FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

June 4, 2021
Virtual Meeting

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A virtual Webex meeting of the Board of Pharmacy was called to order at 9:20 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
Cheryl H. Nelson, Vice Chairman
Bernard Henderson, Jr.
James L. Jenkins, Jr.
William Lee
Sarah Melton
Patricia Richards-Spruill
Dale St.Clair

MEMBER ABSENT:
Glen Bolyard

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Ryan Logan, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Katrina Trelease, Pharmacist Inspector, DHP
Matt Treacy, Media Production Specialist (departed around noon)
Henry Fisher, Video Conferencing Specialist (arrived around noon)

PHARMACISTS AWARDED: Jamin Engel

1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:

QUORUM

With eight members participating, a quorum was established.

APPROVAL OF AGENDA:

Hearing no additional items for consideration, Mr. Ratliff announced that the agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Several amendments were offered to the draft minutes included in the agenda packet.

MOTION:

The board voted unanimously to adopt the minutes for March 30, 2021 through May 13, 2021 as presented and amended as follows:

- **Page 2 of March 30, 2021 full board minutes, under "Approval of Previous Board Meeting Minutes", insert "legislation to authorize adult use marijuana in the December 10, 2020 full board meeting minutes." after "discussions regarding concerns for l";**
- **Page 6 of the May 3, 2021 Regulation Committee meeting minutes, in the motion regarding Section 10, change "delete" to "amend";**
- **Page 6 of the May 3, 2021 Regulation Committee meeting minutes, in the motion, change "Change of timeframe for notification of a change in the PIC from 14 to 30 days" to "Consideration of extending timeframe beyond 14 days for notification of a change in the PIC";**
- **Page 31 of the May 7, 2021 Formal Hearing minutes, in the Decision section, strike "with one abstention (B. Henderson)" and after "revised by the Board.", insert "Mr. Henderson verbally indicated after the vote that he had a temporary technical issue restricting his ability to vote, but that he would have voted in favor of the motion." (motion by Nelson, seconded by Jenkins)**

PUBLIC COMMENTS:

Craig Connors, Senior Director, Payor Relations, Virginia Hospital & Healthcare Association (VHHA) referenced the letter from VHHA included in the agenda packet requesting an interpretation of the final regulations regarding white bagging.

Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA) applauded pharmacist administration of COVID-19 vaccines and stated that VPhA may introduce legislation to codify current PREP Act allowances for pharmacist administration of vaccines to persons age three and up. She stated VPhA will host a virtual training on contraception to support use of the current statewide protocol for pharmacists to initiate treatment. She requested the board delay signing the FDA MOU until the September

meeting.
Mark Hickman, representing the Virginia Society of Health-System Pharmacists (VSHP), commented that VSHP supports the goals of the white bagging regulations and will submit written comment on the subject. He requested the board publish another public comment opportunity regarding the regulatory periodic review since the pandemic and General Assembly session may have distracted individuals from submitting comments in January.

Doug Gray, Executive Director, Virginia Association of Health Plans commented in support of the practice of white bagging as the long term objective is to decrease cost.

DHP DIRECTOR'S REPORT:

Dr. Brown commented that boards are starting to resume in-person meetings. He stated most employees are still teleworking several days each week, but do not need to wear a mask when in the building if fully vaccinated. Staff has been informed that they should make arrangements, if necessary, for potentially working an increased number of days in the building after September 1. The agency hopes to strike a balance between teleworking and working on-site.

Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP, shared that 2/3 of Virginia adults have received a first dose of COVID-19 vaccine and that pharmacists have surpassed local health departments as a source of vaccine. She stated COVID-19 cases continue to decrease.

Jim Jenkins expressed appreciation for their leaderships and commented on the benefits of virtual meetings, e.g., increased public attendance and cost-savings. Dr. Brown stated that DHP may seek to have a legislative proposal introduced to authorize boards to conduct certain meetings virtually, such as committee meetings that are often shorter in duration than full board meetings.

Kris Ratliff questioned if there would be a future opportunity to broadcast in-person meetings. Dr. Brown stated there are technical challenges that would need to be considered such as if there is sufficient bandwidth and IT staff to run multiple meetings at the same time in the conference center.

