

**899 NORTH CAPITOL STREET, NE
2ND FLOOR
WASHINGTON, DC 20002**

October 5, 2023

Time: 9:30 am

**OPEN SESSION AGENDA
(IN-PERSON AND WEBEX)**

Board of Pharmacy Mission Statement:

“To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians.”

Open Session Agenda

Quorum:

Introduction:		
1005-O-01	<u>Approval of the Open Session Meeting Minutes for:</u> August 3, 2023 September 7, 2023	
<u>Consent Agenda</u>	None	
<u>Chairperson Report</u>	<u>Interprofessional Workgroup</u>	Dr. Tamara McCants
<u>Executive Director Report</u>	<ul style="list-style-type: none">▪ Statistical Report on Pharmacy Professionals in the District of Columbia▪ Prescription Drug Monitoring Program Updates▪ DCRx (DC Center for Rational Prescribing)▪ Board of Pharmacy Vacancies: https://motaboardstheresumator.com/apply/1L8k6Q/Board-Of-Pharmacy	Dr. Justin Ortique
<u>Office of Government Relations (OGR) Report</u>	<u>DC Health Director Confirmation Hearing</u> <ul style="list-style-type: none">▪ On October 5th at 10 AM, the Committee on Health will hold a hearing on the Director of the Department of Health Dr. Ayanna Bennett Confirmation Resolution of 2023 (PR25-0290). <u>Council Recess</u> <ul style="list-style-type: none">▪ Council has reconvened from recess, and we anticipate a busy fall.	
<u>Senior Assistant General Counsel Report</u>		
1005-O-02	<u>Notice of Emergency and Proposed Rulemaking to Allow Pharmacists to Administer RSV Vaccinations</u> (a) Amendments to Title 17 DCMR For Pharmacist Chapter 65 section 6512.7 (Administration of Immunizations and Vaccinations by Pharmacists)	Ms. Carla Williams

<u>Subcommittee Reports</u>		
1005-O-03	<u>Legislative and Regulatory Subcommittee Report</u>	Mr. Alan Friedman
1005-O-04	<u>Communications Subcommittee Report</u>	Dr. Ashlee Bow
<u>Presentation</u>		
1005-O-05	Respiratory Season Plans	Ms. Heather Burris
<u>Matter for Consideration</u>		
1005-O-06	National Association of Boards of Pharmacy (NABP) New Pharmacist Exam Eligibility Service	
NABP E-Newsletter	<p>September 20, 2023</p> <p>FDA Advisory Panel Determines Oral Phenylephrine Ineffective in OTC Medications</p> <p>FDA Authorizes Emergency Use of Updated COVID-19 Vaccines for 2023-2024</p> <p>HHS Proposes Rule to Prohibit Discrimination Based on Disability in Health Care and Human Service Programs</p> <p>LAPPA Publishes Report on Status of Good Samaritan Fatal Overdose Prevention Laws in US</p> <p>UMass Memorial Medical Center’s Mobile Addiction Service Helped Over 1,100 Individuals Within a Two-Year Period</p> <p>September 27, 2023</p> <p>APhA, ASHP, and NABP Unveil Strategies to Bolster Pharmacy Workforce</p> <p>FDA Issues Document on Regulation of Prescription Drug Use-Related Software</p> <p>Nearly \$300 Million Awarded to 49 States, District of Columbia, and 40 Local Health Departments for Drug Overdose Prevention</p> <p>Innovations: Ten Years After DSCSA, Final Provisions Set to Go Into Effect</p> <p>In 2021, 72% of Adults Who Acknowledged Having a Substance Use Problem Reported Being in Recovery or Recovering From Substance Use</p>	Dr. Tamara McCants

	<p>States With Less Restrictive Telepharmacy Policies Experienced Fewer Pharmacy Deserts, According to Recent Study</p> <p>About One in Five Adults With OUD Receive Medication Treatment, Based on the 2021 NSDUH</p> <p>Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.</p>	
<u>Comments from the Public</u>		
<u>Motion to Adjourn the Open Session</u>	<p>"Madam Board Chair, I move that the Board close the Open Public session portion of the meeting and move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the following purposes: to discuss disciplinary matters pursuant to § 2-575(b)(9); to seek the advice of counsel to the board, to preserve the attorney-client privilege, or to approve settlement agreements pursuant to § 2-575(b)(4); and to plan, discuss, or hear reports concerning ongoing or planned investigations pursuant to § 2-575(b)(14)." ROLL CALL VOTE</p>	

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at :

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

**899 NORTH CAPITOL STREET, NE
2ND FLOOR
WASHINGTON, DC 20002**

August 3, 2023

9:36 AM – 10:55 AM

**OPEN SESSION MINUTES
(IN-PERSON AND WEBEX)**

Board of Pharmacy Mission Statement:

“To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians.”

