and the Board's rules for all compliance requirements. A summary of key notification requirements is also included in Section E.16 of the Missouri Pharmacy Practice Guide.

Individual Notification Requirements

WHAT NEEDS TO BE REPORTED?	WHEN?	STATUTE/RULE
Address changes (all licensees/ registrants) **Complete form on Board's website*	Within fifteen (15) days	20 CSR 2220-2.010(1)(N)
Employment changes (all licensees/registrants) **Complete form on Board's website*	Within fifteen (15) days	20 CSR 2220-2.010(1)(N)
Exclusion from any state or federal healthcare program for fraud, abuse, or submitting any false or fraudulent claims or request for payment/ reimbursement (e.g., Medicare, Medicaid, MO HealthNet) **Submit on Board's website*	Within fifteen (15) days after action/exclusion	§ 338.075; 20 CSR 2220-2.010(4)
Final adverse licensing action against the licensee/registrant by another state, jurisdiction, or governmental agency. (All licensees/ registrants) **Submit on Board's website*	Within fifteen (15) days after action/resignation	§ 338.075; 20 CSR 2220-2.010(4)
Surrender of a pharmacist, intern, technician, pharmacy, drug distributor/manufacturer or drug outsourcer license while under disciplinary investigation by another state, jurisdictional or governmental entity or in lieu of discipline/adverse action. **Submit on Board's website*	Within fifteen (15) days after action/resignation	§ 338.075; 20 CSR 2220-2.010(4)

Pharmacy Notification Requirements

WHAT NEEDS TO BE REPORTED?	WHEN?	STATUTE/RULE
Breach of Security (Bd. registered offsite warehouse/storage facility)	Within fifteen (15) days of breach	20 CSR 2220-2.010(1)(J)
Breach of Security (Data processing systems or confidential documents at an offsite location where non-dispensing activities are performed)	Within seven (7) days of breach	20 CSR 2220-6.055(2)
Breach of Security (Remote Data Entry Sites)	Within seven (7) days of breach	20 CSR 2220-2.725(3)(A)
Dispensing Errors That Reach the Patient (Technology-Assisted Verification Systems)	Within ten (10) days of discovery.	20 CSR 2220-2.012(5)
Final disciplinary action against a technician or a qualifying voluntary resignation under § 338.055 **Use Technician Disciplinary Action Form on the Board's Website*	Within fifteen (15) days after action/resignation	§ 338.013; 20 CSR 2220-2.010(4)
Final disciplinary action against a pharmacist employed to provide health care services or a pharmacist's voluntary resignation against whom a complaint/report has been filed that could have led to discipline. **Submit on Board's website*	Within fifteen (15) days after action/resignation	§ 383.133

Exclusion from any state or federal healthcare program for fraud, abuse, or submitting any false or fraudulent claims or request for payment/ reimbursement (e.g., Medicare, Medicaid, MO HealthNet) **Submit on the Board's website*	Within fifteen (15) days after action/resignation	§ 338.075; 20 CSR 2220-2.010(4)
Final adverse licensing action by another state, jurisdiction, or governmental agency. **Submit on Board's website*	Within fifteen (15) days after action/resignation	§ 338.075; 20 CSR 2220-2.010(4)
Surrender of a pharmacy, drug distributor/manufacturer/outsourcer license while under disciplinary investigation by another state, jurisdictional or governmental entity or in lieu of discipline/ adverse action. **Submit on Board's website*	Within fifteen (15) days after action/resignation	§ 338.075; 20 CSR 2220-2.010(4)
Pharmacy Remodeling	Remodeling affidavit & project plans filed with Board within thirty (30) days before the change	20 CSR 2220-2.020(4)(A)
PIC Change	PIC Change application must be filed within fifteen (15) days after new PIC is designated. **Pharmacy may not operate without a PIC or designated interim supervising pharmacist.*	20 CSR 2220-2.010(1)(M)
Compounding (Sterile & Non-Sterile): Recall of a compounded preparation deemed to be misbranded or adulterated.	Within three (3) business days after the recall. ***Prescriber notification also required***	20 CSR 2220-2.200(8)(C)
Sterile Compounding: Recall of a compounded preparation deemed to be non-sterile or if end-preparation testing results are out of specification.	Within three (3) business days after the recall. ***Prescriber notification also required***	20 CSR 2220-2.400(8)(C)
Sterile Compounding: Any environmental sample conducted as part of a remedial investigation that exceeds USP Chapter 797 action levels.	Within three (3) days of detection	20 CSR 2220-2.200(20)(C)
Theft/diversion of or from a medication collection receptacle under 20 CSR 2220-2.095	Within fourteen (14) days	20 CSR 2220-2.095(4)(F)
Unauthorized access to a Class R Remote Dispensing Site	Within seven (7) days of discovery	20 CSR 2220-2.680(6)(A)

