COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY November 6, 2025

The regular session is open to the public by video or phone.

Join link:

https://eohhs.webex.com/eohhs/j.php?MTID=m9ea3db8b3c27ab61b5ec6b9d9b787c4a

Webinar number: 2537 024 7621 Webinar password: BOP123

+1-617-315-0704 United States Toll (Boston) +1-650-479-3208 United States Toll

Join by phone:

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Stacy Hart, Stacy. Hart@mass.gov or 857-274-1120 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodation may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

8:00		CALL TO ORDER		S.
				Ahmed
8:05	II	APPROVAL OF AGENDA		
8:10	Ш	APPROVAL OF BOARD MINUTES		
		Draft of October 9, 2025, Regular Session Minutes		
	IV	REPORTS		
8:15		Applications approved pursuant to Licensure Policy 13-01		
		Monthly report from Probation		
		Board Delegated Review pursuant to Licensure Policy 14-02		
		URAMP report		

		FLEX					
8:30	V	Nomination of Board Officers					
		NABP District 1&2 meeting summary					
		New pharmacy labeling requirement (Shield Law 2.0)					
		New priarriacy labeling requirement (Silield Law 2.0) Pharmacy Advisory Committee meeting summary					
		Recommendation for automated non-sterile compounding devices					
8:45	VI	POLICY					
		Policy 2020-15: Scope of Practice					
8:50		APPLICATIONS					
		Freedom Fertility Pharmacy, DS89717 Detition for Wairer DSDW10064					
		Petition for Waiver DSPW10064 Freedom ED Fortility Phormocy, DSS0716					
	\///	 Freedom FP Fertility Pharmacy, DS89716 Petition for Waiver DSPW10086 					
	VII	MedMinder Pharmacy, DS90408					
		Waiver Performance Data					
		Medwiz of Mass, LLC DS90404					
		Petition for Waiver					
		REVIEW OF COMPLIANCE					
	VIII	Option Care, DS90107; PHA-2020-0066, PHA-2022-0016, PHA-2022-0045,					
9:30		PHA-2022-0135, PHA-2023-0267, PHA-2024-0079, PHA-2024-0080, PHA-					
		2024-0081 and PHA-2024-0082					
		FILE REVIEW					
		1 CASE-2025-0983 PHA-2025-0100 Christopher Ryan, PH	22331 SA to				
9:45	IX	PHA	22331 3/(10				
		2 CASE-2025-1526 PHA-2025-0058 CVS/specialty OR Car	elonRx				
		Specialty Pharmacy, I	NDS31709				
		EXECUTIVE SESSION					
		The Board will meet in Executive Session as authorized pursuant to	M.G.L. c. 30A, §				
		21(a)(1) for the purpose of discussing the reputation, character, phy	sical condition,				
10:00	Х	dual, or to					
		discuss the discipline or dismissal of, or complaints or charges broug					
		public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for a pending applicant.					
10:30	ΧI	M.G.L. c. 112, § 65C SESSION					
12:00	XII	ADJOURNMENT					
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COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting November 6, 2025

Board Members Present

Board Members Not Present

Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President
Saad Dinno, RPh, FACP/FACA, President-Elect
Katie Thornell, RPh, MBA
Mark Sciaraffa, CPhT, Secretary
Caryn Belisle, RPh, MBA
John Rocchio, RPh, PharmD
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Julie Dorgan, RN
Timothy Fensky, RPh
Frank Lombardo
Stephanie Patel, MD, MBA, FFHPM, HMDC

Board Staff Present

Michael Godek, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Julienne Tran, PharmD, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Keith Johnstone, Compliance Officer
David Sencabaugh
Gayatri Ramasubramanian, Pharmacy Intern
Madhurima Chowdhury, Pharmacy Intern

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

A quorum of the Board was present, established by roll call. President Sami Ahmed chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: S. Dinno, yes; M. Sciaraffa, yes; D. Barnes, yes; C. Belisle, yes; J. Dorgan, yes; T. Fensky, yes; F. Lombardo, yes; R. Morelli, yes; S. Patel; yes; J. Rocchio, yes; K. Thornell, yes; J. Ahmed, yes.

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Topic II. Approval of Agenda TIME 8:03 AM

Agenda: 11/06/25

DISCUSSION: No changes.

<u>ACTION:</u> Motion by R. MORELLI, seconded by D. BARNES and voted unanimously by those present to approve the agenda with the noted change by roll call vote.