Open Session Agenda

Quorum: Yes

Introduction:		
o803-O-01	<p><u>Approval of the Open Session Meeting Minutes for:</u></p> <p>June 1, 2023</p> <p>Motion: Vice Chair, Mr. Alan Friedman, moves the Board to approve the June 1, 2023 open session meeting minutes.</p> <p>Seconded by: Board Member, Dr. Benjamin Miles.</p> <p>Roll Call Vote:</p> <p>Mr. Alan Friedman: Voted in favor of the motion. Dr. Benjamin Miles: Voted in favor of the motion. Dr. Ashlee Bow: Voted in favor of the motion. Dr. Allison Hill: Voted in favor of the motion.</p> <p>Abstentions: None.</p> <p>Motion Carried</p>	
<u>Consent Agenda</u>	None	
<u>Chairperson Report</u>	<p><u>Interprofessional Workgroup</u></p> <p>Board Chair, Dr. McCants reports that the Interprofessional Workgroup is meeting regularly. The workgroup is currently finalizing the date for its interprofessional board member symposium, which will include information sharing from DC Health on the structure and programs that are available to the public. The agenda for the Fall symposium suggests a morning meeting from 8:00 AM to 1:00 PM, with a one-hour networking lunch scheduled at 12:00 PM. The symposium will ensure discussions on the following topics:</p> <p>Healthcare Workforce · Telehealth · Compact Licensing · Artificial Intelligence (AI) · Healthcare and Regulations · Scope of Practice</p> <p>Dr. McCants will report to the Board, the date and location of the symposium when finalized. She encourages the Board members to attend the event, particularly in support of the Pharmacy Practice Act.</p>	Dr. Tamara McCants

Dr. McCants highlights DC Council’s Committee on Health’s openness to new ideas and hearing about the role of the pharmacist in addressing health disparities.

Dr. McCants announces the new Director for DC Health, Dr. Ayanna Bennett, and suggests that the Board of Pharmacy has an opportunity to schedule a meeting with the director to discuss the Board’s activities.

Dr. McCants announces the resurgence of the DC Medical Reserve Corps and encourages the Board members and colleagues to register to volunteer with the reserve corps.

The NABP Districts 1 and 2 meetings are scheduled to occur September 20 through September 22, 2023 in Atlantic City, NJ. Board member and Treasurer for NABP’s District 2, Dr. Allison Hill, will attend the meetings. Dr. McCants encourages all Board members and the public to attend the meetings.

Executive Director Report

Statistical Report on Pharmacy professionals in the District of Columbia

Dr. Justin Ortique

PHARMACEUTICAL DETAILERS	793
PHARMACISTS	2,090
PHARMACY INTERNS	336
PHARMACY TECHNICIANS	1,029
PHARMACY TECHNICIAN TRAINEES	122
PHARMACISTS WITH VAC AUTHORITY	759
PHARMACY TECHNICIAN TRAINING PROGRAMS	8

Prescription Drug Monitoring Program Updates

- All pharmacists are reminded to register for the *Prescription Drug Monitoring Program* (PDMP) within ninety (90) days of licensure in the District of Columbia at <https://districtofcolumbia.pmpaware.net/login>.
- As a reminder, new licensees will receive notifications regarding registration for the program every thirty (30) days after licensure.
- The public is invited to attend the next Prescription Drug Monitoring Program Advisory Meeting, which is scheduled for August 15, 2023 at 10:00 AM.

DCRx (DC Center for Rational Prescribing)

- The DC Center for Rational Prescribing (DCRx) has published a new module on [*Ethics in Healthcare: Exploring Bioethics, Clinical Ethics, and Health Equity*](#), which “focuses on the complex ethical dilemmas that face healthcare practitioners by

reinforcing the foundational concepts of clinical bioethics, primarily the four principles, and educating the learner on how to apply these foundational concepts to the pressing ethical issues related to health equity and prescribing and access to medications and treatments.” This module is available to the public at an assessment of 1.0 credit hour. Further information on DCRx is available at <https://dchealth.dc.gov/dcrx>.

