DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

899 NORTH CAPITOL ST. NE – 2ND FLR.
WASHINGTON, DC 20002

August 6, 2020

9:30 am

OPEN SESSION AGENDA
(VIA ZOOM MEETING DUE TO THE COVID-19 PUBLIC HEALTH EMERGENCY)

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."

CALL TO ORDER:

PRESIDING:

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR .TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	
	DR. BENJAMIN MILES, PHARM.D. R.PH	
	MR. ALAN FRIEDMAN, R.PH	
	DR. ASHLEE BOW, PHARM.D. R.PH	
	DR. ALLISON HILL, PHARM.D. R.PH	
	CHIKITA SANDERS, CONSUMER BOARD MEMBER	
	GREGORY CENDANA, CONSUMER MEMBER	
STAFF:	SHAUNA WHITE, EXECUTIVE DIRECTOR	
	KARIN BARRON, HEALTH LICENSING SPECIALIST	
	LUANNE GREENAWAY, PROGRAM SPECIALIST	
	COUNTEE GILLIAM, BOARD INVESTIGATOR	
LEGAL STAFF:	CARLA WILLIAMS, ASSISTANT GENERAL COUNSEL	
VISITORS:		

Open Session Agenda

Quorum:

Introduction:		
0806-O-01	**Approval of the Open Session Meeting Minutes** (a) June 4, 2020 (b) July 2, 2020	
Consent Agenda	**None**	
Chairperson Report	Interprofessional Workgroup MPJE Item Writer	Dr. Tamara McCants
Executive Director Report	**Licensing Report** ▪ Statistical Report on pharmacy professionals in the District of Columbia ▪ Prescription Monitoring Program Update ▪ Opioid Strategic Plan ▪ CE Programs ▪ Pharmacist COVID-19 Testing Guidance Document ▪ Emergency Regulations Pharmacist COVID-19 Testing (Document Attached) ▪ NCPA Letter-Pharmacist COVID-19 Testing (Document Attached)	Dr. Shauna White
Assistant General Counsel Report		Ms. Carla Williams
0806-O-02	**Status Update on the Rulemaking Adding Continuing Education Requirements in Public Health Priorities**	
0806-O-03	**Draft Collaborative Practice Agreement Regulations with Nurse Practitioners** (a) Chapter 104 Collaborative Practice Agreements Between Nurse-Practitioners and Pharmacists	
Subcommittee Reports		
	Legislative and Regulatory Subcommittee Report	Mr. Alan Friedman
0806-O-04	**CPA – Board of Medicine Update**	

0806-O-05	**Communications Subcommittee Report**	Dr. Ashlee Bow
Matters for Consideration		
0806-O-06	**DC Board of Pharmacy Bylaws** (a) Bylaws	
0806-O-07	**CE Audit Fine for Pharmacy Technicians**	
Intern Presentation		
0806-O-08	**Intern Presentation Summary of NABP E-News**	Olyad Begna
NABP E-Newsletter	**July 29, 2020** FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids or Treatment for OUD USP to Host Virtual Public Open Forum Regarding BUDs in Chapters <795> and <797> HHS Announces National COVID-19 Testing Implementation Forum CDC Data Analysis Surveys Opioid Use by Pregnant Women **July 22, 2020** Opioid-Related Deaths in Cook County, IL, Rise Due to Need for COVID-19 Prevention Measures FIP Releases New COVID-19 Guidance for Pharmacists FDA Adds Dexamethasone Sodium Phosphate to List of Drugs for Temporary Compounding SAMHSA's Health Privacy Rule 42 CFR Part 2 Revised to Better Integrate, Coordinate Care for Substance Use Disorders NABP Offers Opportunities to Earn Home Study CPE **July 15, 2020** HHS Secures More Than 500,000 Courses of Remdesivir for US Hospitals to Treat COVID-19 Patients Reminder: Four-Part Webinar Series on Confluence of the COVID-19 Pandemic and the Opioid Epidemic Begins July 20	Dr. Tamara McCants

	New HHS Web Page Shares COVID-19 Testing Plans for Each State, Jurisdiction Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.	
Public Comments		
Motion to Adjourn the Open Session	"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)." (Roll Call Vote)	

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.

DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

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

June 4, 2020

8:34 am

OPEN SESSION MINUTES
(VIA ZOOM MEETING DUE TO THE COVID-19 PUBLIC HEALTH EMERGENCY)

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."

CALL TO ORDER:8:34 AM

PRESIDING: MR. ALAN FRIEDMAN, R.PH, CHAIRPERSON

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR .TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	ABSENT
	DR. BENJAMIN MILES, PHARM.D. R.PH	PRESENT
	MR. ALAN FRIEDMAN, R.PH	PRESENT
	DR. ASHLEE BOW, PHARM.D. R.PH	PRESENT
	DR. ALLISON HILL, PHARM.D. R.PH	PRESENT
	CHIKITA SANDERS, CONSUMER BOARD MEMBER	PRESENT
	GREGORY CENDANA, CONSUMER MEMBER	ABSENT
STAFF:	SHAUNA WHITE, EXECUTIVE DIRECTOR	PRESENT
	KARIN BARRON, HEALTH LICENSING SPECIALIST	PRESENT
	LUANNE GREENAWAY, PROGRAM SPECIALIST	PRESENT
	COUNTEE GILLIAM, BOARD INVESTIGATOR	PRESENT
LEGAL STAFF:	CARLA WILLIAMS, ASSISTANT GENERAL COUNSEL	PRESENT
VISITORS:	DON ZAWADER, PUBLIC INTEREST PARTY	
	ROB GETTIS, ALBERTSON'S/SAFEWAY PHARMACY	
	LIANNA WINN, SIBLEY MEMORIAL HOSPITAL	
	MCKENZIE H, KAISER PERMANENTE	
	KIM JOHNSON, MAX SOURCE	
	TURAN TAFADE, HOWARD UNIVERSITY COLLEGE OF PHARMACY	
	DERON HALL, MAXWELL PHARMACY	
	CASSANDRA LACKNEY, HOWARD UNIVERSITY COLLEGE OF PHARMACY	
	ANDREW GENTILS, DC PHARMACY ASSOCIATION	
	JASMINE INMAN, DC PHARMACY ASSOCIATION	

Open Session Agenda

Quorum: Yes

Introduction:		
0604-O-01	**Approval of the Open Session Meeting Minutes** April 15, 2020 **Motion**: Board Member moves the Board Dr. Miles to approve the April 15, 2020 open session minutes. **Seconded by**: Dr. Ashlee Bow. **Abstentions**: None. **Roll Call Vote:** 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. Ms. Chikita Sanders: Votes in favor of the motion. **Motion Carried.** **Approval of the Open Session Meeting Minutes** May 7, 2020 **Motion**: Board Member Ms. Sanders moves the Board to approve the May 7, 2020 open session minutes. **Seconded by**: Dr. Alison Hill. **Abstentions**: None. **Roll Call Vote:** 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. Ms. Chikita Sanders: Votes in favor of the motion. **Motion Carried.**	
Consent Agenda	**None**	
Executive Director Report	**Licensing Report** **Statistical Report on pharmacy professionals in the District of Columbia** ➢ Pharmacists: 2,180 ➢ Pharmacists with Vaccination and Immunization Authority: 732 ➢ Pharmacy Interns: 665	Dr. Shauna White

	➢ Pharmacy Technicians: 995 ➢ Pharmacy Technician Trainees: 103 ➢ Pharmacy Technician Training Programs: 13 ➢ Pharmaceutical Detailers: 538 **Prescription Drug Monitoring Program** All practitioners are encouraged to register for the Prescription Drug Monitoring Program. Providers are likewise encouraged to use the program whenever necessary. Impending legislation regarding this program will require all pharmacists and licensees who prescribe medications to register as a participant of the program within ninety (90) days of licensure. **Opioid Strategic Plan** For current information on the District's stance regarding the opioid crisis, the programs, the strategic plan, and community partners involved, go to https://livelong.dc.gov/page/about-live-long-dc.	
Assistant General Counsel Report		Ms. Carla Williams
0604-O-02	**Status Update on the Rulemaking Adding Continuing Education Requirements in Public Health Priorities-Verbal Report** Several rulings regarding the continuing education requirements were made by the District of Columbia Board of Pharmacy in response to the directive from the office of the Director of DC Health, which requires all health professionals to complete at least ten (10) percent of the total continuing education credits in subject matter pertaining to public health priorities. The rulemaking process was completed and uploaded to the District of Columbia Register, and will be published on June 12, 2020. The new requirements will be in effect for the license renewal period ending in 2023. For the Pharmacist, a total of four (4) continuing education credit hours must be completed in the public health priorities, a list of which will be published on the Board's website. In summary, the District of Columbia's Board of Pharmacy will require that pharmacists complete the following continuing education credits for the 2023 license renewal cycle: ➢ Two (2) continuing education hours of medication dispensing training. ➢ Two (2) continuing education hours of cultural competency for the LGBTQ population. ➢ Four (4) continuing education hours in the public health priorities.	

	For Pharmacists renewing a vaccination and immunization authority, an additional two (2) hours pertaining to vaccination and immunization administration will be required. Also, beginning in 2023 the Board will not require that Pharmacists complete two (2) continuing education hours in HIV training, as this requirement was voted down by the Board during the rulemaking process. Mr. Friedman raises the following comment regarding completion of <u>live</u> continuing education requirements during the COVID-19 public health emergency: ➢ Completing <u>live</u> continuing education credits are difficult due to the COVID-19 public health emergency as several conferences and other public events providing continuing education credits are cancelled. Mr. Friedman expects that the Board will discuss this matter in the near future and before the Board's Chair, Dr. McCants, for a decision on an amendment to the requirements.	
0604-O-03	**<u>Pharmacist COVID-19 Testing Emergency Regulations</u>** This matter is currently in process in consideration of conflicting issues stemming from the Department of Health and Human Services (HHS), which states pharmacists can conduct COVID-19 testing, but the District's Department of Health has no established regulations and guideline for pharmacists to conduct COVID-19 testing. DC Health is currently engaged in the rulemaking process, that would establish: 1. How testing can be done safely and effectively. 2. The provisions for pharmacists who are conducting COVID-19 tests. The emergency regulations are a work in progress and several entities are involved in crafting the regulations. These new regulations will establish guideline on the testing process. Additional information on this matter will be disseminated at the August, 2020 monthly meeting. Finally, the interpretation of HHS' Prep Act authorizes Pharmacists to conduct COVID-19 testing, and DC Health has not stated that Pharmacists are disallowed to conduct testing, especially if a Pharmacist is working with Department of Health and Human Services (HHS) through an associated program. DC Health is engaged in the rulemaking process regarding this issue because there are currently no regulations, which allow Pharmacists to conduct COVID-19 testing, and how testing can be done safely and effectively. ➢ Howard University College of Pharmacy announces its availability to assist the District of Columbia's Board of Pharmacy in the rulemaking process, wherever possible.	