REVISED STATE NALOXONE STANDING ORDER

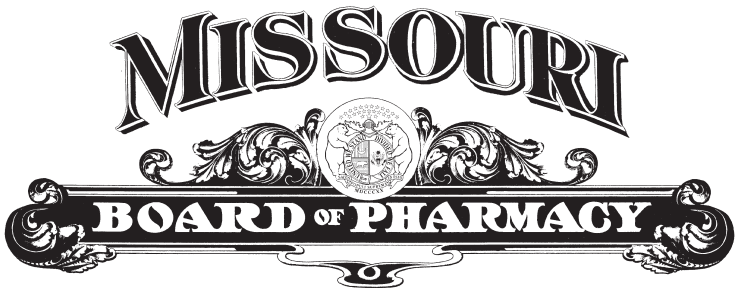
The MO Department of Health and Senior Services (DHSS) has updated the **Missouri State Standing Order for Naloxone**, effective **June 3, 2024**. The DHSS State **Standing Order for Naloxone**, dated 8/22/23 has been replaced and is no longer active.

Per DHSS, some of the key changes include:

1. Prescription updates to include the most evidence-based formulations and doses,
2. Patient eligibility updates to be more accurate, inclusive, and patient-centered,
3. Revision of refill instructions to allow additional naloxone units to be dispensed without sending refill requests to DHSS' authorizing physician's clinical practice,
4. Updated labeling and communication specifications that align with prescription bottle character limits and prescription software restrictions, and
5. Addition of primary care community health centers in the appendix list of facilities that provide treatment for substance use disorders.

A copy of the revised Standing Order for Naloxone is available on DHSS' website: https://health.mo.gov/data/opioids/pdf/naloxone-standing-order.pdf

GOLD CERTIFICATES



Congratulations to our newest "gold certificate" pharmacists who have maintained a Missouri pharmacist license for 50 years:

Randy N. Charles

Carlon R. Huff

TECH CERTIFICATION

Pharmacy technicians are not required to be certified to be registered in Missouri. However, certification from a valid entity is required for pharmacy technicians who are:

- Administering immunizations
- Administering medication by prescription order
- Performing technology assisted verification (TAV) under 20 CSR 2220-2.012
- Being remotely supervised at a Class R Remote Dispensing Site Pharmacy
- Assisting at a Class Q Charitable Pharmacy without a pharmacist present (see 20 CSR 2220-2.685 for restrictions)

Licensees/Registrants should check with the applicable certification body to ensure required certifications are still valid and active (e.g., PTCB, NHA/ExcPT). Certifications are handled by private third-party entities. The Board does not have or maintain information on certification status.

RECENT DISCIPLINARY ACTIONS

DRUG DISTRIBUTOR:

Midwest Veterinary Supply Inc, #900036, Lakeville, MN. Public Censure. Entered into a plea agreement with the United States of America in Case No. 1;23-mj-00044-PMS for shipping misbranded drugs from 2011 to 2021. Section 338.055.2 (2) and (15), RSMo.

Midwest Veterinary Supply Inc, #2012007999, Sun Prairie, WI. Public Censure. Entered into a plea agreement with the United States of America in Case No. 1;23-mj-00044-PMS for shipping misbranded drugs from 2011 to 2021. Section 338.055.2 (2) and (15), RSMo.