Office of Government Relations (OGR) Updates (Report by Kera Johnson, Policy Analyst)

Health Professional Licensing Boards Residency Requirement Amendment Act of 2023:

- Councilmembers Henderson and Parker introduced the *Health Professional Licensing Boards Residency Requirement Amendment Act of 2023* ([B25-0312](#)) on June 2, 2023.
 - This legislation will permit non-District residents to serve on health professional licensing boards.
 - The legislation includes restrictions, and as such, District of Columbia residents will hold the Board Chair and Consumer Members’ seats and no more than 50% of the Board will be made up of non-District residents.
 - This bill received a hearing on [July 13, 2023](#). DC Health testified during this hearing, thereby expressing support for innovative solutions to fill board vacancies, while offering changes to the bill.

DC Health Director Appointment:

- On June 8, 2023, Mayor Bowser announced the appointment of Dr. Ayanna Bennett as DC Health’s Acting Director.
 - Dr. Bennett is a healthcare and public health executive with more than 20 years of experience in clinical practice, clinical service design, system integration, and quality improvement. Dr. Bennett most recently served as Chief Health Equity Officer and Director of the San Francisco Department of Public Health’s Office of Health Equity.
 - The Council will therefore consider the *Director of the Department of Health Dr. Ayanna Bennett Confirmation Resolution of 2023* ([PR25-0290](#)), and the Committee on Health will discuss this resolution by hearing on [October 5, 2023](#).

Access to Emergency Albuterol and Glucagon Amendment Act of 2023:

- Councilmember Henderson introduced the *Access to Emergency Albuterol and Glucagon Amendment Act of 2023* ([B25-0226](#)) on March 20, 2023.
 - This legislation will designate albuterol and glucagon as emergency medications under the *Student Access to Treatment Act of 2007*. Under this bill, employees in

	<p>public schools, certified under an administration of medication training, will administer to students, with or without a medication action plan, <i>Albuterol</i>, where the student is suffering or about to suffer an asthma attack; and <i>Glucagon</i>, where the student is suffering or about to suffer hypoglycemia due to diabetes. Currently, only students with medication action plans can receive these medications.</p> <ul style="list-style-type: none"> ➤ This bill received a hearing on July 13, 2023. DC Health testified during this hearing and expressed support for the bill with recommendations addressing the operational and regulatory authority to define, add, and remove medications by rulemaking. <p>Prescription Drug Monitoring Program Amendment Act of 2023:</p> <ul style="list-style-type: none"> • Chairmen Mendelson, at the request of the Mayor, introduced the <i>Prescription Drug Monitoring Program Amendment Act of 2023</i>, on April 11, 2023. <ul style="list-style-type: none"> ➤ This legislation seeks to make changes to the disclosure of information through the District’s Prescription Drug Monitoring Program (PDMP). These changes would give DC Health the authority to release additional de-identified information for the purposes of statistical analysis, research, education, or grant applications. ➤ This bill received a hearing on July 6, 2023. DC Health testified in support of the bill highlighting the importance of data sharing as a tool to advance population health in the District of Columbia. <p>Council Recess:</p> <ul style="list-style-type: none"> • The DC Council is on recess, as of July 14, 2023 and will return to session on September 15, 2023. <p>Board of Pharmacy Vacancies:</p> <ul style="list-style-type: none"> • The DC Board of Pharmacy is currently seeking two District of Columbia residents to serve as consumer members on the Board. • Interested parties who are health professionals or in training to become one or in a household where there is a health professional or someone training to become one are not qualified for the role of consumer member. • For further information regarding the vacancies, please go to: https://motaboards.theresumator.com/apply/1L8k6Q/Board-Of-Pharmacy 	
<p><u>Senior Assistant General Counsel Report</u></p>		