Subcommittee Reports		
0604-O-04	**Legislative and Regulatory Subcommittee Report** The Legislative and Regulatory Subcommittee has accomplished the following: 1. A draft of the collaborative practice agreement between Pharmacists and Nurse Practitioners, which will be brought before the Board for discussion at the August, 2020 monthly meeting. 2. Significant progress on the review of Chapter 65, the *District of Columbia Municipal Laws of Pharmacy*. Recommendations on these regulations will be presented to the Board in the near future, as the subcommittee must consult with the Board's Chair on specific sections of the regulations. **Further Insight on the Collaborative Practice Agreement process:** While collaborative practice rules are established between Physicians and Pharmacists, the Board is now establishing the same with Nurse Practitioners. Using comments that were submitted by stakeholders at previous meetings, and considering the current [public health emergency] environment, the subcommittee has drafted a new agreement, which is currently under review by the Board's members on the subcommittee. After presenting the newly-established agreement to the Board at the August, 2020 monthly meeting, it will be submitted to the Board of Nursing for that Board's approval of the agreement. Subsequently, the newly-established collaborative practice agreement between Pharmacists and Nurse Practitioners will be published in the DC Register for public comment.	Mr. Alan Friedman
0604-O-05	**Re-Visit DC Board of Pharmacy Bylaws** **BYLAWS OF THE DISTRICT OF COLUMBIA BOARD OF PHARMACY** **ARTICLE I: GENERAL** The calendar year for the Board shall be from January 1st through December 31st. The Mayor shall appoint the Chairperson pursuant to D.C. Official Code § 3-1205.05(a) (2012 Repl.). The Chairperson shall remain in office until removed by the Mayor. The Board shall appoint from its members, a Vice Chairperson. The term of office for the Vice Chairperson shall be **two (2)** years. A person shall not serve as Vice Chairperson for more than **two (2)** consecutive terms. For the purposes of these Bylaws, the Board meets in open (public) sessions on the even-numbered months of the year, i.e. February,	

April, June, August, October, and December. On the odd-numbered months of the year, i.e. January, March, May, July, September, and November, the Board may meet in subcommittees and/or hold executive (closed) session meetings as needed Pursuant to D.C. Official Code § 2-575(b) (2012 Repl.), and for the purposes set forth therein, executive (closed) session meetings are not open to the public. The Board has the right to change the dates, schedule additional meetings as needed, or cancel any Board meeting. Board members shall attend all Board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the appointed members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, as may be amended from time to time, shall apply unless overruled by law, regulation, or these Bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

A. The officers of the Board shall be the Chairperson and the Vice Chairperson.

B. The Chairperson presides at all meetings and formal administrative hearings, and requires adherence of same on the part of the Board members.

C. The Vice Chairperson shall act as Chairperson in the absence of the Chairperson.

D. In the absence, or inability to serve, of both the Chairperson and Vice Chairperson, the Chairperson shall appoint another Board member to preside at the meeting and/or formal administrative hearing.

E. The Executive Director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business is generally set as follows:

1. Call to order with statement made for the record of how many Board members are present and that it constitutes a quorum

2. Approval of Agenda

3. Senior Deputy Director Report

4. Executive Director Report

5. Board Counselor Report

6. Subcommittee Reports

7. Old Business

8. New Business

9. Communications

10. Approval of Minutes

11. Public Comment Received

12. The remainder of the agenda shall be established by the Executive Director in consultation with the Chairperson, and is subject to change as needed.

ARTICLE IV: SUBCOMMITTEES

A. Subcommittees are established by motion and vote of the Board. There shall be the following standing subcommittees (permanent)/or special and select subcommittees (permissive);
   - Legislative and Regulatory Subcommittee
   - Communications Subcommittee

1. Legislative and Regulatory Subcommittee. This subcommittee shall consist of three Board members, Executive Director, and the Board's Legal Counsel. This subcommittee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comments as required in conjunction with rulemaking; conducting the required review of all existing regulations, and any other required tasks related to regulations. In accordance with the Administrative Procedure Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

2. Communications Subcommittee. This subcommittee shall consist of three Board members and the Executive Director. This subcommittee develops communication strategies for the Board

to reach out to members of the public and the pharmacy community, this includes but is not limited to, publishing newsletters, sending information mass emails, and making presentations on behalf of the Board for the pharmacy community, other health professionals, and members of the public as requested.

B. Ad Hoc Subcommittees.
The Board may create such other subcommittees as deemed necessary by motion and vote of the Board.

C. A majority of the subcommittee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the subcommittee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

The Board delegates the following functions:

1. The Board delegates to the Executive Director and her/his staff the authority to renew licenses and registrations where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

2. The Board delegates to the Executive Director the authority to issue new licenses and registrations where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

3. The Board delegates to the Executive Director the authority to reinstate licenses and registrations when the reinstatement is due to the lapse of the license or registration and where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

4. The Board delegates to the Executive Director the authority to sign orders and agreements on behalf of the Chairperson resulting from the disciplinary process or other administrative proceeding.

5. The Board delegates to the Executive Director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the Chairperson. Should the Executive Director and Chairperson not reach agreement, the matter shall be referred to the full Board.

6. The Board delegates to the Chairperson, the authority to represent the Board in instances where Board "consultation" or "review" may be

requested, but where a vote of the Board is not required and a meeting is not feasible.

7. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

8. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to initiate an investigation or request that a Board investigator acquires additional information pertaining to an ongoing investigation, should the investigation or additional information be needed between Board meetings to ensure the efficient administration of Board matters.

9. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to respond to an application for which the applicant's criminal background check has returned positive results by a) approving the application with no further action, b) issuing a negotiated settlement agreement with the appropriate fine, or c) referring to the Board for further action, pursuant to the Criminal Background Check Categories document issued by the Board.

ARTICLE VI: AMENDMENTS

These Bylaws shall be voted on every year, and amended as needed. Amendments to these Bylaws may be proposed by a Board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

- Chairperson Mr. Friedman requests that the Board nominate the Vice Chairperson at the June, 2020 monthly meeting. Consequently, the Board makes one nomination.

- Board Member Dr. Ashlee Bow nominates Mr. Alan Friedman as Vice Chairman of the District of Columbia Board of Pharmacy. Board Member Dr. Benjamin Miles votes in favor of the nomination. This nomination will be brought before the Board at the August, 2020 meeting for a final vote.

Matters of

Consideration		
0604-O-06	**MPJE Retake Policy Clarification** Executive Director of the Board, Dr. White, raises the following clauses of the District's MPJE Re-Take Policy for the Board's discussion: 1. "An applicant that fails to pass the MPJE during the first three (3) attempts, shall be required to meet with the Board before the Board may approve the applicant for subsequent testing. If approved by the Board to retake the examination, the applicant shall be required to wait sixty (60) days before retaking the examination." 2. "An applicant that fails to pass the MPJE during the first four (4) attempts, shall be required to wait ninety (90) days before retaking the examination." For clarification, Dr. White asks the Board the following: *"Does the time period of sixty (60) days and ninety (90) days begin after the applicant meets with the Board, or doe the time period begin after the applicant's last date of testing?"* Dr. Benjamin Miles introduces a motion to clarify the language: **Motion**: Board Member Dr. Benjamin Miles moves the Board to amend the MPJE Re-Take Policy to state the following: 1. "An applicant that fails to pass the MPJE during the first three (3) attempts, shall be required to meet with the Board before the Board may approve the applicant for subsequent testing. If approved by the Board to retake the examination, the applicant shall be required to wait ***sixty (60) days from the date of last test*** before retaking the examination." 2. "An applicant that fails to pass the MPJE during the first four (4) attempts, shall be required to wait ***ninety (90) days from the date of last test*** before retaking the examination." **Seconded by**: Board Member, Dr. Ashlee Bow. **Roll Call Vote:** Mr. Alan Friedman: Votes in favor of the motion. Dr. Ashlee Bow: Votes in favor of the motion. Dr. Benjamin Miles: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion. Ms. Chikita Sanders: Votes in favor of the motion. **Abstentions**: None **Motion Carried** Mr. Friedman informs the Board of the delays in NAPLEX testing and suggests that pharmacy college graduates are experiencing difficulty in finding preferred dates and time at testing locations. Consequently,	

	graduates are traveling to other states to sit the NAPLEX and/or MPJE but are finding that test dates and time are delayed for several months. Dr. White informs the Board that eight (8) testing locations remained opened during the COVID-19 public health emergency where *Stay At Home* Orders were implemented across states. In addition, these test locations limited seating capacity to comply with social distancing rules. However, as states re-open, additional locations are opening as well. The District of Columbia's Board of Pharmacy continues to approve applicants to test for both examinations. While the applicants may experience a delay in preferred testing locations and times, they may contact the NABP for more information on locations that have re-opened and are re-opening soon.	
0604-O-07	**Vote on the Next Percentage of Pharmaceutical Detailers to Audit Continuing Education** Executive Director, Dr. White, informs the Board that its authorization is need to conduct an audit of the Pharmaceutical Detailers to ensure compliance with continuing education credit requirements. **Motion**: Board Member Dr. Ashlee Bow moves the Board to authorize the audit of ten (10) percent of the licensed Pharmaceutical Detailers in the District of Columbia. **Seconded by**: Board Member, Ms. Chikita Sanders **Roll Call Vote:** Mr. Alan Friedman: Votes in favor of the motion. Dr. Ashlee Bow: Votes in favor of the motion. Dr. Benjamin Miles: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion. Ms. Chikita Sanders: Votes in favor of the motion. **Abstentions**: None **Motion Carried**	
0604-O-08	**Communications Subcommittee Report** The Communications Subcommittee has submitted a newsletter to NABP for the June publication, which will be disseminated via email. The publication will also be posted on the Board's website for public access. The Subcommittee will meet in August, 2020 to discuss and prepare for the next newsletter publication.	
NABP E-Newsletter	**May 26, 2020** FDA Updates Guidance Documents on Compounding For Hospitalized Patients During the COVID-19 Pandemic	Dr. Tamara McCants