LEGISLATIVE/
REGULATORY/ GUIDANCE

CHART OF REGULATORY ACTIONS:

Ms. Yeatts provided an overview of the current regulatory actions on pages 34-35 of the agenda packet. She stated the medication carousel and RFID

technology regulations had recently moved from the Department of Planning and Budget to the Secretary's office.

ACTION ITEM:

There was some discussion regarding the "prohibition against incentives to transfer prescriptions" action, the length of time the action has been in the Governor's office, and whether the board may want to consider withdrawing the action at some point. Several members commented on the risks associated with the practice and the need for the regulation. Mr. Henderson suggested that staff first ask the policy office to explain their concerns regarding the action and report back at a future meeting.

REGULATORY/POLICY ACTIONS RESULTING FROM THE 2021 GENERAL ASSEMBLY:

Ms. Yeatts briefly reviewed the chart on pages 36 and 37 of the agenda. Ms. Juran commented that the workgroup to discuss pharmacy technician duties will tentatively meet on September 23rd, the workgroup to establish statewide protocols will tentatively meet on August 9th and 11th (if a second meeting is necessary), and the workgroup to provide recommendations regarding development of future statewide protocols will tentatively meet on August 16th. The special conference committee to review innovative pilot applications will be rescheduled to August 17th.

NOTICE OF PUBLIC COMMENT PERIOD – REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS:

Ms. Yeatts stated that a notice of public comment regarding the Regulations Governing Pharmaceutical Processors was posted on May 6th and will expire on July 5th. The legislation requires a 60-day public comment period and that regulations must be effective by September 1, 2021. Comments are strongly encouraged to be submitted by June 18th to allow sufficient time to be included in the agenda package for the July 6th meeting.

REPORT FROM REGULATION COMMITTEE

PETITION FOR RULEMAKING, SHORTENING EXPIRATION DATE OF SCHEDULE II PRESCRIPTIONS:

The board discussed the Regulation Committee's recommendation to deny the petition. Some members expressed support for the petitioner's request to shorten the expiration date of a Schedule II prescription. Dr. St.Clair stated that he has concern for shortening the expiration to less than 90 days. Ms. Juran commented that the petition references "opioid prescriptions" and "Schedule II prescriptions" and requested clarification if staff's research should focus on Schedule II prescriptions or all opioid prescriptions. The Board stated that staff should focus its research on all Schedule II prescriptions.

MOTION:

The board voted 6:2 in favor of the Regulation Committee's recommendation to deny the petition for rulemaking to shorten the expiration date of Schedule II prescriptions. (opposed by Henderson and Lee)

MOTION/ACTION ITEM:

The Board voted unanimously to include in the upcoming periodic regulatory review process consideration for whether to shorten the expiration date of Schedule II prescriptions and directed staff to find out what actions other states have taken on this subject and obtain feedback from the prescriber boards. (motion by Henderson, seconded by Lee)

RECOMMENDED SUBJECTS FOR PERIODIC REVIEW OF REGULATIONS:

MOTION:

The Board voted unanimously in favor of the Regulation Committee's recommendation to include the following items in the periodic review and solicit the public for other items following the June board meeting:

- **Section 10, amend definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies**
- **Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.**
- **Consideration of including a requirement for an e-profile identification number for facilities**
- **Consideration of extending timeframe beyond 14 days for notification of a change in the PIC**
- **Consider amending 18VAC110-20-550 to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs**
- **Amend 18VAC110-20-110 (J) to include allowance to consider prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy by the pharmacist-in-charge or immediate family members of the pharmacist-in-charge, and owners, directors, or officers**
- **Amend 18VAC110-21-90(A) by requiring FPGEC prior to obtaining pharmacist license through endorsement or score transfer and delete exemption from FPGEC in subsection D**
- **Amend 18VAC110-20-690 and 18VAC110-30-80 to prohibit registration and permit from being issued to private dwelling or residence.**

AMENDED GUIDANCE DOCUMENTS 110-2 AND 110-17

MOTION:

The Board voted unanimously in favor of the Regulation Committee's

recommendation to amend Guidance Documents 110-2 and 110-17 as presented.

ACPE STANDARDS 2025

MOTION/ACTION ITEM:

The Board voted unanimously in favor of the Regulation Committee's recommendation to provide supportive feedback on the 2025 ACPE Standards as presented in ACPE's survey.