o803-O-02	<p><u>Notice of Emergency and Proposed Rulemaking</u></p> <p>(a) Amendments to Title 17 DCMR For Pharmacist Chapter 65 section 6512 (Administration of Immunizations and Vaccinations by Pharmacists).</p> <p>The Department of Health issued emergency and proposed rulemaking. The notice of emergency rulemaking became effective on June 22, 2023, thereby permitting pharmacists who are licensed by the District of Columbia’s Board of Pharmacy to administer vaccinations that are ASIP recommended, to persons that are aged 3 through 18, where minors are required to secure a parent or parents’ consent; and persons over 18 years of age are required to produce a government-issued photo ID.</p> <p>This emergency rulemaking seeks to remain consistent with the authority granted via the PREP Act during the COVID-19 Pandemic, which resulted in a public emergency. While COVID and Influenza vaccines are exempt from written protocol or a prescription/standing order, the District of Columbia requirement is still effective for the administration of all other vaccines.</p> <p>The proposed rulemaking was published in the Register on July 7, 2023, and the public comment period for the proposed rulemaking will end on August 7, 2023. If no comments are received, the emergency rulemaking will remain effective until October 20, 2023, or until final rulemaking is established.</p> <p>While such provisions will allow pharmacists to continue [the administration of ASIP recommended vaccines] until December 31, 2024 (for consistency [of provisions] under the PREP Act, DC Health expects that its amendments to the HORA will have been implemented before or by the 2024 deadline, thereby allowing for continuity of the provisions, but under the District’s law).</p> <p>This matter will be advanced by DC Health.</p> <p>As the Board discusses and explores merging the application for vaccination and immunization authority with the pharmacist licensure application, Board Counsel, Ms. Carla Williams states that this change will require an amendment to the HORA as the current regulation requires certification [in vaccination and immunization administration].</p>	Ms. Carla Williams
<p><u>Regarding Subcommittee Reports</u></p>		
o803-O-03	<p><u>Legislative and Regulatory Subcommittee Report</u></p> <p>The Legislative and Regulatory Subcommittee met on July 13, 2023. The subcommittee focused its discussion on self-administered hormonal contraception, thereby reviewing all prior documents negotiated between the District of Columbia’s Legislative and</p>	Mr. Alan Friedman

	<p>Regulatory Subcommittees for the Boards of Medicine and Pharmacy, dated 2018 through 2019.</p> <p>The subcommittee assessed forms indicative of when the pharmacist would prescribe versus when he/she would not and compared protocol, currently under development, with updated medical eligibility. The subcommittee also reviewed a patient pamphlet on contraceptive methods, which requires development. Changes were suggested and an updated pamphlet has been published.</p> <p>The next steps are as follows:</p> <ol style="list-style-type: none"> 1. The subcommittee will review, consider, and respond to comments submitted during the public comment period of the legislation concerning a pharmacist’s authority to prescribe mono contraception. 2. The subcommittee’s review of comments may fuel regulatory changes to the proposed legislation that may impact forms already developed. 3. The subcommittee will review the most updated draft of the pamphlet, establish a final recommendation, which may necessitate further amendments. 4. Board Chair, Dr. McCants, will coordinate with Dr. Anderson, the Board Chair for the Board of Medicine, regarding review and approval of the package – inclusive of the pamphlet, regulations, forms, and protocol. 5. The subcommittee expects to present the package at the Board’s open session meeting in October, 2023. 	
o803-O-04	<p><u>Communications Subcommittee Report</u></p> <ul style="list-style-type: none"> • The subcommittee is currently drafting the Boards next newsletter, which is scheduled for an October release. • Dr. Bow is welcoming of ideas or articles for the October edition, in support of American Pharmacists Month. • All requests for newsletter publication are accepted at ashlee.bow@dcbc.dc.gov. • Board Chair, Dr. Tamara McCants, requests that information regarding the Capital City Medical Reserve Corps is included in October’s publication. • Vice Chair, Mr. Alan Friedman, requests that the public shares with the Board, through its newsletter, the activities it will engage in for American Pharmacists Month, October, 2023. 	Dr. Ashlee Bow
<u>Matter for Consideration</u>		
o803-O-05	<p><u>Question Regarding Patient Consent and CPAs</u></p> <p>“To improve quality of clinical services provided at our ambulatory clinics, we are setting up collaborative practice agreements in MedStar Health ambulatory clinics consisting of only physicians and pharmacists</p>	