	Over 6,800 Applications Received for NABP Passport, a Service Supporting Boards' COVID-19 Response List of Antibody Tests Being Removed From FDA's 'Notification List' $225 Million Approved for COVID-19 Testing in Rural Communities, HHS Reports FDA, FTC Issue Warning Letters to Two Amazon Associated Companies Selling Fake COVID-19 Treatments **May 21, 2020** FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages FDA Shares Recommendations With Providers About Antibody Tests for COVID-19 COVID-19 Pandemic May Lead to New Complications in the Opioid Crisis FDA Warns About Possible Accuracy Issues With Certain COVID-19 Tests FDA, FTC Take Additional Action Against Companies Selling Fraudulent COVID-19 Treatments Note to the Public: To receive weekly updates from NABP, please sign up by using the following link: https://nabp.pharmacy/newsroom/news/.	
Public Comments	Turan Tafade, Howard University College of Pharmacy asks the Board the following: "Are webinars that are conducted live, accepted by the Board for continuing education credit during the COVID-19 public health emergency? ➢ Executive Director of the Board, Dr. White, explains that a code is affixed to all continuing education credits. The participant engaging in the course must ensure that the code "L" for live is affixed to the continuing education credit, if he/she intends to submit the webinar to the Board as a live continuing education credit. Andrew Gentils, DC Pharmacy Association asks the Board the following: "What are the Board's plans on COVID-19 testing, which can be relayed to the Pharmacist community?" Board Counsel, Ms. Williams, informs Mr. Gentils that the Board is currently engaged in the rulemaking process regarding this matter. (Please refer to item **0604-O-03** for further details regarding *Pharmacist COVID-19 Testing Emergency Regulations*). Don Zawader, Public Interest Party asks the Board the following:	

	"Will the future meetings start at 8:30 am for the rest of the year, or will the start time move back to 9:30 am?" Executive Director of the Board, Dr. White, states that the start time for the Open Session of the Board's monthly meeting will vary and depend on the matters to be discussed in the meeting. With access to the WebEx platform, the Board will be flexible in deciding the start time of each meeting based on the obligations and other business matters on the Board's agenda.	
Motion to Adjourn the Open Session	**Board member, Dr. Benjamin Miles moves as follows:** "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)." **Seconded by**: Ms. Chikita Sanders. **Roll Call Vote:** 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. Ms. Chikita Sanders: Votes in favor of the motion. **Motion Carried.**	

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 9:30 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.

DC | HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

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

July 2, 2020

9:02 AM – 9:06 AM

OPEN SESSION MINUTES

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."

CALL TO ORDER: 9:02 AM

PRESIDING: DR. TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON

BOARD MEMBERSHIP/ATTENDANCE:

BOARD MEMBERS:		
	DR. TAMARA MCCANTS, PHARM.D. R.PH CHAIRPERSON	PRESENT
	DR. BENJAMIN MILES, PHARM.D. R.PH	PRESENT
	MR. ALAN FRIEDMAN, R.PH	PRESENT
	DR. ASHLEE BOW, PHARM.D. R.PH	PRESENT
	DR. ALLISON HILL, PHARM.D.R.PH.	PRESENT
	CHIKITA SANDERS, CONSUMER BOARD MEMBER	PRESENT
	GREGORY CENDANA, CONSUMER MEMBER	ABSENT
STAFF:	SHAUNA WHITE, EXECUTIVE DIRECTOR	ABSENT
	KARIN BARRON, HEALTH LICENSING SPECIALIST	PRESENT
	LUANNE GREENAWAY, HEALTH LICENSING SPECIALIST	PRESENT
	COUNTEE GILLIAM, BOARD INVESTIGATOR	PRESENT
LEGAL STAFF:	CARLA WILLIAMS, ASSISTANT GENERAL COUNSEL	PRESENT
VISITORS:	N/A	

Open Session Agenda

Quorum: Yes

Introduction:	None	
Consent Agenda	None	
Motion to Adjourn the Open Session	**Board member, Dr. Benjamin Miles moves as follows:** "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)." **Seconded by**: Board Member, Mr. Alan Friedman. **Roll Call Vote:** Dr. Tamara McCants: Votes in favor of the motion. Mr. Alan Friedman: Votes in favor of the motion. Dr. Ashlee Bow: Votes in favor of the motion. Dr. Allison Hill: Votes in favor of the motion. Dr. Benjamin Miles: Votes in favor of the motion. Ms. Chikita Sanders: Votes in favor of the motion. **Abstentions**: None **Motion Carried**	

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 9:06 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 RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth under §§ 102(11), 302 (14), and 1006 of the District of Columbia Health Occupation Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1202.01, 3-1203.02 (14)), and 3-1210.06, D.C. Official Code § 47-2885.01, D.C. Official Code § 47-2885.18, Mayor's Order 98-48 dated April 15, 1998, Mayor's Order 98-140, dated August 20, 1998, Mayor's Order 2020-045, dated March 11, 2020; and Mayor's Order 2020-050, dated March 20, 2020, gives notice of the adoption, on an emergency basis, of the following amendment to chapter 65 of Title 17 of the District of Columbia Municipal Regulations (DCMR) (Pharmacists) adding a new § 6516 (COVID-19 Testing by Pharmacists).

This emergency rulemaking is necessary to protect the health, safety, and welfare of the District's residents by reducing the spread of COVID-19 by establishing minimum standards for the safe and effective operation of pharmacies where pharmacists, and pharmacy interns under the direct supervision of a pharmacist, administer COVID-19 tests, and observe and facilitate collection of a self-administered COVID-19 test.

This emergency rulemaking was adopted on June 5, 2020, and became effective immediately on that date. The emergency rule will expire one hundred twenty (120) days from the date of adoption (October 3, 2020) or forty-five (45) days after the public health emergency declared by Mayor's Order 2020-050 dated March 20, 2020 or any substantially similar subsequent Mayor's Order is declared over, whichever occurs first.

A new Section 6516 is added to read as follows:

6516 COVID-19 Testing by Pharmacists

6516.1 A pharmacist licensed in good standing in the District of Columbia shall only perform COVID-19 tests as set forth in this section.

6516.2 For purposes of this section, the terms "COVID-19 test" and "COVID-19 testing" shall refer to COVID-19 diagnostic tests, COVID-19 antibody tests, and any other tests and testing mechanisms for COVID-19 that become approved by the United Stated Food and Drug Administration. Also, for purposes of this section, the term "perform COVID-19 tests" or "perform COVID-19 testing" shall mean to administer or supervise administration of COVID-19 tests or testing, or observe and facilitate collection of self-administered COVID-19 tests or testing.

6516.3 A pharmacist licensed in good standing in the District of Columbia shall only perform COVID-19 testing at a location site that meets the requirements set forth in § 6516.4 of this chapter.

6516.4 A COVID-19 testing location operated by a pharmacy in a non-institutional setting shall:

(a) Be an outdoor location in close proximity to the pharmacy building, such as a parking lot; which may include drive up, curbside, or walk up access;

(b) Not be located within six (6) feet of the entrance of the pharmacy building;

(c) Have and follow a plan for the safe operation of the testing site, and an infection control plan; and

(d) Maintain a record of all patients who have undergone COVID-19 testing at the testing location. This information shall be maintained by the pharmacy for at least one year unless otherwise directed by the Department of Health.

6516.5 All COVID-19 testing conducted in a non-institutional pharmacy location shall be performed by appointment only, which may be scheduled the same-day and onsite.

6516.6 Prior to performing COVID-19 testing, a pharmacist shall review and familiarize himself/herself with the Center for Disease Control's "Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)" and ensure that the pharmacist has appropriate personal protective equipment (PPE) to safely perform the testing.

6516.7 All pharmacists and pharmacy personnel involved in COVID-19 testing shall wear appropriate PPE, which shall include at a minimum, a mask, gloves (which may be nonsterile), a face shield, and a protective gown.

6516.10 The pharmacist-in-charge of a pharmacy where COVID-19 testing will be performed, shall:

(a) Implement appropriate policies and procedures for the safe performance of COVID-19 testing at that location, which shall include appropriate training, collection procedures, availability and use of PPE, and proper disposal of used PPE; and

(b) Staff the pharmacy in a manner to ensure that the pharmacist(s) who is administering COVID-19 testing is engaged solely in performing COVID-19 testing, and is not dispensing prescriptions or counseling patients in between administering COVID-19 testing. The pharmacist performing COVID-19 testing shall only dispense prescriptions and counsel patients after all COVID-19 testing has been completed for the period during which he or she has been assigned to perform testing, after properly disposing of his or her PPE, and after thoroughly washing his or her hands.

6516.11 The health care practitioner who orders the COVID-19 test, who may be the same pharmacist who administers the test, shall be responsible for receiving the test results and directing a patient with a positive test result to receive care and monitoring.

6516.12 A pharmacist licensed in good standing in the District of Columbia may permit a licensed pharmacy intern to administer COVID-19 testing under the pharmacist's direct supervision, on an individual who is eighteen (18) years of age or older, in accordance with the requirements set forth in this section.