Midwest Veterinary Supply Inc, #2012001755, Fort Wayne, IN. Public Censure. Entered into a plea agreement with the United States of America in Case No. 1;23-mj-00044-PMS for shipping misbranded drugs from 2011 to 2021. Section 338.055.2 (2) and (15), RSMo.

Midwest Veterinary Supply Inc, #2016009525, Des Moines, IA. Public Censure. Entered into a plea agreement with the United States of America in Case No. 1;23-mj-00044-PMS for shipping misbranded drugs from 2011 to 2021. Section 338.055.2 (2) and (15), RSMo.

PHARMACIST:

Donnelly, Vicki L., #043896, Elizabethtown, KY. Public Censure. As pharmacist-in-charge, entered into an Agreed Order with the Kentucky Board of Pharmacy for multiple controlled substance losses at the Pharmacy. Failed to report Kentucky Order to the Missouri Board. Section 338.055.2 (6) and (8) RSMo.

Heuring, Brett, #2005016304, Florissant, MO. Five (5) years probation. As pharmacist, diverted hydromorphone for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (13), (15) and (17), RSMo.

Lukehart, Morgan G., #2015031938, Raytown, MO. Five (5) years probation. Kansas discipline against pharmacist license for diversion and dependency on amphetamines. Pharmacist admitted to diverting controlled substances, including Vyvanse and Adderall. Section 338.055.2(5), (13), (15) and (17) RSMo

Pierson, Brian S, #2007026592, Springfield, MO. Five (5) years probation. As pharmacist, terminated from employment for diverting controlled substances, including phenobarbital. Section 338.055.2(5), (13), (15) and (17) RSMo

Thomas, Wilkinson, #042248, Grand Prairie, TX. Revoked, and cannot reapply for seven (7) years. Found guilty of three felonies by jury verdict in the United States District Court, Northern District of Texas, Fort Worth Division, Case. No. 4:20-SR-290-O. Section 338.065.1 RSMo.

Woerfel, Max, #2019035650, Saint Clair Shores, MI. Five (5) years probation. As pharmacist, diverted atomoxetine and gabapentin for personal use and consumption from the pharmacy without a valid prescription. Section 338.055.2 (5), (6), (13), and (15), RSMo.

PHARMACIES:

Walgreen #05873, 2001014018, Independence, MO. Eighteen (18) months probation. Multiple controlled substance losses, failure to implement effective security controls. Section 338.055.2 (6), (13), and (15), RSMo.

Walgreen #04970, 006515, St. Charles, MO. Eighteen (18) months probation. Multiple controlled substance losses, failure to implement effective security controls. Section 338.055.2 (6), (13), and (15), RSMo.

NEED HELP?

The Missouri Pharmacy Well-Being Program (WBP)* is a confidential resource for Missouri licensed/ registered pharmacists, intern pharmacists, and pharmacy technicians who have life problems, including substance disorders, mental health stress, and other issues which prevent them from functioning at full capacity.

The Missouri Pharmacy WBP can help with locating counseling and treatment resources, including:

- Addiction/Impairment
- Mental health
- Substance abuse disorders
- Cognitive impairments
- Medical conditions
- Disruptiveness
- Burnout

See additional information online.

Download a copy of the Pharmacy WBP Brochure.

If you or someone you know needs help, contact the Pharmacy Well-Being Program at: (573) 632-5562 or contact:

Heather Johns, LCSW, Director
hjohns1@crmc.org

Lori Rosburg, Ed.S Mental Health Counseling
PHP Program Coordinator
Lori.Rosburg@crmc.org

William “Russ” Carpenter, DO
Medical Director
wcarpenter@crmc.org

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS – SECOND QUARTER 2024

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

HEALTH CARE PROVIDERS URGED BY CDC TO BE ON ALERT FOR MEASLES CASES

Between December 1, 2023, and January 23, 2024, the United States Centers for Disease Control and Prevention (CDC) recorded 23 confirmed cases of measles, with seven linked to international travel and two outbreaks exceeding five cases each. Unvaccinated children and adolescents were most affected. CDC is advising pharmacists and other health care providers to be vigilant for patients with febrile rash illness who recently traveled abroad, especially to countries with measles outbreaks. Measles patients are contagious four days before and four days after the onset of their rash. A heightened global measles threat underscores the importance of these measures. Additional information for health care providers is available on the CDC website.