Topic III Approval of Board Minutes TIME: 8:04 AM

Minutes

1. Draft 10/09/25

Change: None

<u>ACTION:</u> Motion by S. DINNO seconded J. DORGAN and voted to approve the regular session minutes of 10/09/2025 with the noted changes by roll call vote.

TIME: 8:04 AM

TIME: 8:05 AM

Topic IV. REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION:</u> R. Harris reported a total of 35 Resident Change Pharmacist Manager of Record applications, 9 Non-resident Change Designated Pharmacist-in-Charge applications, and 6 facility closures that have been approved via Staff <u>ACTION</u> since the September 4th Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: R. HARRIS

<u>DISCUSSION:</u> R. Harris indicated a total of 2 compliance monitoring cases that have been closed since the last report and 1 notice of violation with an opportunity to respond.

So noted.

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Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris reported a total of 3 failures to report disciplinary <u>ACTION</u>, 2 instances of controlled substances losses, and 1 waiver approval since the last Board meeting.

TIME: 8:06 AM

TIME: 8:06 AM

So noted.

Topic IV. REPORTS

Research Drug Study report pursuant to Staff <u>ACTION</u> Policy 18-02

PRESENTED BY: M. CHAN

<u>DISCUSSION:</u> M. Chan reported 2 pharmacies participating in research drug studies with 1 new study approved since the last report. Currently, there are a total of 14 active studies, 3 involving investigational drug substances.

So noted.

V. FLEX

Nomination of Board Officers
 TIME: 8:04 AM

PRESENTED BY: M. Godek

RECUSAL: None

<u>DISCUSSION:</u> Since this is the second last board meeting of the year, we need to go through nominations of board officers. We need elections for president elect and for secretary. There's a handful of people that are eligible because of their terms. We can start with President elect for next year, then move on to Secretary:

<u>ACTION</u>: D. Barnes made a nomination for T. Fensky to be the President, seconded by R. Morelli and voted unanimously by roll call of members present.

<u>ACTION</u>: Second nomination for President made by S. Ahmed for M. Sciaraffa, seconded by C. Belisle and voted unanimously by roll call of members present.

<u>ACTION</u> R. Morelli made a nomination for J. Dorgan to be the Secretary, seconded by M. Sciaraffa and voted unanimously by roll call of members present.

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Topic V. FLEX

NABP District 1&2 meeting summary

PRESENTED BY: J. Rocchio

performing these actions.

DISCUSSION: These were the meetings of the districts where resolutions are raised which we brought forth on Lyophilization and those resolutions are going to the national meeting in Bay, next year for consideration of all NABP membership. I'll go through the resolutions for your awareness. The first one was our own resolution on lyophilization and USP, a NABP and FDA collaboration that clarify federal prohibitions for compounding essential copies and under what circumstances a pharmacy may perform lyophilization in, to amend model on regulations as necessary.

Another resolution that was brought about are on Blueprint inspections for USP standard alignment. In 2013, NABP offered the blueprint inspection to help with sterile compounding and USP standard inspections and NABP is being asked to convene a work group to review the blueprint inspection reports to ensure it fully complies with USP standards and can be completed by state inspectors within a reasonable amount of time as the licensure depends on these inspections taking place quite often and ensure participating blueprint states are fully inspected for compliance with the USP compounding standards so all states are comfortable with the reports and the compliance of the pharmacies

TIME: 8:11 AM

A third was around virtual specific licenses for wholesalers and virtual manufacturer distributors. Virtual wholesaling is where the ownership of the product is not owned or at least under the ownership of the managing company. It's used through other wholesale distribution networks, and the laws are seemingly similar in many states with respect to virtual and onsite wholesalers and manufacturers. So, NABP is being asked to convene a work group to recommend amendments to model law and regulations to create virtual specific license for manufacturers and wholesaler distributors. Develop specific requirements that are appropriate for the facility that does not physically possess the drug and consider whether the designated representative who is in charge of the facility that's holding the drug should be a licensed individual.

The last was around vaccines. We're seeking NABP to create a model language that pharmacists should be authorized to prescribe, order and administer as well as delegate all vaccinations to pharmacy technicians and pharmacy interns under the supervision of pharmacists and encourage states to adapt to standard of care approach and evidence-based approach that empower pharmacist's clinical judgement and define eligible vaccines as any vaccines that's been approved by the FDA.