	<p>directly employed by MedStar Health. Are we able to use the enterprise-wide patient consent form (attached)?”</p> <p>(a) Copy MedStar’s Entity General Consent Form (b) Chapter 100 Collaborative Practice Agreements Between Physicians and Pharmacists.</p> <p>Board Counsel, Ms. Carla Williams, informs Dr. Joshua Bailey that, per section 1004.4 of Chapter 100, <i>Collaborative Practice Agreements Between Physicians and Pharmacists</i>, the Board requires Medstar to update its general consent form for compliance with the District of Columbia’s Board of Pharmacy’s regulations.</p> <p>Dr. Bailey agrees, but suggests that Medstar will “dot phrase within the progress note and authorize the form with a signature” as this process would ensure patient consent in less time than would be required to secure the general consent of all Medstar entities.</p> <p>Board Counsel, Ms. Carla Williams, states that the Board will accept the process described by Dr. Bailey “if it is documented that these elements were what was discussed with the [patient and he/she] authorizes service(s) from Medstar, by signature.”</p>	
<p>NABP E-Newsletter</p>	<p><u>July 26, 2023</u></p> <p>DEA Amends Rules Regarding Partial Filling of Prescriptions for Schedule II CS</p> <p>FDA Approves New RSV Vaccine for Newborns and Toddlers</p> <p>Operation Broader Sword Ceases Over 500 International Shipments of Illegal Drugs From Entering the US</p> <p>US and Mexican Law Enforcement Officials Dismantle Transnational Drug Trafficking Organization</p> <p>Get to Know the Mississippi Board’s Executive Director</p> <p>DOJ Publishes Guidelines for Handling Substance Withdrawal in Jails</p> <p>CDC Issues Health Advisory About Measles During Summer Travel</p> <p><u>July 19, 2023</u></p> <p>First OTC Daily Oral Contraceptive Approved by FDA</p> <p>FDA and White House Outline Plan to Combat Illicit Xylazine Entering the US</p> <p>Senate Passes TRANQ Research Act</p>	<p>Dr. Tamara McCants</p>

	<p>FDA Offers Educational Webinars on Prescription Drug Labeling, DSCSA, and Generic Drugs</p> <p>FDA Podcast Highlights Strategies to Encourage Harm Reduction and Reduce Obstacles for Overdose Reversal Agents</p> <p>DEA Releases Instructional Video Explaining MATE Act Requirements</p> <p>Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.</p>	
<p><u>Comments from the Public</u></p>	<p>No comments from the public.</p>	
<p><u>Motion to Adjourn the Open Session</u></p>	<p>Board Member, Dr. Ashlee Bow, moves as follows:</p> <p>“Madam Chair, I move that the Board close the Open Public session portion of the meeting and move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the following purposes: to discuss disciplinary matters pursuant to § 2-575(b)(9); to seek the advice of counsel to the board, to preserve the attorney-client privilege, or to approve settlement agreements pursuant to § 2-575(b)(4); and to plan, discuss, or hear reports concerning ongoing or planned investigations pursuant to § 2-575(b)(14).”</p> <p>Seconded by: Dr. Allison Hill.</p> <p>Roll Call Vote:</p> <p>Mr. Alan Friedman: Votes in favor of the motion. Dr. Benjamin Miles: Votes in favor of the motion. Dr. Ashlee Bow: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion.</p> <p>Abstentions: None.</p> <p>Motion Carried.</p>	

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at 10:55 AM

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

**899 NORTH CAPITOL ST. NE
2ND FLOOR
WASHINGTON, DC 20002**

September 7, 2023

9:35 AM – 9:38 AM

**OPEN SESSION MINUTES
(VIA WEBEX MEETING)**

Board of Pharmacy Mission Statement:

“To protect and improve the public health through the efficient and effective regulation of the practice of Pharmacy and Pharmaceutical Detailing; through the licensure of Pharmacists, Pharmaceutical Detailers, Pharmacy Interns, and Pharmacy Technicians.”

Open Session Agenda

Quorum: Yes

Introduction:		
Motion to Adjourn the Open Session	<p>Board Member, Dr. Benjamin Miles moves as follows:</p> <p>“Madam Chair, I move that the Board close the Open Public session portion of the meeting and move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the following purposes: to discuss disciplinary matters pursuant to § 2-575(b)(9); to seek the advice of counsel to the board, to preserve the attorney-client privilege, or to approve settlement agreements pursuant to § 2-575(b)(4); and to plan, discuss, or hear reports concerning ongoing or planned investigations pursuant to § 2-575(b)(14).”</p> <p>Seconded by: Dr. Ashlee Bow.</p> <p>Roll Call Vote:</p> <p>Mr. Alan Friedman: Votes in favor of the motion. Dr. Benjamin Miles: Votes in favor of the motion. Dr. Ashlee Bow: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion.</p> <p>Abstentions: None.</p> <p>Motion Carried.</p>	

This concludes the Public Open Session of the meeting. The Board will now move into the Closed Executive Session portion of the meeting pursuant to D.C. Official Code § 2-575(b) for the reasons set forth in the motion.

Open Session Meeting Adjourned at 9:38 am

This meeting is governed by the Open Meetings Act. Please address any questions or complaints arising under this meeting to the Office of Open Government at opengovoffice@dc.gov.