June 18, 2020

Shauna White, PharmD, RPh, MS
Executive Director
District of Columbia, Board of Pharmacy
899 North Capitol Street, NE – 2nd Floor
Washington, DC 20002

RE: DEPARTMENT OF HEALTH EMERGENCY RULEMAKING – COVID-19 TESTING BY PHARMACISTS

Dear Director White,

The National Community Pharmacists Association (NCPA), the National Association of Chain Drug Stores (NACDS), the National Grocers Association (NGA), and the Food Industry Association (FMI) is writing you today in regards to the recently adopted Department of Health (DOH), Board of Pharmacy (BOP) emergency rule - **§ 6516**, *COVID-19 Testing by Pharmacists*. We commend the DOH's efforts to curb the spread of the 2019 novel coronavirus disease (COVID-19) while protecting the health, safety, and welfare of the District's residents. However, the adopted rules for safe and effective operation of pharmacies that participate in COVID-19 testing entails restrictive requirements on types of COVID-19 tests authorized to use for the service, restrictions on personal protective equipment (PPE), exclusion of certified pharmacy technician participation in testing efforts, and inaccurate classification of all testing as the same, notably requiring testing outdoors, regardless of the differences in testing processes. These requirements create inefficiencies in the District's efforts to expand COVID-19 testing and negatively impacts patient access to testing. As such, we request the Department of Health to approach this opportunity for pharmacists to provide the service from a broad standards of care approach instead of implementing prescriptive rules to provide quality patient care. In addition, the emergency rules as written, may expire before the HHS public health emergency declaration.

NCPA represents the interest of America's community pharmacists, including the owners of more than 21,000 independent community pharmacies across the United States and 44 independent community pharmacies in the District of Columbia (D.C.) that employ about 488 full-time employees who filled over 2.5 million prescriptions last year. Our members are small business owners who are among America's most accessible health care providers in many communities and are critical for the expansion of testing and eventually to furnish a COVID-19 vaccine to D.C. residents once available.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Our members operate nearly 40,000 pharmacies and include regional chains, with as few as four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. For more information, please visit nacds.org.

FMI represents the entire food industry – from producers that supply food and other products, to food retailers that sell to consumers as well as supermarket pharmacies – to amplify the collective work of the industry. Health and wellness, including pharmacy-specific programs, is of the utmost importance to our industry. In total, FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. The reach and impact of our work is extensive, ultimately touching the lives of over 100 million households in the United States and representing an $800 billion industry with nearly 6 million employees.

The National Grocers Association (NGA) is the national trade association representing the retail and wholesale grocers that comprise the independent sector of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. The independent grocery sector is accountable for close to one percent of the nation's overall economy and is responsible for generating $131 billion in sales, 944,000 jobs, $30 billion in wages, and

$27 billion in taxes. NGA members include retail and wholesale grocers – including over 3,000 grocery pharmacies, state grocers associations, as well as manufacturers and service suppliers.

Pharmacist COVID-19 Testing Authority

We applaud the DOH and BOP for enacting this emergency rule, granting pharmacists the authority to conduct COVID-19 testing. However, rule 6516.2 requires pharmacists to use COVID-19 tests that have been "approved by the United States Food and Drug Administration (FDA)." The U.S. Department of Health and Human Services (HHS) advisory opinion clarified that pharmacists are authorized to order, administer, and perform COVID-19 tests, including serological tests, ***authorized*** by the FDA. HHS and the majority of other states that have addressed COVID-19 testing authority have used authorized instead of approved because, to date, no COVID-19 diagnostic or serologic tests have been approved by the FDA, but several have been authorized via emergency use authorization (EUA). We strongly urge the DOH and the BOP to amend rule 6516.2 to align with federal guidance and expand pharmacist testing access to neighborhoods across the District.

PPE Requirements

We support ensuring the safety of patients, pharmacists, and pharmacy staff during testing but rule 6516.7 requirement for pharmacy personnel involved in testing to be fully gowned, including having a face shield, regardless of direct or non-direct test administration, is counterproductive to the efficient use of PPE. During the process of a COVID-19 drive-up test, the patients remain in their vehicle with their windows rolled up during the collection process, and the pharmacy staff does not get within the recommended distance of six (6) feet from the patient.

Furthermore, the adopted rules go far beyond the CDC[1] PPE guidance, and even the FDA[2] relaxed its PPE rules due to shortages and increased demand. Moreover, the CDC takes the position that face shields are to be used during procedures and activities that could generate splashes, body fluids, secretions, and excretions.[3] Thus, we recommend that the minimum PPE requirements, including wearing face shields be required only when the testing protocol could expose the pharmacy personnel to patient excretions while performing COVID-19 testing (i.e. performing a nasal swab).

Pharmacy Technician Participation

Rule 6516.12 prohibits the pharmacist from authorizing a certified pharmacy technician to assist in the COVID-19 testing process. All members of the pharmacy team should be leveraged to their fullest capability in order to effectively deliver quality patient care. Pharmacists should focus their time on patient care activities, and they have the flexibility to do so when other members of the pharmacy team can step up and support administrative pharmacy roles, including administrative aspects of COVID-19 testing. Much like the pharmacist's scope of practice, certified pharmacy technician roles have advanced from pill counting to remote data entry, taking medical histories, vaccine administration, and administering pharmacist-authorized tests. In a number of states, including Ohio[4] and Vermont[5], certified pharmacy technicians are authorized to administer COVID-19 tests under pharmacist supervision. The increased role of the certified pharmacy technicians is a natural progression to be embraced for its part in supporting a better standard of pharmacy care. We urge the DOH to allow the pharmacist in charge to utilize their highly trained certified pharmacy technicians in COVID-19 testing to increase testing capacity while managing the pharmacy's daily workflow to serve all patients well.

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[1]CDC, Strategies to Optimize the Supply of PPE and Equipment

[2]FDA, Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding

[3]CDC, https://www.cdc.gov/hicpac/recommendations/core-practices.html

Testing Categories and Location

Rule 6516.2 incorrectly categorizes all testing as the same. A distinction taking into account the test type and location is necessary for administering COVID-19 diagnostic tests, antibody tests, and self-administered sample collection. These processes vary in safety concerns and warrant separate considerations in how and where they are carried out. Rule 6516.4 requires that all testing occurs outdoors. Given that outdoor space is hard to find in urban settings, requiring all testing to occur outdoors may prevent pharmacies from participating. Employers are also well aware of the importance in taking the necessary safety precautions when providing patient care services, adhering to CDC guidance and developing the necessary protocols to ensure healthcare workers and patient safety. They are well-positioned to determine the appropriate location to conduct testing, without additional burdensome requirements. Additionally, CDC states that asymptomatic patients who test positive via serological testing and do not have recent COVID-19 compatible illness have relatively low likelihood of active infection.[6] Thus, we recommend the DOH and BOP give pharmacies the option of choosing to test indoor or outdoor when performing COVID-19 antibody tests, while requiring facemasks and ensuring that social distancing standards are maintained during testing, as well as remove unnecessary distance and location requirements to provide the service.

Accessible COVID-19 Testing Services

In order for D.C. to reopen safely, testing capacity must be increased significantly. The accessibility and convenience of community pharmacies allows D.C. residents the ability to receive quality COVID-19 testing services within their own neighborhood. However, rule 6515.5 limits pharmacies' ability to extend their patient reach by requiring appointments for patients to receive COVID testing. Pharmacists are well-positioned and capable of conducting COVID-19 testing services without the need of an appointment. In fact, just recently 8 fire houses across D.C. offered residents walk-up testing delivered by paramedics and EMTs with no appointment needed. Given pharmacists' extensive educational background and training adequately qualifies them to provide testing services and we would posit similar flexibility should be extended to pharmacy healthcare destinations. Thus, we strongly urge the DOH and the BOP to remove rule 6516.5 in an effort to expand access to COVID-19 testing and protecting D.C. residents.

Conclusion

Frontline community pharmacists stand ready to continue helping in their authorized capacity, and they remain well-positioned to play an essential role to expand testing and provide mass vaccination to D.C. residents once a vaccine is available. The recommendations above will remove existing restrictive barriers to testing and enhance patient care in D.C. Thank you for your time and consideration, please do not hesitate to contact NCPA's Ronna Hauser, Vice President – Policy & Government Affairs Operations at ronna.hauser@ncpa.org with any questions you may have.

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[4] Expansion Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician Testing Authority During COVID-19

[5] Pharmacis Ordering and Administration of Testing for COVID-19 in Vermont

[6] CDC, Interim Guidelines for COVID-19 Antibody Testing

Sincerely,

B. Douglas Hoey, RPh, MBA

Chief Executive Officer

National Community Pharmacists Association

Greg Ferrara

President & CEO

National Grocers Association

Steven C. Anderson, FASAE, CAE, IOM

President and Chief Executive Officer

National Association of Chain Drug Stores

Jennifer Hatcher

Chief Public Policy Officer & Senior Vice President, Government Relations

FMI – The Food Industry Association

CC:

Sharon Lewis, Carla Williams, Frank Meyers, Tamara McCants

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The District of Columbia Boards of Pharmacy and Nursing (the "Boards") jointly, pursuant to the authority set forth under Section 2(b) of the Collaborative Care Expansion Amendment Act of 2012, effective October 22, 2012 (D.C. Law 19-0185; D.C. Official Code § 3-1202.08 (h)(2) (2016 Repl.)) (the "Act"), hereby give notice of their intent to adopt the following new Chapter 104, entitled "Collaborative Practice Agreements Between Nurse-practitioners and Pharmacists" of Title 17 (Business, Occupations, and Professionals) of the District of Columbia Municipal Regulations (DCMR), in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

The adoption of Chapter 104, which had until now been reserved, is necessary to implement the provision of the Act that permits nurse-practitioners and pharmacists licensed in the District of Columbia to enter into collaborative practice agreements.

Title 17 DCMR, BUSINESS, OCCUPATIONS, AND PROFESSIONALS, is amended by adding a new Chapter 104 to read as follows:

CHAPTER 104 COLLABORATIVE PRACTICE AGREEMENTS BETWEEN NURSE-PRACTITIONERS AND PHARMACISTS

10400 GENERAL PROVISIONS

10400.1 Participation in a collaborative practice agreement shall be voluntary, and no licensed nurse-practitioner, pharmacist or institution shall be required to participate.

10400.2 Neither a pharmacist nor Nurse-practitioner shall provide economic incentives to the other for the purpose of entering into a collaborative practice agreement.