So	no	ted	

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Topic V. **FLEX**

New pharmacy labeling requirement (Shield Law 2.0)

PRESENTED BY: M. Chan

RECUSAL: None

DISCUSSION: M. Chan explained that the updated shield law that was assigned in august requires pharmacies to label schedule VI medications prescribed for reproductive or gender affirming care with the name of the healthcare practice instead of the individual prescriber but only upon request from the prescriber. The prescriber can make their preference known by indicating it on the prescription or otherwise contacting the pharmacy with the name of the healthcare practice that they want on the prescription. DPH is developing guidance and that hopefully will be coming soon.

TIME: 8:15 AM

So noted.

Topic V. **FLEX**

TIME: 08:16 AM **Pharmacy Advisory Committee meeting summary**

PRESENTED BY: M. Sciaraffa

RECUSAL: None

DISCUSSION: M. Sciaraffa highlighted that there was a presentation of a recommendation, Document 25-03: Automated nonsterile compounding devices by a board member for the PAC seeking its advisory opinion on pharmacy use of Automated nonsterile compounding devices. The board voted as of 10/09/ 2025, respectfully requesting PAC's advisory opinion on the use of such devices and the summary discussion and next steps were:

Pharmacy needs to ensure that they're in compliance with all Federal and state regulations including USP 795, 797, and 800 to compound a product.

If they choose to use some type of non-sterile technology or robotics, they need to ensure that the technology/ robotic is FDA/ evidence based approved and has safety and efficacy studies using FDA approved API's. For an investigational drug, they should have a approved investigational study to use the technology.

Ensure prevention/ minimize the risk of cross-contamination and implement safety guidelines when utilizing the machines.

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So noted.

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Topic V. FLEX

• Recommendation for automated non-sterile compounding devices TIME: 8:19 AM

PRESENTED BY: W. Frisch

RECUSAL: None

<u>DISCUSSION:</u> W. Frisch noted that the PAC has issued an opinion regarding 503 A pharmacy use of automated non-sterile compounding devices. In general, the pharmacy is responsible regardless of devices or equipment utilized for the accuracy of compounding process and the quality of the final compound/ preparation in accordance to all laws and regulations including USP standards especially USP 795 and USP 800. The committee's specific recommendations are as follows:

The pharmacy must determine if the device has or requires FDA approval or otherwise can verify through documentation that the manufacturer has validated the device for it's use in non-sterile drug compounding.

The pharmacy must confirm that any FDA approved pharmaceutical ingredients or ingredients that are approved for an investigational drug study as applicable are compatible with the device they intend to utilize.

The pharmacy should confirm that such devices are easily cleanable to minimize cross contamination. Pharmacies must ensure that hazardous drug compounding is conducted in full compliance with USP 800.

And the suggested board action today is that PAC, respectfully requests the board to vote to allow 503A pharmacies to utilize automated non-sterile compounding devices as long as the pharmacy ensures compliance with all relevant USP chapters, all applicable State and federal laws and regulations.

ACTION: C. Belisle made a motion to accept the PAC recommendation, seconded by T. Fensky and voted unanimously by roll call of members present.

TOPIC VI POLICY

Policy 2020-15: Scope of Practice Time: 8:22 AM

Presented by: M. CHAN

Discussion: Updates to this policy define "handling" of medications and that it requires an individual pharmacy license as well as defining the "prescription area" and who may access it.

Action: Motion by J. ROCCHIO, seconded by T. FENSKY, and voted unanimously by roll call of those present, to approve the updates to the policy.

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VII: APPLICATIONS

Freedom Fertility Pharmacy, DS89717

Petition for Waiver DSPW10064

Represented by: Recusal: None

Discussion: Freedom recently moved and made some significant technological advancements. We added on a proprietary back end fulfillment system and upgraded or front-end processing systems. Both systems have increased safety systems including barcodes and hard stops integrated into the system. We were on paper, and now we are end-to-end electronic. Every items is scanned multiple times before it gets shipped to the patient.

Questions:

- What work are the pharmacy technicians doing in comparison to the Certified Pharmacy Technicians?
 - The certified technicians are the ones who are doing the compounding work. The noncertified technicians primarily are in our fulfillment center doing the picking and packing of orders.