LEGISLATIVE PROPOSALS

It was reported that the Regulation Committee did not have any legislative proposals to recommend to the Board for its consideration.

ADOPTION OF EXEMPT REGULATIONS TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

MOTION:

Pursuant to 54.1-3443 (D) of the Code of Virginia, the Board voted unanimously to adopt the exempt regulatory action to amend 18VAC110-20-322 as presented to place the following chemicals into Schedule I for up to 18 months from the effective date of the regulation unless enacted into law in the Drug Control Act:

Compound expected to have hallucinogenic properties.

- **4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

Cannabimimetic agents.

- **ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

- **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation. (motion by Jenkins, seconded by St.Clair)**

INTERPRETATION REQUEST FROM VHHA

The Board reviewed the letter from the Virginia Hospital and Healthcare Association (VHHA) included in the agenda packet on pages 65 and 66.

REGARDING PROPOSED WHITE BAGGING REGULATIONS:

VHHA seeks an interpretation of the proposed regulations regarding the practice of white bagging. Ms. Juran reminded the Board that the proposed regulations exempt the pharmacy and alternate delivery site from certain requirements if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm.

MOTION:

The Board voted unanimously to capture in the meeting minutes and in a guidance document to be prepared by staff that compliance with subsections B through E of 18VAC110-20-275 would be required under the following circumstances: a pharmacy makes regular deliveries of a standardized list of multiple drugs to the same alternate delivery site over time; the delivery of a drug would not result in potential patient harm. (motion by St.Clair, second by Jenkins)

AMEND GUIDANCE DOCUMENT 110-9, INSPECTION MONETARY PENALTY GUIDE:

Staff commented that Guidance Document 110-9 needs to be amended based on the recent creation of a pharmacy technician trainee registration.

MOTION:

The Board voted unanimously to amend Guidance Document 110-9 as presented. (motion by Nelson, seconded by Richards-Spruill)

FAQS FOR ADDRESSING THE PHARMACEUTICAL PROCESSOR RFA

Because the Board is legally prohibited currently from reviewing the applications submitted during the recent RFA for a pharmaceutical processor permit in Health Service Area I, the RFA process is taking much longer than originally anticipated. Staff shared that applicants have expressed concern that temporary building and land leases are expiring and inquiring as to what action is permissible under the RFA process. Ms. Juran and Ms. Kelley reviewed a document of draft frequently asked questions for the Board's consideration for adoption which may assist the RFA applicants. The document was shared on the screen for all to see.

MOTION:

The Board voted unanimously to adopt the frequently asked questions as presented and listed below:

Q: Is the Board currently reviewing applications that were submitted prior to the December 4, 2020 deadline?

A: No. PharmaCann appealed the Board's rescission of conditional approval and denial of its application in health service area 1. On

January 14, 2021, the Henrico County Circuit Court ordered the Board to cease reviewing applications until further order by the Court. As a result, the Board must wait for the Court's resolution of PharmaCann's appeal.

Q: When will the Board resume review of the applications?

A: The Board must wait for the resolution of PharmaCann's appeal in the Henrico County Circuit Court.. If the Court authorizes the Board to resume review of applications, the Board will do so as soon as possible.

Q: Will the Board allow for updated information to be submitted prior to resuming review of the applications?

A: The Board is aware that changes in the original application submission, which may include changes in location or ownership, may have occurred since the December 4th deadline. Prior to resuming the application review process, staff will communicate with the applicants and provide a 60-day notice for any changes in the original application to be submitted as a revised application.

Q: If the Henrico County Circuit Court vacates the Board's Order denying PharmaCann's application, what impact will this decision have on the existing RFA?

A: The Board will make a decision on how to proceed in the event that this occurs.

Q: Is the Board able to issue more than one pharmaceutical processor permit in Health Service Area I?