10400.3 A Nurse-practitioner shall not be employed by any pharmacist or pharmacy for the sole purpose of collaborative practice.

10400.4 Patient entry into a collaborative practice arrangement shall be initiated by an authorizing protocol that includes coverage of the patient(s), or a written referral from the licensed nurse-practitioner to the pharmacist for a specific patient.

10400.5 When patient entry is initiated by the pharmacist, the pharmacist shall:

(a) Instruct the patient to follow up with the authorizing nurse-practitioner within the time period established in the collaborative practice agreement;

(b) Notify the authorizing nurse-practitioner of the encounter in writing within twenty-four (24) hours or one (1) business day; and

(c) Obtain a referral from the authorizing nurse-practitioner before providing further collaborative practice services to the patient.

10400.6 A pharmacist who is a party to a collaborative practice agreement shall utilize an area for in person, telephonic or other approved electronic consultations relating to the management of drug therapy that ensures the confidentiality of the patient information being discussed.

10400.7 Nothing in these regulations shall be construed or interpreted to allow a pharmacist to accept delegation of a nurse-practitioner's authority outside of or beyond the scope of the pharmacist's practice.

10401 REQUIREMENTS FOR PARTICIPATION IN A COLLABORATIVE PRACTICE AGREEMENT

10401.1 A pharmacist shall only participate in a collaborative practice agreement in accordance with this chapter.

10401.2 A licensed nurse-practitioner shall have a valid patient-nurse-practitioner relationship with a patient that he or she refers to a pharmacist for participation in a collaborative practice agreement under this chapter.

10401.3 For purposes of this chapter, an internet based or telephone consultation or questionnaire evaluation is not adequate to establish a valid patient-nurse-practitioner relationship unless and except as otherwise specifically permitted by District law.

10401.4 The licensed nurse-practitioner and pharmacist who are parties to a collaborative practice agreement shall hold an active license in good standing in the District of Columbia.

10401.5 The Boards may deny approval of a nurse-practitioner or pharmacist to participate in a collaborative practice agreement if the nurse-practitioner or pharmacist has:

(a) A final order by the governing Board disciplining the nurse-practitioner or pharmacist's license for a practice issue within the five (5) years immediately preceding the formation of the agreement; or

(b) Limitations placed on the nurse-practitioner or pharmacist's license by the governing board.

10401.6 The collaborative practice agreement shall be within the scope of the licensed nurse-practitioner's current practice.

10401.7 To be eligible to participate in a collaborative practice agreement, a pharmacist:

(a) Shall possess relevant advanced training as indicated by one of the following:

(1) Certification as a specialist by:

(i) The Board of Pharmaceutical Specialties;

(ii) The Commission for Certification in Geriatric Pharmacy; or

(iii) Another credentialing body approved by the Board of Pharmacy; or

(2) Successful completion of:

(i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education; or

(ii) A certificate program approved by the Board of Pharmacy; or

(b) Shall have successfully completed:

(1) A minimum of three (3) years of relevant clinical experience, if the pharmacist holds an academic degree of Doctor of Pharmacy; or

(2) A minimum of five (5) years of relevant clinical experience, if the pharmacist holds an academic degree of Bachelor of Science in Pharmacy; and

(c) Shall have documented training related to the area of practice covered by the collaborative practice agreement.

10402 USE OF COLLABORATIVE PRACTICE AGREEMENTS AND REQUIRED CONTENT

10402.1 The management of drug therapy pursuant to a collaborative practice agreement shall be initiated by an authorizing protocol that includes coverage of the patient(s) or a written referral from the licensed nurse-practitioner to the pharmacist for a specific patient.

10402.2 When a patient encounter is initiated through an authorizing protocol, the pharmacist shall notify the authorizing nurse-practitioner in writing within twenty-four (24) hours or one (1) business day.

10402.3 The authority granted by the nurse-practitioner to the pharmacist must be within the scope of the nurse-practitioner's practice.

10402.4 The collaborative practice agreement may allow the pharmacist, within the pharmacist's scope of practice, to conduct activities approved by the nurse-practitioner pursuant to the agreement and within the authority established by the law and regulations.

10402.5 The collaborative practice agreement shall not prohibit the pharmacist from providing other pharmaceutical services that are within the pharmacist's scope of practice.

10402.6 A collaborative practice agreement shall be based upon treatment protocols that are generally accepted as the clinical standard of care within the medical and pharmacy professions, or approved by the Boards of Nursing and Pharmacy in accordance with § 10006 of this chapter, and shall include:

(a) Identification of the Nurse-practitioners(s) and pharmacist(s) who are parties to the agreement;

(b) The location(s) where the pharmacist(s) and nurse-practitioner(s) may provide services under the collaborative practice agreement;

(c) The name, address, and telephone number of the person(s) who are to receive correspondence from the Boards related to the collaborative practice agreement;

(d) A detailed description of the disease state or condition, drugs or drug categories, drug therapies, devices, and any necessary incidental tests,

authorized by the nurse-practitioner, and the activities allowed in each case;

(e) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(f) A detailed description of the activities and procedures that the pharmacist is to follow, including documentation of decisions made, and a plan or appropriate mechanism for communication, feedback, and reporting to the nurse-practitioner activities and results concerning specific decisions made;

(g) The conditions under which the pharmacist may initiate, modify, or discontinue a drug therapy;

(h) Directions concerning the monitoring of a drug therapy, including the conditions that would warrant a modification to the dose, dosage regime, or dosage form of the drug therapy;

(i) The frequency and the manner in which the pharmacist conducts the management of drug therapy;

(j) A method for the nurse-practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary;

(k) A description of the continuous quality improvement efforts used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(l) A provision that allows the nurse-practitioner to override a collaborative practice decision made by the pharmacist whenever he or she deems it necessary or appropriate, with notification to the pharmacist of the override within twenty-four (24) hours or one (1) business day, or as noted in the collaborative practice agreement;

(m) A provision that allows either party to cancel the collaborative practice agreement by written notification;

(n) An effective date; and

(o) The signatures of all collaborating pharmacists and Nurse-practitioners who are party to the collaborative practice agreement, as well as dates of signing.

10402.7 The collaborative practice agreement may include treatment protocols that include a nurse-practitioner(s) delegation of authority to the pharmacist(s) to obtain

laboratory tests provided the tests relate directly to the drug therapy management under the protocol.

10402.8 In addition to the requirements set forth in the collaborative practice agreement, documentation of each intervention, including changes in dose, duration or frequency of medication prescribed, shall be recorded in the pharmacist's prescription record, patient profile, a separate log book, or in some other appropriate system.

10402.9 Except as provided in section 10402.10, pharmacists engaging in collaborative practice shall not delegate any collaborative practice activities to any other staff.

10402.10 A pharmacist may delegate collaborative practice activities that are strictly administrative tasks that do not require the use of professional judgment to staff licensed or registered under the Act.

10402.11 Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information.

10402.12 Oral communications between the nurse-practitioner and pharmacist shall be summarized in the documentation maintained by the pharmacist and forwarded to the nurse-practitioner.

10402.13 Unless an alternative time period is stated in the collaborative practice agreement, the pharmacist shall inform the nurse-practitioner within forty-eight (48) hours if the pharmacist modifies the drug dose or agent.

10402.14 Unless an alternative time period is stated in the collaborative practice agreement, the pharmacist shall inform the nurse-practitioner within twenty-four (24) hours if the pharmacist detects an abnormal result from an assessment activity.

10402.15 Amendments to a collaborative practice agreement must be documented, signed, and dated, and for collaborative practice agreements containing approved protocols outside the generally accepted clinical standard of care, the amendments must be approved by the Boards before they are implemented.

10402.16 At a minimum, the collaborative practice agreement shall have a documented review and, if necessary, be revised every year.

10403 SIGNED AUTHORIZATION

10403.1 The signatories to a collaborative practice agreement shall be a District of Columbia licensed nurse-practitioner involved directly in patient care where

patients receive services and a District of Columbia licensed pharmacist involved directly in patient care where patients receive services.

10403.2 The nurse-practitioner may designate alternate Nurse-practitioners, and the pharmacist may designate alternate pharmacists, provided that the alternates are signatories to the agreement, meet the educational, licensure, and training requirements of this Chapter, and are involved directly in patient care where patients receive services. Nothing in this Section shall be construed as prohibiting the practice of telemedicine if it is otherwise permitted by District law.

10404 INFORMED PATIENT CONSENT AND WITHDRAWAL OF PARTICIPATION

10404.1 Documented informed consent from the patient shall be obtained by the nurse-practitioner who authorizes the patient to participate in the collaborative practice agreement or by the pharmacist who is also a party to the collaborative practice agreement, and ~~10004.2 For purposes of this section, documented informed consent shall mean either written consent signed by a patient, or its electronic equivalent~~, maintained in the patient's record.

10404.2 The patient may decline to participate or withdraw from participation at any time.

10404.3 Prior to obtaining a patient's consent to participate in a collaborative practice agreement, the nurse-practitioner or pharmacist, or both, shall inform a patient:

(a) Of the procedures that will be utilized for drug therapy management under the collaborative practice agreement, and such discussion shall be documented in the patient record;

(b) That the patient may decline to participate or withdraw from participating in the drug therapy management at any time; and

(c) That neither the nurse-practitioner nor the pharmacist has been coerced, given economic incentives, excluding normal reimbursement for services rendered, or involuntarily required to participate.

10405 TERMINATION OR ALTERATION OF THE COLLABORATIVE PRACTICE AGREEMENT

10405.1 The collaborative practice agreement may be terminated at any time upon written notice by the pharmacist, nurse-practitioner, or the patient. Notice of termination shall be provided to all affected and potentially affected parties to the collaborative practice agreement and the patient within fourteen (14) days of termination.

10405.2 A nurse-practitioner may override the collaborative practice agreement whenever he or she deems such action necessary or appropriate for a specific patient, and shall notify the pharmacist of the override within twenty-four (24) hours or one (1) business day.

10405.3 If either the nurse-practitioner or the pharmacist who is a party to the collaborative practice agreement has a change of practice location, employer, or ownership, that person shall notify the other party and all of the nurse-practitioner's or pharmacist's patients who are participants in the collaborative practice agreement.