TIME: 8:27 AM

- Are there any controlled substances?
 - We have no Sch IIs here, primarily it is Sch VI that the technicians are working with, and the SCH III-V are kept in a locked cabinet that only the pharmacists have access to.
- Do you engage in sterile and/or nonsterile compounding?
 - o Just nonsterile compounding, we are waiting for the cleanrooms to be completed.
- In your compounding is that fully electronic now too?
 - No, not yet there are still some paper elements to the actual compounding process but the fulfillment is all electronic
- What are the hours?
 - Monday through Friday 8am 9pm
 - Saturdays 9am 6pm
 - o Sundays 10am to 4pm
- What is your current staffing looking like?
 - We are following Massachusetts ratio requirements

Requested waiver:

247CMR8.06(3)a: A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions shall comply with the following minimum supervisory ratios:

Action: T. Fensky made a motion to approve the limited waiver of 247CMR8.06(3)(a) to allow for a maximum of 6 support personnel, of which at least 2 must be certified Pharmacy technicians or Pharmacy Interns, to one pharmacist; this only applies to the fulfillment area and not the compounding area. Seconded by C. Belisle and voted unanimously by roll call of those present to approve the motion.

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VII: APPLICATIONS

- Freedom Fertility Pharmacy, DS897176
 - Petition for Waiver DSPW10086

Represented by: Recusal: None

Discussion: See Above Application for Freedom Fertility Pharmacy, DS89717

- What are the hours?
 - Monday through Friday 9am 9pm
 - o Saturdays 2pm 6pm
 - Sundays closed

Action: T. Fensky made a motion to approve the limited waiver of 247CMR8.06(3)(a) to allow for a maximum of 6 support personnel, of which at least 2 must be certified Pharmacy technicians or Pharmacy Interns, to one pharmacist; this only applies to the fulfillment area and not the compounding area. Seconded by C. Belisle and voted unanimously by roll call of those present to approve the motion.

TIME: 8:27 AM

TIME: 8:49 AM

VII: APPLICATIONS

- MedMinder Pharmacy, DS90408
 - Waiver Performance Data

Represented by: Thuan Nguyen

Recusal: None

Discussion: Board staff explained that on 9/5/2024 The licensee received a limited waiver of 247 CMR 8.04(4)(e), where The Board asked for the licensee to provide data regarding the impact of this waiver. However, Board staff did not receive this data. Thuan explained that the data was sent every quarter (3 months) but sent to the wrong email address and that the licensee would provide the BORP with the emails that were sent to the wrong email address to show attempted compliance.

Thuan Nguyen then presented the data collected to The Board members.

Action: None

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VII: APPLICATIONS

Medwiz of Mass, LLC DS90404
 Petition for Waiver

Represented by: Jeffrey Kehl

Recusal: None

Discussion: Licensee has requested for 247 CMR 8.04(4)(e), to allow for Technicians to complete final validation. However, the licensee did not include an additional waiver that would be needed.

Action: M. Sciaraffa made a motion to defer the matter; Seconded by S. Dinno and voted unanimously by roll call of those present to defer the matter.

Topic VIII.

REVIEW OF COMPLIANCE

TIME: 9:31 AM

TIME: 9:17 AM

Option Care, DS90107; PHA-2020-0066, PHA-2022-0016, PHA-2022-0045, PHA-2022-0135,
 PHA-2023-0267, PHA-2024-0079, PHA-2024-0080, PHA-2024-0081 and PHA-2024-0082

PRESENTED BY: K. Fishman

RECUSAL: NONE

<u>DISCUSSION</u>: KAREN FISHMAN explained that Option Care originally entered into a consent agreement for a probation for a 2-year period on August 29, 2024. BORP later extended the probation on July 2, 2025 to a 4-year period due to probation violations in the interim.

FISHMAN next explained that Option Care was issued a Notice of Violation with Opportunity to Respond on July 23, 2025 after a report of a defective drug preparation which involved a prescription for ceftriaxone 1GM every 12 hours. The prescription was compounded using the wrong container, syringes, instead of the correct container, elastomeric pumps. The patient's caregiver recognized and reported the error to Option Care prior to administration of any drug. In turn, Option Care was able to promptly exchange the syringes with a newly prepared ceftriaxone 1gram in elastomeric pumps. Thus, no delay in therapy occurred. The root cause was identified as human error by the Pharmacy technician and pharmacy staff.

FISHMAN then requested that BORP determine whether a violation of probation occurred and if a violation occurred to consider issuing a Notice of Violation with No Further Action due to the recent extension of the probation period to 4-years.