DEPARTMENT OF HEALTH

NOTICE OF EMERGENCY AND PROPOSED RULEMAKING

The Acting Director of the Department of Health, pursuant to section 302(14) of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02 (14)), and Mayor's Order 98-140, dated August 20, 1998, hereby gives notice of the adoption, on an emergency basis, of the amendment of subsection 6512.7 of chapter 65 (Pharmacists) of Title 17 (Business, Occupations, and Professionals) of the District of Columbia Municipal Regulations (DCMR).

In the United States, respiratory syncytial virus (RSV) infections typically cause an estimated 60,000–160,000 hospitalizations, nationally, among adults aged sixty-five (65) and older each year. RSV usually causes illness in the US between October and April, peaking in December or January.

The respiratory syncytial virus (RSV) vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) and has been officially adopted by the Director of the Centers for Disease Control and Prevention. However, it is not yet included in the vaccine schedule. The ACIP vaccine schedule is typically updated annually, and is next expected to be updated in February 2024. The current regulations in place for pharmacists licensed in the District of Columbia, authorize certified pharmacists to administer, pursuant to a written protocol and standing order or prescription," any vaccination that the Advisory Committee on Immunization Practices ('ACIP') recommends according to ACIP's standard immunization schedule."

This emergency action is necessary to protect the health, safety, and welfare of the District's population ages sixty (60) and older, and those persons with chronic medical conditions or other underlying conditions or factors that a medical provider determines might increase the risk for severe RSV-associated respiratory disease. This emergency rulemaking will permit pharmacists, who have been certified by the Board of Pharmacy to administer immunizations and vaccinations, to administer the RSV vaccine now in preparation for the anticipated peak of the illness. This emergency rulemaking eliminates the need for District pharmacists to wait for RSV to be added to the ACIP standard immunization schedule in February 2024.

This emergency rule was adopted on September 27, 2023 and became effective immediately on that date. The emergency rule will expire on January 25, 2024, or upon publication of a Notice of Final Rulemaking in the D.C. Register, whichever occurs first.

The Acting Director also gives notice of the Acting Director's intent to take final rulemaking action to adopt this amendment in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

Making this regulatory change permanent will allow pharmacists to provide necessary vaccines before being added to the ACIP vaccine schedule. A similar situation will most likely occur again. Publishing final rulemaking will allow for more flexibility for Pharmacists to Provide

ACIP-recommended vaccines even if they have not yet made it on the ACIP Recommended vaccine schedule.

Section 6512, ADMINISTRATION OF IMMUNIZATIONS AND VACCINATIONS BY PHARMACISTS, of chapter 65, PHARMACISTS, of title 17, BUSINESS, OCCUPATIONS, AND PROFESSIONS, is amended as follows:

Subparagraph 6512.7(c)(6) is amended to read as follows:

- (6) Any person aged three (3) and older with parental consent, or valid identification if eighteen (18) or older or otherwise capable of consenting to the vaccination pursuant to section 2 of the Consent for Vaccinations of Minors Amendment Act of 2022, effective March 10, 2023 (D.C. Law 24-12; D.C. Official Code § 7-1653.01), for any vaccination that the Advisory Committee on Immunization Practices (“ACIP”) recommends according to ACIP’s standard immunization schedule, or any vaccination that ACIP recommends that has been officially adopted by the Director of the Centers for Disease Control and Prevention; and

All persons desiring to comment on the subject matter of this proposed rulemaking should file comments in writing not later than thirty (30) days after the date of the publication of this notice in the *D.C. Register*. Comments should be sent to the Department of Health, Phillip L. Husband, General Counsel, Office of the General Counsel, 899 North Capitol Street, N.E., 6th Floor, Washington, D.C. 20002 at Phillip.Husband@dc.gov. Copies of the proposed rules may be obtained during the hours of 9 a.m. to 5 p.m., Monday through Friday, excluding holidays, at the address listed above, or by contacting Angli Black, Paralegal Assistant, at Angli.Black@dc.gov, (202) 442-5977.

Oral Phenylephrine Deemed Ineffective in OTC Medications, According to FDA Advisory

NABP <news@nabp.pharmacy>

Wed 9/20/2023 7:35 PM

To: Barron, Karin (DOH) <karin.barron@dc.gov>

CAUTION: This email originated from outside of the DC Government. Do not click on links or open attachments unless you recognize the sender and know that the content is safe. If you believe that this email is suspicious, please forward to phishing@dc.gov for additional analysis by OCTO Security Operations Center (SOC).