10406 APPROVAL OF PROTOCOLS OUTSIDE THE STANDARD OF CARE

10406.1 If a nurse-practitioner and a pharmacist intend to manage or treat a condition or disease state for which there is not a protocol that is generally accepted as the clinical standard of care, the nurse-practitioner and pharmacist shall apply for approval. The Boards shall receive and review the proposed treatment protocol and jointly approve or disapprove.

10406.2 Any procedure outside generally accepted clinical practice shall be approved by the Boards, and any changes to a protocol for procedures outside the generally accepted clinical practice shall be approved by the Boards before they are implemented.

10406.3 Application and approval are not needed for treatment of conditions for which there is a generally accepted clinical standard of care, but for which the nurse-practitioner wants to increase the monitoring and oversight of the condition over what the protocol recommends.

10406.4 In order to apply for approval of a protocol outside the generally accepted clinical standard of care, the nurse-practitioner and the pharmacist shall jointly submit:

(a) An application on the required form and the required fee;

(b) A copy of the proposed protocol; and

(c) Supporting documentation that the protocol is safe and effective for the particular condition or disease state for which the nurse-practitioner and the pharmacist intend to manage or treat through a collaborative practice agreement.

10406.5 To apply for approval to make changes to an approved protocol outside of the generally accepted clinical standard of care, the nurse-practitioner and the pharmacist shall jointly submit:

(a) An application on the required form and the required fee;

(b) A copy of the proposed changes to the protocol; and

(c) Supporting documentation that the change(s) to the protocol is safe and effective for the particular condition or disease state for which the nurse-practitioner and the pharmacist intend to manage or treat through a collaborative practice agreement.

10407 RECORDKEEPING

10407.1 Signatories to a collaborative practice agreement shall keep a copy of the agreement on file at their primary places of practice.

10407.2 The referral of a patient from the nurse-practitioner authorizing the implementation of drug therapy management pursuant to the collaborative practice agreement shall be noted in the patient's medical record and kept on file by the pharmacist.

10407.3 The patient's documented informed consent shall be retained by the parties to the collaborative practice agreement.

10407.4 A copy of the collaborative practice agreement, any amendments to the agreement, and the subsequent termination of any such agreement, if applicable, shall be available as follows:

(a) At the practice site of any nurse-practitioner who is a party to the collaborative practice agreement;

(b) At the practice site of any pharmacist who is a party to the collaborative practice agreement;

(c) At the institution or facility where a collaborative practice agreement is in place;

(d) To any patient who is being managed under the collaborative practice agreement, upon request; and

(e) Upon request, to representatives of the Boards of Pharmacy and Nursing.

10407.5 Documentation of activities performed under a collaborative practice agreement or the nurse-practitioner's specific instructions shall be maintained in such a manner that it is accessible to the:

(a) Nurse-practitioner;

(b) Pharmacist; and

(c) The Boards of Pharmacy and Nursing upon request.

10407.6 Documentation may be maintained in written or electronic form.

10407.7 A pharmacist or nurse-practitioner who is a party to the collaborative practice agreement shall have access to the records of the patient who is the recipient of the management of drug therapy.

10407.8 A patient's records related to the management of drug therapy under a collaborative practice agreement may be maintained in a computerized recordkeeping system which meets all requirements for Federal and State certified electronic health care records.

10407.9 The handling of all patient records by the pharmacist providing the management of drug therapy must comply with the Health Insurance Portability and Accountability Act of 1996 (Pub.L. 104-191, 110 Stat. 1936).

10407.10 The Boards may conduct random audits to ensure compliance with the provisions of the Act and this chapter.

10408 DISAPPROVAL AND REVOCATION OF COLLABORATIVE PRACTICE AGREEMENTS

10408.1 The Board of Pharmacy and the Board of Nursing may disapprove or revoke a collaborative practice agreement if the Boards find:

(a) Inadequate training, experience, or education of the nurse-practitioner(s) or pharmacist(s) to implement the protocol or protocols specified in the nurse-practitioner-pharmacist agreement;

(b) The collaborative practice agreement fails to comply with the requirements of this chapter or the Act;

(c) The collaborative practice agreement is intended to manage or treat a condition or disease state for which there is not a protocol that is generally accepted as the clinical standard of care, or which is not approved by the Boards; or

(d) Either party to the agreement has been formally disciplined by any health professional licensing board in any jurisdiction, or is otherwise no longer licensed in good standing in the District of Columbia.

10409 COLLABORATIVE PRACTICE IN INSTITUTIONAL FACILITIES

10409.1 The provisions of this subchapter shall apply to collaborative practice arrangements between pharmacists and Nurse-practitioners in institutional facility settings.

10409.2 To the extent that there is any conflict between this subchapter and any other section of this chapter, the provisions of this subchapter shall prevail with respect to collaborative practice arrangements between pharmacists and Nurse-practitioners in institutional facility settings.

10409.3 Nothing in this chapter shall be construed to prohibit pharmacists who practice in institutional facility settings from participating in collaborative practice arrangements pursuant to an institutional facility practice protocol approved by the institutional facility's Pharmacy and Therapeutics Committee ("P and T Committee"), the institutional facility's medical staff executive committee, or the institutional facility's medical director.

10409.4 Pharmacists who practice in institutional facility settings shall only participate in collaborative practice arrangements pursuant to an institutional facility practice protocol approved by the institutional facility's P and T Committee, the institutional facility's medical staff executive committee, or the institutional facility's medical director.

10409.5 Nothing in this subchapter shall be construed or interpreted to allow a pharmacist to accept delegation of a nurse-practitioner's authority outside of or beyond the scope of the pharmacist's practice.

10409.6 The licensed nurse-practitioner and pharmacist who are parties to an institutional facility practice protocol shall hold an active license in good standing in the District of Columbia.

10409.7 The Boards may deny approval of a nurse-practitioner or pharmacist to participate in collaborative practice under an institutional facility practice protocol if the nurse-practitioner or pharmacist has:

(a) A final order by the governing Board disciplining the nurse-practitioner or pharmacist's license for a practice issue within the five (5) years immediately preceding the formation of the agreement; or

(b) Limitations placed on the nurse-practitioner or pharmacist's license by the governing board.

10409.8 The collaborative practice services under an institutional facility practice protocol shall be within the scope of the licensed nurse-practitioner(s)'s current practice.

10409.9 To be eligible to participate in an institutional facility practice protocol, a pharmacist:

(a) Shall possess relevant advanced training as indicated by one of the following:

(1) Certification as a specialist by:

(i) The Board of Pharmaceutical Specialties;

(ii) The Commission for Certification in Geriatric Pharmacy; or

(iii) Another credentialing body approved by the Board of Pharmacy; or

(2) Successful completion of:

(i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education; or

(ii) A certificate program approved by the Board of Pharmacy; or

(b) Shall have successfully completed:

(1) A minimum of three (3) years of relevant clinical experience, if the pharmacist holds an academic degree of Doctor of Pharmacy; or

(2) A minimum of five (5) years of relevant clinical experience, if the pharmacist holds an academic degree of Bachelor of Science in Pharmacy; and

(c) Shall have documented training related to the area of practice covered by the institutional facility practice protocol.

10409.10 Prior to providing collaborative practice services, pharmacists who practice in institutional facility settings shall review the following information in the patient's chart:

(a) Patient's name, gender, date of birth, height, and weight;

(b) Patient's diagnosis or diagnoses from the treating nurse-practitioner;

(c) Patient's medication history;

(d) Patient's prior lab values;

(e) Patient's vital signs; and

(f) Patient's known allergies.

10409.11 The institutional facility shall create an institutional facility practice protocol identifying where the information required in § 10009.10 will be located, and how it will be accessed throughout the facility by the participating pharmacists and Nurse-practitioners.

10409.12 The institutional facility practice protocol shall serve as the collaborative practice agreement in these settings, and the institutional facility practice protocol shall identify which Nurse-practitioners and pharmacists are authorized and have agreed to provide collaborative practice services.

10409.13 The institutional facility practice protocol shall contain a plan for development, training, administration, and quality assurance of the protocol.

10409.14 An institutional facility practice protocol based upon treatment protocols that are generally accepted as the clinical standard of care within the medical and pharmacy professions, and that complies with the applicable requirements of this subchapter is deemed approved by the Boards.

10409.15 An institutional facility practice protocol approved by the Boards of Nursing and Pharmacy in accordance with §10006 or § 10009.14 of this subchapter shall contain the following information:

(a) Identification of the Nurse-practitioners(s) and pharmacist(s) who are parties to the institutional facility practice protocol;

(b) The location(s) where the pharmacist(s) and nurse-practitioner(s) may provide services under the institutional facility practice protocol;

(c) The name, address, and telephone number of the person(s) who are to receive correspondence from the Boards related to the institutional facility practice protocol;

(d) A detailed description of the disease state or condition, drugs or drug categories, drug therapies, devices, and any necessary incidental tests, authorized by the nurse-practitioner, and the activities allowed in each case;

(e) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(f) A detailed description of the activities and procedures that the pharmacist is to follow, including documentation of decisions made, and a plan or appropriate mechanism for communication, feedback, and reporting to the nurse-practitioner activities and results concerning specific decisions made;

(g) The conditions under which the pharmacist may initiate, modify, or discontinue a drug therapy;

(h) Directions concerning the monitoring of a drug therapy, including the conditions that would warrant a modification to the dose, dosage regime, or dosage form of the drug therapy;

(i) The manner in which pharmacist's drug therapy management will be monitored by the prescriber, including method and frequency;

(j) A specified time within which the pharmacist must notify the prescriber of any modifications of drug therapy;

(k) A description of the continuous quality improvement efforts used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(l) A provision that allows the prescriber to override any action taken by the pharmacist when the prescriber deems it to be necessary;

(m) The effective date; and

(n) A provision addressing how drug therapy management will be handled when the patient has more than one prescriber involved in evaluating or treating the medical condition which is the subject of the protocol. All prescribers who are actively involved in the management of the relevant conditions shall be parties to the protocol.