ISMP SAFETY BRIEF: PREVENT ADDITIONAL PATIENT HARM AND DEATHS FROM ACCIDENTAL DAILY METHOTREXATE DOSING

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.

Methotrexate is a folic acid antagonist that was originally approved to treat a variety of cancers. Used for oncologic indications, methotrexate is administered in cyclical frequencies and in variable doses based on body surface area and the type of cancer being treated. The labeled indications for methotrexate later expanded to include the treatment of non-oncologic conditions, including psoriasis and rheumatoid arthritis. For most non-oncologic indications (eg, rheumatoid arthritis), a low dose of methotrexate is administered weekly – for example, 7.5 mg per week when initiating treatment for rheumatoid arthritis.

Accidental daily dosing of oral methotrexate has occurred all too frequently. This type of wrong frequency error has originated in all stages of the medication-use process, from prescribing to self-administration. These errors have resulted in serious methotrexate overdoses that led to mouth sores, stomatitis, serious skin lesions, liver failure, renal failure, myelosuppression, gastrointestinal bleeding, life-threatening pulmonary symptoms, and death.

Methotrexate Errors

The death of a patient reported in the media is a stark reminder of the harm that can occur. A patient had been admitted to a rehabilitation facility following a fall at home. A prescription for methotrexate 20 mg daily was sent to the pharmacy instead of a prescription for methotrexate 20 mg weekly. The pharmacy dispensing system allowed the pharmacist to bypass a high-dose alert. As a result, the patient received 20 mg of methotrexate daily for a week (a total of 100 mg). The patient became ill and died about a week later. Now, both the prescriber and pharmacist are facing criminal charges.

Since 1996, errors with daily oral methotrexate for non-oncologic use have been reported to ISMP and published in dozens of ISMP Medication Safety Alert! newsletters. For

example, in one case, methotrexate 15 mg once weekly was prescribed for treatment of an autoimmune disorder in an elderly patient. The community pharmacy dispensed a three-month quantity of medication but provided instructions on the label to take 15 mg (six 2.5 mg tablets) once daily. The error was discovered three weeks later during patient counseling with a pharmacist when the patient requested a refill. The error resulted in severe harm, which led to a long hospital stay and treatment with the rescue agent leucovorin calcium.

Safe Practice Recommendations

Most of these wrong frequency errors with methotrexate can be prevented by implementing known risk-reduction strategies. It is time for technology vendors, regulators, standards-setting organizations, health care organizations, and practitioners to make the system improvements outlined in Best Practice #3 in the ISMP Medication Safety Best Practices for Community Pharmacy, including:

- Use a weekly dosage regimen default for oral methotrexate in electronic systems when medication orders are entered.
- Require verification and entry of an appropriate oncologic indication in order entry systems for daily orders. Ideally, computer systems would require a hard-stop verification of an appropriate oncologic indication for all daily oral methotrexate orders.
- Create a forcing function (eg, electronic stop in the sales register that requires intervention and acknowledgement by a pharmacist) to ensure that every oral methotrexate prescription is reviewed with the patient or a family member when a prescription is presented or refills are processed.
- Provide specific patient and/or family education for all oral methotrexate prescriptions.

To learn more about how to identify medication safety risks before they cause harm, consider attending an ISMP Medication Safety Intensive workshop designed for those working in community and specialty pharmacies. For more details about the program, please visit the ISMP workshop web page.

FDA ISSUES FINAL GUIDANCE DOCUMENT ON DEVELOPING MONOCLONAL ANTIBODIES FOR TREATING COVID-19

Food and Drug Administration (FDA) has released a final guidance document offering recommendations to sponsors on developing monoclonal antibody products targeting SARS-CoV-2 intended to prevent or treat COVID-19. Additionally, the guidance document lists the criteria needed for FDA to issue emergency use authorizations. The Development of Monoclonal Antibody Products Targeting SARS-CoV-2 for Emergency Use Authorization document replaces the Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency guidance document that was published on February 22, 2021.