FDA Advisory Panel Determines Oral Phenylephrine Ineffective in OTC Medications

The Nonprescription Drugs Advisory Committee has determined that the recommended dosage of oral phenylephrine is not effective as a nasal decongestant. However, neither the committee nor Food and Drug Administration (FDA) raised safety concerns about the use of orally administered phenylephrine at the recommended dose. Although phenylephrine is an ingredient in over-the-counter (OTC) cold and cough medications as well as nasal sprays, the committee's discussion pertained to only orally administered phenylephrine. FDA will consider the data and recommendations from the committee before making any final decisions.

[Find Out More](#)

FDA Authorizes Emergency Use of Updated COVID-19 Vaccines for 2023-2024

FDA has authorized for emergency use updated mRNA COVID-19 vaccines for 2023-2024 that are supposed to target current variants and provide protection against consequences of COVID-19. Both Moderna and Pfizer vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5; these vaccines replace the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines. The updated mRNA vaccines are expected to be available this fall.

[Learn More](#)

HHS Proposes Rule to Prohibit Discrimination Based on Disability in Health Care and Human Service Programs

The United States Department of Health and Human Services (HHS) is proposing a rule that will protect individuals with disabilities from discrimination when seeking access to health care and human services. The rule would revise regulations and critical areas in Section 504 of the Rehabilitation Act of 1973 to better align with the Americans with Disabilities Act (ADA), the ADA Amendments Act, and amendments to the Rehabilitation Act. The critical areas addressed include prohibiting “the use of value assessment methods that place a lower value on life-extension for individuals with disabilities when that method is used to limit access or to deny aids, benefits, and services;” outlining the responsibilities for web, mobile, and kiosk accessibility; and more.

[Read the Article](#)

LAPPA Publishes Report on Status of Good Samaritan Fatal Overdose Prevention Laws in US

The Legislative Analysis and Public Policy Association (LAPPA) has published a comprehensive report of the status of Good Samaritan fatal overdose prevention laws throughout the US and its territories. The *Good Samaritan Fatal Overdose Prevention Drug-Induced Homicide: Summary of State Laws* report includes the statutory citation, initial effective date, individuals eligible for the Good Samaritan protection, requirements for

the protections to apply and exceptions to protection, and more. Even though Good Samaritan fatal overdose prevention laws offer certain levels of protection for individuals who summon emergency assistance for overdose victims, LAPPAs notes that drug-induced homicide/drug delivery resulting in death laws may discourage individuals from reporting an overdose situation.

[Download the Summary of State Laws](#)

UMass Memorial Medical Center's Mobile Addiction Service Helped Over 1,100 Individuals Within a Two-Year Period

"Road to Care," the UMass Memorial Medical Center's mobile addiction service, has delivered holistic addiction care to 1,121 patients in two years. The service has also distributed about 250 naloxone kits directly on site and more than 300 kits through prescriptions to local Massachusetts pharmacies between May 2021 and April 2023. The goal of the Road to Care program was to supply addiction care services (including medication for opioid use disorder) to community members encountering systematic and individualized obstacles.

Learn how mobile pharmacies, which were once designated to respond to natural disasters and other emergencies, are providing pharmacy services to underserved populations in the [April 2023 issue of *Innovations*[®]](#).

[Read About the Road to Care Program](#)

APhA, ASHP, and NABP Unveil Strategies to Bolster Pharmacy Workforce

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*Educational, Regulatory,
and Association News*



APhA, ASHP, and NABP Unveil Strategies to Bolster Pharmacy Workforce

The American Pharmacists Association (APhA), the American Society of Health-System Pharmacists (ASHP), and the National Association of Boards of Pharmacy (NABP) are pleased to share a new report including actions to implement solutions to improve pharmacy workplace conditions. Workplace problems are leading to high stress levels and occupational burnout across various pharmacy practice settings. APhA, ASHP, and NABP undertook a collaborative effort to address these challenges head-on **during a recent invitation-only event**, and identified transformative and actionable changes for the pharmacy and related communities.