A: Virginia Code § 54.1-3442.6(B) of the Code of Virginia restricts the Board to issuing only one pharmaceutical processor permit per health service area. (motion by Richards-Spruill, seconded by Nelson)

OLD BUSINESS

FDA MOU ON COMPOUNDING INORDINATE AMOUNTS:

Ms. Juran provided a brief overview of the subject. Mr. Rutkowski commented that he has reviewed the MOU. He reminded the Board that the decision to sign the MOU or not is ultimately Dr. Brown's as DHP Director. He stated that there are three potential barriers that DHP may be able to overcome: 1) the Board will need to be able to identify pharmacies that are dispensing inordinate amounts of compounds out-of-state and report certain information to the FDA; 2) investigators will need to be able to assess if there is a public health risk and if it has been contained; and 3) DHP would need to sign a 20.88 agreement with FDA. During discussion, it was acknowledged that use of NABP's Information Sharing Network would allow the board to

identify pharmacies dispensing inordinate amounts of compounds out-of-state and report the required information to the FDA, however, a legislative or regulatory requirement for pharmacies to report information to NABP's Information Sharing Network must first be enacted. Ms. Juran commented that she was seeking clarification from the FDA regarding whether VA could sign the MOU contingent upon legislation or regulation becoming effective or if VA is prohibited from signing the MOU until such requirement is effective. No response had been received at the time of the meeting.

MOTION:

The Board voted 7:1 to recommend to Dr. Brown that DHP sign the FDA MOU on Compounding Inordinate Amounts pending legislation being passed that would require compounding pharmacies to report certain information to NABP's Information Sharing Network. (motion by St.Clair, seconded by Nelson; opposed by Melton)

NEW BUSINESS

ELECTION OF CHAIRMAN AND VICE-CHAIRMAN

Dr. Ratliff called for open nominations for the position of Board Chairman. One member was nominated, Dr. Cheryl Nelson. Hearing no additional nominations, Dr. Ratliff declared the open nominations closed.

MOTION:

The Board voted unanimously to elect Dr. Cheryl Nelson as Board Chairman for the term July 1, 2021 through June 30, 2022.

Dr. Ratliff called for open nominations for the position of Board Vice-Chairman. One member was nominated, Dr. Dale St.Clair. Hearing no additional nominations, Dr. Ratliff declared the open nominations closed.

MOTION:

The Board voted unanimously to elect Dr. Dale St.Clair as Board Vice-Chairman for the term July 1, 2021 through June 30, 2022.

SELECT 2022 MEETING DATES FOR FULL BOARD MEETINGS AND REGULATION COMMITTEE MEETINGS:

Staff shared a list on the screen of possible dates for all to see. Staff acknowledged that conference room availability in December 2022 was very limited, but that more rooms may become available in the future. If so, staff may request that the Board revisit the December full board meeting date to ensure that the scheduled room can accommodate everyone.

The Board concluded that full board meetings will be tentatively held on:

- March 15, 2022
- June 6, 2022
- September 6, 2022
- December 6, 2022

Regulation Committee meetings will be tentatively held on:

- May 3, 2022

- November 1, 2022

REPORTS

CHAIRMAN'S REPORT:

Dr. Ratliff expressed appreciation to pharmacists who have worked tirelessly to administer COVID-19 vaccines. He also welcomed Mr. Ryan Logan to Board staff as the newly hired Deputy Executive Director. He congratulated Ms. Juran for assuming the role of NABP President at the recent NABP annual meeting in May. He expressed appreciation for the honor of serving as Board Chairman for the last year and congratulated Dr. Nelson on being elected the next Chairman.

REPORT ON BOARD OF HEALTH PROFESSIONS

Mr. Logan reported that at the May 13 Board of Health Professions meeting, Dr. Brown provided a review of the legislation for this session. He stated that the Board of Pharmacy will be impacted by several marijuana bills including the legalization of marijuana on July 1, 2021. He also reported that the agency was very involved in the emergency bill expanding the pool of qualified vaccinators. Dr. Allison-Bryan reported that the rate of COVID 19 infections has slowed down and that the Pfizer vaccine has been approved for children aged 12 and older. Dr. Allison-Bryan also discussed the FOIA code section on electronic meetings (2.2-3708.2) during the regulatory report. The Board Chair announced that there are nine board members with terms expiring on June 30, 2021. And finally, Board members were asked and provided great feedback about the benefits and concerns of virtual meetings over the past year. The feedback from the Board members seemed to favor a hybrid model moving forward (part virtual & part in-person). The next full Board of Health Professions meeting is scheduled for August 19, 2021.