10409.16 The institutional facility practice protocol may include a nurse-practitioner(s) delegation of authority to the pharmacist(s) to obtain laboratory tests provided the tests relate directly to the drug therapy management under the protocol.

10409.17 Unless an alternative time period is stated in the institutional facility practice protocol, the pharmacist shall inform the nurse-practitioner within forty-eight (48) hours if the pharmacist modifies the drug dose or agent.

10409.18 Unless an alternative time period is stated in the institutional facility practice protocol, the pharmacist shall inform the nurse-practitioner within twenty-four (24) hours if the pharmacist detects an abnormal result from an assessment activity.

10409.19 Amendments to an institutional facility practice protocol must be documented, signed, and dated, and for institutional facility practice protocols containing approved protocols outside the generally accepted clinical standard of care, the amendments must be approved by the Boards before they are implemented.

10409.20 At a minimum, the institutional facility practice protocol shall have a documented review and, if necessary, be revised every year.

10409.21 The institutional facility's P and T Committee, medical staff executive committee, or medical director shall serve as the authorizing agent for the organization's medical staff, identifying which Nurse-practitioners or nurse-practitioner groups are authorized to participate under the institutional facility practice protocol, may restrict authorization for certain protocols to specific Nurse-practitioners, nurse-practitioner groups, or specialties, and shall ensure that the participating Nurse-practitioners are informed of the protocol and consent to participation.

10409.22 A pharmacist engaging in collaborative practice under an institutional facility's practice protocol shall read, sign, and date the protocol.

10409.23 The institutional pharmacy manager, or other designated person set forth in the institutional facility practice protocol, shall ensure that the institutional facility practice protocol is maintained current, that changes to the protocol are updated timely including the identification of the persons authorized to participate under the protocol, that copies of the protocol shall be maintained onsite where collaborative practice services take place, and that the protocol is revised as medically necessary.

10409.24 Except as provided in section 10409.25, pharmacists engaging in collaborative practice shall not delegate any collaborative practice activities to any other staff.

10409.25 A pharmacist may delegate collaborative practice activities that are strictly administrative tasks that do not require the use of professional judgment to staff licensed or registered under the Act.

10409.26 All activity by the pharmacist, including changes in dose, duration or frequency of medication prescribed, shall be recorded in the pharmacist's prescription record, patient profile, a separate log book, or in some other appropriate system.

10409.27 A copy of the institutional facility practice protocol, any amendments to the protocol, and the subsequent termination of any such protocol, if applicable, shall be available to:

(a) Any nurse-practitioner who is a party to the institutional facility practice protocol;

(b) Any pharmacist who is a party to the institutional facility practice protocol;

(c) Any patient who is being managed under the institutional facility practice protocol, upon request; and

(d) Representatives of the Boards of Pharmacy and Nursing, upon request.

10409.28 Documentation of activities performed under an institutional facility practice protocol or the nurse-practitioner's specific instructions shall be maintained in such a manner that it is accessible to the:

(a) Nurse-practitioner;

(b) Pharmacist; and

(c) The Boards of Pharmacy and Nursing upon request.

10409.29 Documentation may be maintained in written or electronic form.

10409.30 The Board of Pharmacy and the Board of Nursing may disapprove or revoke an institutional facility practice protocol if the Boards find:

(a) Inadequate training, experience, or education of the nurse-practitioner(s) or pharmacist(s) to implement the protocol or protocols;

(b) The institutional facility practice protocol fails to comply with the requirements of this subchapter or the Act;

(c) The institutional facility practice protocol is intended to manage or treat a condition or disease state for which there is not a protocol that is generally accepted as the clinical standard of care, or which is not approved by the Boards; or

(d) Any party to the protocol has been formally disciplined by any health professional licensing board in any jurisdiction, or is otherwise no longer licensed in good standing in the District of Columbia.

10409.31 The Boards may conduct random audits to ensure compliance with the provisions of the Act and this subchapter.

10410 COLLABORATIVE PRACTICE IN GROUP MODEL HEALTH MAINTENANCE ORGANIZATIONS

10410.1 The provisions of this subchapter shall apply to collaborative practice arrangements between pharmacists and Nurse-practitioners in Group Model Health Maintenance Organizations ("GMHMO") facility settings.

10410.2 To the extent that there is any conflict between this subchapter and any other section of this chapter, the provisions of this subchapter shall prevail with respect to collaborative practice arrangements between pharmacists and Nurse-practitioners in GMHMO facility settings.

10410.3 Nothing in this chapter shall be construed to prohibit pharmacists who practice in GMHMOs facility settings from participating in collaborative practice arrangements pursuant to a GMHMO facility practice protocol approved by the GMHMOs facility's Pharmacy and Therapeutics Committee ("P and T Committee"), the GMHMO facility's medical staff executive committee, or the GMHMOs facility's medical director.

10410.4 Pharmacists who practice in GMHMO facility settings shall only participate in collaborative practice arrangements pursuant to a GMHMO facility practice protocol approved by the GMHMO facility's P and T Committee, the GMHMOs facility's medical staff executive committee, or the GMHMO facility's medical director.

10410.5 Nothing in this subchapter shall be construed or interpreted to allow a pharmacist to accept delegation of a nurse-practitioner's authority outside of or beyond the scope of the pharmacist's practice.

10410.6 The licensed nurse-practitioner and pharmacist who are parties to a GMHMO facility practice protocol shall hold an active license in good standing in the District of Columbia.

10410.7 The Boards may deny approval of a nurse-practitioner or pharmacist to participate in collaborative practice under a GMHMO facility practice protocol if the nurse-practitioner or pharmacist has:

(c) A final order by the governing Board disciplining the nurse-practitioner or pharmacist's license for a practice issue within the five (5) years immediately preceding the formation of the agreement; or

(d) Limitations placed on the nurse-practitioner or pharmacist's license by the governing board.

10410.8 The collaborative practice services under a GMHMO facility practice protocol shall be within the scope of the licensed nurse-practitioner(s)'s current practice.

10410.9 To be eligible to participate in a GMHMO facility practice protocol, a pharmacist:

(a) Shall possess relevant advanced training as indicated by one of the following:

(1) Certification as a specialist by:

(i) The Board of Pharmaceutical Specialties;

(ii) The Commission for Certification in Geriatric Pharmacy; or

(iii) Another credentialing body approved by the Board of Pharmacy; or

(2) Successful completion of:

(i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education; or

(ii) A certificate program approved by the Board of Pharmacy; or

(b) Shall have successfully completed:

(3) A minimum of three (3) years of relevant clinical experience, if the pharmacist holds an academic degree of Doctor of Pharmacy; or

(4) A minimum of five (5) years of relevant clinical experience, if the pharmacist holds an academic degree of Bachelor of Science in Pharmacy; and

(c) Shall have documented training related to the area of practice covered by the GMHMO facility practice protocol.

10410.10 Prior to providing collaborative practice services, pharmacists who practice in GMHMO facility settings shall review the following information in the patient's chart:

(g) Patient's name, gender, date of birth, height, and weight;

(h) Patient's diagnosis or diagnoses from the treating nurse-practitioner;

(i) Patient's medication history;

(j) Patient's prior lab values;

(k) Patient's vital signs; and

(l) Patient's known allergies.

10410.11 The GMHMO facility shall create a GMHMO facility practice protocol identifying where the information required in § 10009.10 will be located, and how it will be accessed throughout the facility by the participating pharmacists and Nurse-practitioners.

10410.12 The GMHMO facility practice protocol shall serve as the collaborative practice agreement in these settings, and the GMHMO facility practice protocol shall identify which Nurse-practitioners and pharmacists are authorized and have agreed to provide collaborative practice services.

10410.13 The GMHMO facility practice protocol shall contain a plan for development, training, administration, and quality assurance of the protocol.

10410.14 A GMHMO facility practice protocol based upon treatment protocols that are generally accepted as the clinical standard of care within the medical and pharmacy professions, and that complies with the applicable requirements of this subchapter is deemed approved by the Boards.

10410.15 A GMHMO facility practice protocol approved by the Boards of Nursing and Pharmacy in accordance with §10006 or § 10009.14 of this subchapter shall contain the following information:

(d) Identification of the Nurse-practitioners(s) and pharmacist(s) who are parties to the GMHMO facility practice protocol;

(e) The location(s) where the pharmacist(s) and nurse-practitioner(s) may provide services under the GMHMO facility practice protocol;

(f) The name, address, and telephone number of the person(s) who are to receive correspondence from the Boards related to the GMHMO facility practice protocol;

(d) A detailed description of the disease state or condition, drugs or drug categories, drug therapies, devices, and any necessary incidental tests, authorized by the nurse-practitioner, and the activities allowed in each case;

(e) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(f) A detailed description of the activities and procedures that the pharmacist is to follow, including documentation of decisions made, and a plan or appropriate mechanism for communication, feedback, and reporting to the nurse-practitioner activities and results concerning specific decisions made;

(g) The conditions under which the pharmacist may initiate, modify, or discontinue a drug therapy;

(h) Directions concerning the monitoring of a drug therapy, including the conditions that would warrant a modification to the dose, dosage regime, or dosage form of the drug therapy;

(i) The manner in which pharmacist's drug therapy management will be monitored by the prescriber, including method and frequency;

(j) A specified time within which the pharmacist must notify the prescriber of any modifications of drug therapy;

(k) A description of the continuous quality improvement efforts used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(l) A provision that allows the prescriber to override any action taken by the pharmacist when the prescriber deems it to be necessary;

(m) The effective date; and

(n) A provision addressing how drug therapy management will be handled when the patient has more than one prescriber involved in evaluating or treating the medical condition which is the subject of the protocol. All prescribers who are actively involved in the management of the relevant conditions shall be parties to the protocol.

10410.16 The GMHMO facility practice protocol may include a nurse-practitioner(s) delegation of authority to the pharmacist(s) to obtain laboratory tests provided the tests relate directly to the drug therapy management under the protocol.

10410.17 Unless an alternative time period is stated in the GMHMO facility practice protocol, the pharmacist shall inform the nurse-practitioner within forty-eight (48) hours if the pharmacist modifies the drug dose or agent.