[Read the News Release](#)

FDA Issues Document on Regulation of Prescription Drug Use-Related Software

Food and Drug Administration (FDA) has issued a draft guidance document explaining the ways FDA plans to apply its drug labeling

authorities to certain prescription drug use-related software. The *Regulatory Considerations for Prescription Drug Use-Related Software* document clarifies FDA's current perspective on software that accompanies or supplements prescription drugs that is made by or on behalf of a drug sponsor, such as a mobile application that acts as a digital medication log, a diary that patients or caretakers use to enter data, or a device-connected product like hardware attached to an asthma inhaler. The guidance addresses how drug sponsors can describe their own software in FDA-required labeling and promotional labeling, including the Prescribing Information, and explain certain characteristics of the software to maximize its safety and effectiveness. Furthermore, FDA mentions that any updates to the software that impact the end-user's output would need to be submitted to the agency.

[Find Out More](#)

Nearly \$300 Million Awarded to 49 States, District of Columbia, and 40 Local Health Departments for Drug Overdose Prevention

On August 31, 2023, Centers for Disease Control and Prevention (CDC) granted \$279 million to 49 states, the District of Columbia, and 40 local health departments to help stop overdoses within their communities. The

resources were awarded from two new Overdose Data to Action funding opportunities. CDC also listed three suggestions that can help prevent overdose deaths, such as expanding access and reducing obstacles to treatment and recovery support services; increasing knowledge about polysubstance use and illegally made fentanyl; and expanding the distribution of and education on lifesaving opioid overdose reversal treatments.

[Read the Article](#)

Innovations: Ten Years After DSCSA, Final Provisions Set to Go Into Effect

More than a decade ago, the United States pharmacy profession experienced one of the most significant adverse public health tragedies in recent history when improperly compounded and contaminated injectable drugs were produced at the New England Compounding Center and shipped to multiple states. The reckless actions of the pharmacy resulted in a large-scale fungal meningitis outbreak, resulting in at least 750 infections and 64 deaths. Many of the patients who survived the infection continue to experience adverse effects.

In response to these events and to overall concerns about the integrity of the pharmaceutical supply chain, lawmakers in Congress passed the

Drug Quality and Security Act with broad bipartisan support. The complex law was divided into two parts. Title I, known as the Compounding Quality Act, gave FDA more authority to regulate and monitor compounded drugs that are shipped across state lines. Title II, the Drug Supply Chain Security Act (DSCSA), established requirements for the tracing of prescription drug products throughout the supply chain.

Since the publication of the September issue of *Innovations*[®], FDA has delayed enforcement of certain DSCSA requirements until November 27, 2024, a recommendation that the Association offered in a [letter](#) addressed to the agency. Read more about NABP's role in helping regulators and trading partners meet DSCSA requirements in the September issue of *Innovations*.

[Learn More](#)

In 2021, 72% of Adults Who Acknowledged Having a Substance Use Problem Reported Being in Recovery or Recovering From Substance Use

The Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a report that provides detailed accounts of Americans and their experiences with recovery from substance use and

mental health problems. The report utilized data collected for the 2021 *National Survey on Drug Use and Health* (NSDUH). Of the 29 million surveyed adults who acknowledged ever having a substance use problem, many (72%) considered themselves to be in recovery or to have recovered from their substance or alcohol use problem. The comprehensive report includes other factors that impacted the percentage of adults in recovery.

[Download the Report](#)

States With Less Restrictive Telepharmacy Policies Experienced Fewer Pharmacy Deserts, According to Recent Study

States that enacted less restrictive telepharmacy policies from 2017-2018 experienced fewer pharmacy deserts compared to states that didn't implement any changes, based on a study published in *JAMA Network Open*. Eight states that implemented telepharmacy policies had a 4.5% decrease in the percentage of areas defined as pharmacy deserts and an 11.1% decrease in the percentage of populations living in one of those areas. Researchers also noted that the outcomes from this two-year study yielded similar results to the North Dakota Telepharmacy Project, which sought to deliver pharmacy care to rural communities in response

to the increasing number of pharmacies closing in those areas. The North Dakota Telepharmacy Project provided pharmacy services to about 80,000 rural citizens during its six-year study.

[View the Study](#)

About One in Five Adults With OUD Receive Medication Treatment, Based on the 2021 NSDUH

Based on data from the 2021 NSDUH, investigators found that only about one in five adults with opioid use disorder (OUD) received medication for OUD; most do not, despite guidelines recommending medication treatment for OUD. The study also highlighted demographic discrepancies among the 47,291 participants who were likely to receive care. Specifically, Black adults, women, unemployed individuals, and those living in nonmetropolitan areas were less likely to receive treatment. Researchers mentioned that these results corroborate prior research and emphasize the positive role telehealth can have in helping patients with OUD receive care.

[Learn More](#)

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