TRANEXAMIC ACID INJECTION ADDED TO ISMP'S LIST OF HIGH-ALERT MEDICATIONS

Tranexamic acid injections have been added to the Institute for Safe Medication Practices' (ISMP's) 2024 List of High-Alert Medications in Acute Care Settings. "High-alert" medications have an increased risk of causing significant harm to patients when they are incorrectly administered. ISMP recommends that practitioners implement safeguarding measures to minimize the risk of error when dispensing these drugs.

The list was updated based on an ISMP 2023 survey in which 100 practitioners, including pharmacists, nurses, pharmacy technicians, and others, reviewed the ISMP 2018 List of High-Alert Medications in Acute Care Settings to determine if those drugs were still considered high-alert medications in 2023 and submitted feedback on new additions.

FDA ISSUES DRAFT INTERIM GUIDANCE DOCUMENTS ON BULK DRUG SUBSTANCES IN COMPOUNDING UNDER SECTIONS 503A AND 503B OF FD&C ACT

Food and Drug Administration (FDA) has issued two draft interim guidance documents that address the use of bulk drug substances in compounding under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under Section 503A of the FD&C Act, compounders can only use bulk substances that are included in the United States Pharmacopeia, the National Formulary monograph, or if it is on a list promulgated as a regulation pursuant to Section 503A(b)(1)(A)(i)(III) of the FD&C Act. Under Section 503B of the FD&C Act, bulk substances can only be used in compounding if they are used to compound a drug that is on FDA's drug shortage list at the time of compounding, distribution, and dispensing or on FDA's 503B bulk list. According to the documents, drug substances that are nominated after (or on the date of) the finalized date cannot be used until FDA has reviewed the nomination to determine if the substance has sufficient supporting information to be included on the bulk list.

POISON CONTROL CENTERS REPORT SHARP INCREASE IN CALLS RELATED TO SEMAGLUTIDE MEDICATIONS

Pharmacists and stakeholders should be aware of a significant increase in calls to poison control centers related to semaglutide products used for diabetes and weight loss. From January to November 2023, poison centers reported nearly 3,000 calls involving semaglutide, a more than 15-fold increase since 2019. The majority of calls resulted from dosing errors, with patients accidentally taking double doses or incorrect amounts. Compounded versions, arising due to demand exceeding supply, have contributed to the issue. These compounded forms, frequently sold in different dosages, may lead to potential risks. Despite calls rising, it is challenging to distinguish between calls related to patented drugs and their compounded versions.

PHARMACIST INTERVENTION IS ASSOCIATED WITH LOWERING PATIENTS' BLOOD GLUCOSE LEVELS

Pharmacist intervention was associated with lowering patients' HbA1C levels by 1% after recommending that primary care providers switch medication treatments for their patients, according to research presented at the American Society of Health-System Pharmacists' midyear meeting. Using information in patients' electronic health records, pharmacists provided 180 recommendations for 102 patients with diabetes and cardiovascular disease at the Memphis VA Medical Center in Tennessee. Primary care providers followed 23 of those recommendations, which included switching patients from sulfonylureas to a GLP-1 receptor agonist or an SGLT-2 inhibitor, hyperlipidemia interventions, hypertension interventions, and recommendations for tobacco cessation. The average HbA1c levels of 7.7% decreased to 6.7% among the 23 patients who were switched to a different treatment suggested by a pharmacist. However, there are some limitations, such as infrequent patient visits, that may impact how quickly the pharmacist recommendations are accepted.

PHARMACISTS RANKED THIRD MOST TRUSTED MEDICAL PROFESSIONALS IN 2023 GALLUP SURVEY

Pharmacists are ranked as the third most trusted medical professionals among various occupations in Gallup's 2023 Annual Rating of Honesty and Ethics survey. From November 9 to December 2, 2022, 58% of Americans ranked pharmacists as having high honest and ethical standards, which is slightly lower than their 2021 and 2020 ratings. In 2022, medical doctors were ranked slightly higher than pharmacists, with 62% of Americans saying doctors have "very high" or "high" honesty and ethical standards; nurses earned the highest ethical rating at 79%. All three health-related professions scored lower compared to their scores before the COVID-19 pandemic.