10410.18 Unless an alternative time period is stated in the GMHMO facility practice protocol, the pharmacist shall inform the nurse-practitioner within twenty-four (24) hours if the pharmacist detects an abnormal result from an assessment activity.

10410.19 Amendments to a GMHMO facility practice protocol must be documented, signed, and dated, and for GMHMO facility practice protocols containing approved protocols outside the generally accepted clinical standard of care, the amendments must be approved by the Boards before they are implemented.

10410.20 At a minimum, the GMHMO facility practice protocol shall have a documented review and, if necessary, be revised every year.

10410.21 The GMHMO facility's P and T Committee, medical staff executive committee, or medical director shall serve as the authorizing agent for the organization's medical staff, identifying which Nurse-practitioners or nurse-practitioner groups are authorized to participate under the GMHMO facility practice protocol, may restrict authorization for certain protocols to specific Nurse-practitioners, nurse-practitioner groups, or specialties, and shall ensure that the participating Nurse-practitioners are informed of the protocol and consent to participation.

10410.22 A pharmacist engaging in collaborative practice under an GMHMO facility's practice protocol shall read, sign, and date the protocol.

10410.23 The GMHMO pharmacy manager, or other designated person set forth in the GMHMO facility practice protocol, shall ensure that the GMHMO facility practice protocol is maintained current, that changes to the protocol are updated timely including the identification of the persons authorized to participate under the protocol, that copies of the protocol shall be maintained onsite where collaborative practice services take place, and that the protocol is revised as medically necessary.

10410.24 Except as provided in section 10410.25, pharmacists engaging in collaborative practice shall not delegate any collaborative practice activities to any other staff.

10410.25 A pharmacist may delegate collaborative practice activities that are strictly administrative tasks that do not require the use of professional judgment to staff licensed or registered under the Act.

10410.26 All activity by the pharmacist, including changes in dose, duration or frequency of medication prescribed, shall be recorded in the pharmacist's prescription record, patient profile, a separate log book, or in some other appropriate system.

10410.27 A copy of the GMHMO facility practice protocol, any amendments to the protocol, and the subsequent termination of any such protocol, if applicable, shall be available to:

(b) Any nurse-practitioner who is a party to the GMHMO facility practice protocol;

(b) Any pharmacist who is a party to the GMHMOs facility practice protocol;

(c) Any patient who is being managed under the GMHMO facility practice protocol, upon request; and

(d) Representatives of the Boards of Pharmacy and Nursing, upon request.

10410.28 Documentation of activities performed under a GMHMO facility practice protocol or the nurse-practitioner's specific instructions shall be maintained in such a manner that it is accessible to the:

(a) Nurse-practitioner;

(b) Pharmacist; and

(c) The Boards of Pharmacy and Nursing upon request.

10410.29 Documentation may be maintained in written or electronic form.

10410.30 The Board of Pharmacy and the Board of Nursing may disapprove or revoke an GMHMO facility practice protocol if the Boards find:

(e) Inadequate training, experience, or education of the nurse-practitioner(s) or pharmacist(s) to implement the protocol or protocols;

(f) The GMHMO facility practice protocol fails to comply with the requirements of this subchapter or the Act;

(g) The GMHMO facility practice protocol is intended to manage or treat a condition or disease state for which there is not a protocol that is generally accepted as the clinical standard of care, or which is not approved by the Boards; or

(h) Any party to the protocol has been formally disciplined by any health professional licensing board in any jurisdiction, or is otherwise no longer licensed in good standing in the District of Columbia.

10410.31 The Boards may conduct random audits to ensure compliance with the provisions of the Act and this subchapter.

10499 DEFINITIONS

10499.1 As used in this chapter, the following terms have the meanings ascribed:

Act- the Collaborative Care Expansion Amendment Act of 2012, effective October 22, 2012 (D.C. Law 19-0185; 60 DCR 7591 (May 31, 2013)).

Collaborative practice agreement- means a voluntary written agreement between a licensed pharmacist and a licensed nurse-practitioner that has been approved by the Board of Pharmacy and the Board of Nursing, or between a licensed pharmacist and another health practitioner with independent prescriptive authority licensed by a District health occupation board, that defines the scope of practice between the licensed pharmacist and licensed nurse-practitioner, or other health practitioner, for the initiation, modification, or discontinuation of a drug therapy regimen.

GMHMO- Group Model Health Maintenance Organization.

Group Model Health Maintenance Organization- (Will be added)

Group model HMO practice protocol – means a written plan, policy, procedure, or agreement that authorizes drug therapy management between pharmacists and nurse-practitioners within a GMHMO practice setting as developed and determined by the GMHMO's P and T Committee, the GMHMO's Service Chiefs, or the GMHMO's medical director.

Institutional facility- means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including a(n):

(1) Hospital;
(2) Convalescent home;
(3) Nursing home;
(4) Extended care facility;
(5) Mental health facility;
(6) Rehabilitation center;
(7) Psychiatric center;
(8) Developmental disability center;
(9) Substance use disorder treatment center;
(10) Family planning clinic;
(11) Correctional institution;
(12) Hospice;
(13) Public health facility.

Institutional facility practice protocol – means a written plan, policy, procedure, or agreement that authorizes drug therapy management between pharmacists and Nurse-practitioners within an institutional facility setting as developed and determined by the institutional facility's P

and T Committee, the institutional facility's medical staff executive committee, or the institutional facility's medical director.

Nurse-practitioner- a person licensed as a nurse-practitioner by the District of Columbia Board of Nursing.

Standard of Care- the course of action that other prudent and well-trained health professionals in the same field of practice would customarily take under the same or similar circumstances.

BYLAWS OF THE DISTRICT OF COLUMBIA BOARD OF PHARMACY

ARTICLE I: GENERAL

The calendar year for the Board shall be from January 1st through December 31st. The Mayor shall appoint the Chairperson pursuant to D.C. Official Code § 3-1205.05(a) (2012 Repl.). The Chairperson shall remain in office until removed by the Mayor. The Board shall appoint from its members, a Vice Chairperson. The term of office for the Vice Chairperson shall be **two (2)** years. A person shall not serve as Vice Chairperson for more than **two (2)** consecutive terms.

For the purposes of these Bylaws, the Board meets in open (public) sessions on the even-numbered months of the year, i.e. February, April, June, August, October, and December. On the odd-numbered months of the year, i.e. January, March, May, July, September, and November, the Board may meet in subcommittees and/or hold executive (closed) session meetings as needed Pursuant to D.C. Official Code § 2-575(b) (2012 Repl.), and for the purposes set forth therein, executive (closed) session meetings are not open to the public. The Board has the right to change the dates, schedule additional meetings as needed, or cancel any Board meeting. Board members shall attend all Board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the appointed members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, as may be amended from time to time, shall apply unless overruled by law, regulation, or these Bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

A. The officers of the Board shall be the Chairperson and the Vice Chairperson.

B. The Chairperson presides at all meetings and formal administrative hearings, and requires adherence of same on the part of the Board members.

C. The Vice Chairperson shall act as Chairperson in the absence of the Chairperson.

D. In the absence, or inability to serve, of both the Chairperson and Vice Chairperson, the Chairperson shall appoint another Board member to preside at the meeting and/or formal administrative hearing.

E. The Executive Director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business is generally set as follows:

1. Call to order with statement made for the record of how many Board members are present and that it constitutes a quorum

2. Approval of Agenda

3. Senior Deputy Director Report

4. Executive Director Report

5. Board Counselor Report

6. Subcommittee Reports

7. Old Business

8. New Business

9. Communications

10. Approval of Minutes

11. Public Comment Received

12. The remainder of the agenda shall be established by the Executive Director in consultation with the Chairperson, and is subject to change as needed.

ARTICLE IV: SUBCOMMITTEES

A. Subcommittees are established by motion and vote of the Board. There shall be the following standing subcommittees (permanent)/or special and select subcommittees (permissive);
   - Legislative and Regulatory Subcommittee
   - Communications Subcommittee

1. Legislative and Regulatory Subcommittee. This subcommittee shall consist of three Board members, Executive Director and the Board's Legal Counsel. This subcommittee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comments as required in conjunction with rulemaking; conducting the required review of all existing regulations, and any other required tasks related to regulations. In accordance with the Administrative Procedure Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

2. Communications Subcommittee. This subcommittee shall consist of three Board members and the Executive Director. This subcommittee develops communication strategies for the

Board to reach out to members of the public and the pharmacy community, this includes but is not limited to, publishing newsletters, sending information mass emails, and making presentations on behalf of the Board for the pharmacy community, other health professionals, and members of the public as requested.

B. Ad Hoc Subcommittees.
The Board may create such other subcommittees as deemed necessary by motion and vote of the Board.

C. A majority of the subcommittee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the subcommittee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

The Board delegates the following functions:

1. The Board delegates to the Executive Director and her/his staff the authority to renew licenses and registrations where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

2. The Board delegates to the Executive Director the authority to issue new licenses and registrations where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

3. The Board delegates to the Executive Director the authority to reinstate licenses and registrations when the reinstatement is due to the lapse of the license or registration and where minimum qualifications have been met, and no disciplinary action or practice issues have been identified.

4. The Board delegates to the Executive Director the authority to sign orders and agreements on behalf of the Chairperson resulting from the disciplinary process or other administrative proceeding.

5. The Board delegates to the Executive Director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the Chairperson. Should the Executive Director and Chairperson not reach agreement, the matter shall be referred to the full Board.

6. The Board delegates to the Chairperson, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.

7. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board

regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

8. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to initiate an investigation or request that a Board investigator acquires additional information pertaining to an ongoing investigation, should the investigation or additional information be needed between Board meetings to ensure the efficient administration of Board matters.

9. The Board delegates to the Executive Director, in consultation with Board counsel, the authority to respond to an application for which the applicant's criminal background check has returned positive results by a) approving the application with no further action, b) issuing a negotiated settlement agreement with the appropriate fine, or c) referring to the Board for further action, pursuant to the Criminal Background Check Categories document issued by the Board.

ARTICLE VI: AMENDMENTS

These Bylaws shall be voted on every year, and amended as needed. Amendments to these Bylaws may be proposed by a Board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.