<u>ACTION</u>: First, SAMI AHMED motioned to issue a NOTICE of VIOLATION of probation; Seconded by DELILAH BARNES; Then, BORP members present voted unanimously by roll call to pass the motion. Second, SAMI AHMED motioned for NO FUTHER imposition of discipline at this time; Seconded by CARYN BELISLE; Then, BORP members present voted unanimously by roll call to pass the motion.

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TOPIC IX: FILE REVIEW

Case #1/CASE-2025-0983

PHA-2025-0100 Christopher Ryan, PH22331 Time: 09:47 AM

RECUSAL: NONE

<u>DISCUSSION</u>: G. MELTON presented and summarized the investigative report that pertained to this matter.

- Pharmacist Ryan entered into a settlement agreement for disciplinary action with CT COP in which he
 was issued a letter of reprimand and fined \$5,000.00 to resolve violations observed during inspection
 at a CT pharmacy while he was MOR. The violations included making false, misleading statements to a
 CT DCA, recordkeeping violations involving CII perpetual inventory log, and expired OTC drugs in front
 store.
- Pharmacist Ryan emphasized that he did not make false, misleading statement to the CT DCA. He was
 not aware that a technician/part owner of the pharmacy was forging his name and signature on DEA
 222s because the other owner did not want to drive to the pharmacy in New Haven, CT from New
 Britain, CT. However, the agent did not believe him.
- Pharmacist Ryan also admitted that OTC drugs in the front were expired. He described that he had
 just relocated and prioritized operation of the pharmacy proper and had not yet vetted the front store
 OTC drugs.

<u>ACTION</u>: Motion by T. FENSKY, seconded by J. DORGAN, and voted unanimously by those present, to refer the matter (PHA-2025-0100), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2/CASE-2025-1526

PHA-2025-0058 CVS/specialty OR CarelonRx Specialty Pharmacy, NDS31709 Time: 09:49 AM

RECUSAL: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

<u>DISCUSSION</u>: J. TRAN presented and summarized the investigative report that pertained to this matter.

- Licensee failed to properly remediate after an Above Action Level (AAL) event occurred on or about 05/07/2025 in violation of Board Policy 2023-09. They had an AAL in the ISO 7, positive, air sample of 18 cfu of various organisms, ISO 7, negative, Air sample of 31 cfu micrococcus, and ISO 7 negative surface sample (19 cfu various organisms).
- Board Policy states, "All sample locations in the affected ISO Classified area must be resampled at the same time." Pharmacy did not resample all the sites, both air and surface, within the affected ISO spaces at the same time. They did re-sample all the sites over 2 re-sampling session approximately 12 days apart in the affected ISO classified spaces with no actionable growth.
- MOR Schwartz and Designated Pharmacist Sarah Greif submitted a signed attestation that the compounding pharmacy staff has reviewed the internal corporate and facility policy and procedure for

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remediation of an AAL event and BORP Policy 2023-09: Action Level Environmental Monitoring Results.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2025-0058), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Topic X:

Executive Session Call to Order:

TIME: 09:52 AM

By: President S. Ahmed reads the executive session language and requests a motion to enter executive session.

ACTION: Motion by M. SCIARAFFA seconded by J. DORGAN, voted unanimously by roll call to enter executive session #1.

Topic XI:

65C Sessions MGL c. 112 section 65C

TIME: 10:59 AM

DISCUSSION:: None

ACTION: President S. Ahmed request a motion to enter M.G.L 65 c Session.

Motion by M. SCIARAFFA, seconded by K. THORNELL and voted unanimously by all those present to enter M.G.L. chapter 65 C Session by roll call vote.

Topic XII:

ADJOURMENT OF MEETING

TIME: 01:24 PM

<u>ACTION:</u> Motion by M. SCIARAFFA seconded by R. MORELLI and voted unanimously by those present, to adjourn the meeting by roll call vote.

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. November 6, 2025, Agenda
- 2. October 9, 2025, Board Minutes
- 3. Licensure Policy 13-01 Report
- 4. Monthly Probation Report
- 5. BDR Licensure Report pursuant Policy 14-02
- 6. Policy 202-15: Scope of Practice
- 7. Freedom Fertility Pharmacy Petition for Waiver
- 8. Freedom FP Fertility Pharmacy Petition for Waiver
- 9. MedMinder Pharmacy Waiver performance data
- 10. Medwiz of Mass Petition for Waiver
- 11. Option Care Review of Compliance
- 12. PHA-2025-0100 Christopher Ryan PH22331
- 13. PHA-2025-0058 CVS/Specialty or Carelon RX Specialty Pharmacy; NDS31709

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