REPORT ON LICENSURE PROGRAM

Ms. O'Halloran provided the licensing report to the board members. Page 101 of the agenda packet provides the number of newly issued licenses, registrations and permits for each category as well as a total number of licensees. Of note is the large number of pharmacy technician trainee registration applications that have been received and issued since January 3, 2021 when the new regulations became effective providing the authority to register this new category of licensees.

REPORT ON INSPECTION PROGRAM

Katrina Trelease, Pharmacist Inspector, stated that Melody Morton was unable to attend due to a conflict, but that she would provide the inspection report. Staff shared a report on the screen for all to see (Attachment I). Members requested that this current report be included in the minutes.

REPORT ON PHARMACEUTICAL PROCESSORS

Dharma Pharmaceuticals completed a change of location from Bristol, Virginia to Abingdon, Virginia. This change of location was necessitated by the allowance of a casino project to be built on the site of the former Bristol Mall, Dharma's former location. The new location is only a few miles from the previous location. Additionally, there have been media reports regarding

pending change of ownership for two of the permitted pharmaceutical processors. Columbia Care, Inc. has entered into a purchase agreement with Green Leaf of Virginia, Inc. and Green Thumb Industries, Inc. has entered into a purchase agreement with Dharma Pharmaceuticals, Inc. Board staff have completed the recruitment process for two full time administrative specialists to assist with processing program applications. Both individuals will start their employment by June 25, 2021. Currently there are just over 23,600 registered patients and the board has approved 302 cannabis oil products to date.

REPORT ON DISCIPLINARY PROGRAM

Dr. Shinaberry reported the overall case load has increased by 36 cases since the previous Board meeting to 300 active cases. She expects that trend to continue based upon feedback from Enforcement. Dr. Shinaberry noted that in-person disciplinary proceedings will resume on June 28, 2021, and thanked the Board members for their participation in recent disciplinary proceedings. A list of dates for upcoming proceedings was provided to the Board members.

EXECUTIVE DIRECTORS REPORT

Staff shared a brief written report on the screen from Ms. Juran for all to see. She commented on the recent NABP annual meeting held in May and welcomed Ryan Logan as a new Deputy Executive Director for the Board of Pharmacy. Mr. Logan will supervise the licensing of individuals and in-state facilities.

MEETING ADJOURNED: 2:30 PM

Chairman

Caroline D. Juran, Executive Director

9-24-21
DATE:

9/24/2021
DATE:

(ATTACHMENT I)

Enforcement Division Inspection Overview
For June 2021 Board of Pharmacy Meeting

Inspection Updates:

- Pharmacy Inspector full-time positon filled in NOVA after a recent retirement.
    - Enrolled in virtual NABP Sterile Compounding Training in June.
- New part-time Pharmacy Inspector hired in NOVA. Previously, position was a Senior Inspector.
- 6 full-time Pharmacy Inspectors, 2 part-time / 4 full-time Senior Inspectors, 1 part-time.
- Staff have resumed in-person inspections and will continue to use limited virtual inspections.
- Sterile Compounding – Staff diligently getting these up to date since restrictions have lifted.

Date Range 02/01/2021 Ending 04/30/2021

Number of Inspections Completed by License Type

Count of Result		InspType							
InspStatus	LicenseType	Change of Location	Compliance	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	4		12		2	3	35	56
	Medical Equipment Supplier			2				10	12
	Non-restricted Manufacturer			1					1
	Pharmaceutical Processor Permit	1					1	3	5
	Pharmacy	2	4	9		2	31	164	212
	Physician Selling Drugs Location	1		3		1		5	10
	Pilot Programs				1				1
	Restricted Manufacturer			1					1
	Warehouser	2		1		2		8	13
	Wholesale Distributor	1		1			1		3
Completed Total		11	4	30	1	7	36	225	314
Completed Virtu	Business CSR	7		17		1	2	60	87
	Medical Equipment Supplier	1		2				1	4
	Pharmacy					5	9		14
	Third Party Logistics Provider			1					1
	Warehouser	1					1	2	4
	Wholesale Distributor					1			1
Completed Virtual Total		9		20		7	12	63	111
Grand Total		20	4	50	1	14	48	288	425

Routine Inspections, Deficiencies by License Type

Count of InspStatus	Result			
LicenseType	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	99		43	142
Medical Equipment Supplier	14		4	18
Pharmaceutical Processor Permit	12			12
Pharmacy	183	167	45	395
Physician Selling Drugs Location	12			12
Warehouser	2		9	11
Grand Total	322	167	101	590

* New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed
** Multiple deficiencies can occur at one site.

Categories of Most Common Deficiencies for Occurrences Recorded >20 Times:

Description	Total
110-20-240	26

Deficiency 113: Inventories taken on time, but not in compliance
Deficiency 114: Records of receipt (e.g. invoices) not on site or retrievable
Deficiency 15: Perpetual inventory not being maintained as required

54.1-3404	44

Some records of receipt of CII-V drugs did not include date of receipt. Invoices for Schedule III-VI drugs do not include date of receipt. Invoices for Schedule II drugs were dated.
The biennial inventory did not include Schedule III-V drugs.
Deficiency 13: Biennial inventory taken at least every two years of all stocks on hand of Schedules I through V drugs.
Deficiency 113: Inventories taken on time, but not in compliance.
Deficiency 112: Required biennial inventory of all schedule II through V drugs available but taken late within 30 days of date due.

110-20-276	41

Deficiency 123: Engaging in remote processing not in compliance

54.1-3410.2	155

800: Assessment of risk has been performed
Deficiency 20a: Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products.
Deficiency 20b: Pharmacist not documenting verification of accuracy of the sterile compounding process and integrity of compounded products.
Deficiency 22: Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual.
Deficiency 23: Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual.
Deficiency 26: No documentation of annual media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.
Deficiency 26a: Documentation that a person who failed gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test.
Deficiency 32: Have clean room, but not all physical standards in compliance
Deficiency 116: Prescriptions do not include required information.
Deficiency 123: Engaging in remote processing not in compliance
Deficiency 130: Records for products compounded pursuant to a prescription order for a single patient.
Deficiency 130a: Compounded products not properly labeled.
Deficiency 131: Does not check or maintain temperature recordings for main pharmacy drug storage area.
Deficiency 132: Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements.
Deficiency 147: Smoke pattern testing not performed under dynamic conditions.
manufacturers' finished products are used as components did not include the total quantity of the finished product or the initials of the pharmacy technician performing the compounding.

Two Year Review: 04/30/2019 Ending 04/30/2021

Number of Inspections Completed by License Type

Count of Result		InspType								
InspStatus	LicenseType	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	50	1			136		6	28	549	770
	Medical Equipment Supplier	20				26			1	105	152
	Non-restricted Manufacturer					5		1	1	1	8
	Pharmaceutical Processor Permit	1				10		8	2	14	35
	Pharmacy	33	6	13	68	1	57	283	1113	1574
	Physician Selling Drugs Location	8		2	25		12	3	105	155
	Pilot Programs		1			6				7
	Restricted Manufacturer	2			4				1	7
	Third Party Logistics Provider				2		2		5	9
	Warehouser	8			12		3	4	58	85
	Wholesale Distributor	1		1	7		3	3	34	49
Completed Total		123	8	16	295	7	92	325	1985	2851
Completed Virtu	Business CSR	21	1		59		4	10	332	427
	Medical Equipment Supplier	5			5			2	42	54
	Pharmacy	11			11		13	43	1	79
	Physician Selling Drugs Location	1			15		3		5	24
	Pilot Programs					12				12
	Third Party Logistics Provider				1					1
	Warehouser	1			3			1	27	32
	Wholesale Distributor				1		2	1	12	16
Completed Virtual Total		39	1		95	12	22	57	419	645
Grand Total		162	9	16	390	19	114	382	2404	3496

Number of Routine Inspection Deficiencies by License Type

Count of InspType	Result				
LicenseType	Deficiency	Deficiency & IPHCO	Deficiency-Response Required	No Deficiency	Grand Total
Business CSR	853		13	436	1302
Medical Equipment Supplier	70		1	108	179
Non-restricted Manufacturer				2	2
Pharmaceutical Processor Permit	39			3	42
Pharmacy	996	1477		368	2841
Physician Selling Drugs Location	277			14	291
Restricted Manufacturer				1	1
Third Party Logistics Provider	5			3	8
Warehouser	22		1	67	90
Wholesale Distributor	39			26	65
Grand Total	2301	1477	15	1028	4821

* Deficiency-Response required is no longer used result type in our database

** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed

*** Multiple deficiencies can occur at one site.