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1	COMMONWEALTH OF PENNSYLVANIA	
2	DEPARTMENT OF STATE	
3	BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS	
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5	<u>FINAL MINUTES</u>	
6		
7	MEETING OF:	
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9	STATE BOARD OF PHARMACY	
10	VIA TELECONFERENCE	
11		
12	TIME: 10:31 A.M.	
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14	PENNSYLVANIA DEPARTMENT OF STATE	
15		
16	August 18, 2020	
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2 1 State Board of Pharmacy 2 August 18, 2020 3 4 5 BOARD MEMBERS: 6 7 Terry M. Talbott, R.Ph., Chairperson 8 K. Kalonji Johnson, Commissioner, Bureau of 9 Professional and Occupational Affairs 10 Robert B. Frankil, R.Ph., Vice Chairman 11 Janet Getzey Hart, R.Ph., Secretary Patrick M. Greene, Esquire, Office of Attorney 12 13 General 14 Thomas P. Carey, Ed.D. - Absent 15 John R. Slagle, R.Ph. 16 Christine Roussel, Pharm.D., BCOP 17 18 19 BUREAU PERSONNEL: 20 21 Juan A. Ruiz, Esquire, Board Counsel 22 Ray Michalowski, Esquire, Senior Board Prosecution 23 Liaison 24 Glenn P. Masser, Esquire, Board Prosecutor 25 Carolyn DeLaurentis, Deputy Chief Counsel, Prosecution 26 Division 27 Carole Clarke Smith, Esquire, Senior Counsel in Charge 28 Melanie Zimmerman, R.Ph., Executive Secretary 29 Theodore Stauffer, Executive 30 Secretary, Bureau of Professional and Occupational 31 Affairs 32 33 34 ALSO PRESENT: 35 36 Andrew LaFratte, MPA, Policy Office, Department of 37 State 38 Marc Farrell, Deputy Policy Director, Department of 39 State 40 Steven Zahn, Pharmacy Inspector, Bureau of Enforcement 41 and Investigation, Department of State 42 Catherine Lutz, Pharmacy Inspector, Bureau of 43 Enforcement and Investigation, Department of State 44 Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists 45 46 Alicia Palombo, Pharm.D., Pharmacy Regulatory Affairs 47 Advisor at CVS Health 48 Andrew Felter, Manager of Pharmacy Compliance and 49 Regulatory Relations, Wegmans Food Markets 50 Christopher N. Skey, Esquire, Quarles & Brady, LLP

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1	State Board of Pharmacy	
2 3	August 18, 2020	
- 3 4 5 6	ALSO PRESENT: (Continued)	
7	Jenna L. McCarthy, Malady & Wooten	
8 9	James Reed, Area Healthcare Supervisor, Walgreens Christine Renfer, CVS Health	
10 11	David Klinger, System Director, Operations & Compliance, Geisinger Health System	
12	Heather Coy, AllianceRx Walgreens Prime	
13 14 15	Jen Smeltz, Executive Director, Consumer Protection and Professional Licensure Committee John Sisto, Express Scripts, Inc.	
16	Lauren Paul, Pharm.D., CVS Health	
17 18	Steve L. Sheaffer, Pharm.D., FASHP, Pennsylvania Society of Health-System Pharmacists	
19 20	Mary Vukas, Pharmacy Manager, ACME Sav-on Pharmacy Frank Trollo, Central Admixture Pharmacy Services	
21 22	John Loxterman, Enclara Pharmacia Judy Kutchman, AllianceRx Walgreens Prime	
23	Nicole Sidle, Majority Committee Executive Director,	
24 25	House Professional Licensure Committee Christopher Miller, Pharm.D., Giant Eagle	
26 27	Patricia A. Epple, CEO, Pennsylvania Pharmacists Association	
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4 \* \* \* 1 2 State Board of Pharmacy 3 August 18, 2020 \* \* \* 4 5 [Pursuant to Section 708(a)(5) of the Sunshine Act, at 9:00 a.m., the Board entered into Executive Session 6 7 with Juan A. Ruiz, Esquire, Board Counsel, to receive legal advice and engage in quasi-judicial 8 9 deliberations. The Board returned to open session at 10 10:30 a.m.] \* \* \* 11 12 The regularly scheduled meeting of the State 13 Board of Pharmacy was held on Tuesday, August 18, 14 2020. Terry M. Talbott, R.Ph., Chairperson, called 15 the meeting to order at 10:31 a.m. K. Kalonji Johnson, Commissioner, Bureau of 16 17 Professional and Occupational Affairs, was present 18 during Executive Session and exited prior to the 19 commencement of the public session of the virtual 20 teleconference. 21 \* \* \* Introduction of the Board Members 22 23 [Chairperson Talbott requested Board members introduce 24 themselves.] 25 \* \* \*

[Juan A. Ruiz, Esquire, Board Counsel, announced the 1 2 Board meeting was being recorded, and those participating by phone or WebEx are consenting to 3 4 being recorded.] \* \* \* 5 Introduction of Audience 6 7 [Chairperson Talbott provided an introduction of Board 8 staff and audience members.] 9 \* \* \* 10 Approval of Agenda 11 CHAIRPERSON TALBOTT: 12 Do I have a motion to amend the agenda 13 regarding an item Melanie wanted to add 14 concerning the executive officer forum 15 and member forum? 16 Could I have a motion to add that to 17 the agenda? MR. FRANKIL: 18 19 So moved. 20 CHAIRPERSON TALBOTT: 21 Do I have a second? 22 MR. GREENE: 23 Second. 24 CHAIRPERSON TALBOTT: 25 All in favor of the amendments to the

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1 agenda? Any opposed? 2 CHAIRPERSON TALBOTT: 3 I will entertain a motion to approve the 4 agenda as amended. 5 MR. FRANKIL: 6 Motion to approve. 7 CHAIRPERSON TALBOTT: 8 Second? 9 MS. HART: 10 Second. 11 CHAIRPERSON TALBOTT: 12 Any discussion? All in favor, say aye. [The motion carried unanimously.] 13 \* \* \* 14 15 Approval of minutes of the June 16, 2020 meeting 16 CHAIRPERSON TALBOTT: The next order of business is the 17 18 approval of the minutes from the June 16 19 meeting. 20 Does anyone have any amendments to 21 those minutes? Hearing none. I will 22 entertain a motion to accept those as 23 presented. 24 MR. FRANKIL: 25 So moved.

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7 CHAIRPERSON TALBOTT: 1 2 Christine, do you want to second? 3 DR. ROUSSEL: Second. 4 5 CHAIRPERSON TALBOTT: 6 Any discussion? All in favor? Any 7 opposed? [The motion carried unanimously.] 8 9 \* \* \* 10 Report of Prosecutorial Division 11 [Glenn P. Masser, Esquire, Board Prosecutor, presented 12 the Consent Agreements for Case No. 20-54-001305 and Case No. 20-54-003461.1 13 \* \* \* 14 15 [Ray Michalowski, Esquire, Senior Board Prosecution 16 Liaison, presented the VRP Consent Agreements for Case No. 20-54-000067, Case No. 20-54-006407, and Case No. 17 20 - 54 - 004715. 18 19 Mr. Michalowski thanked Erik Omlor and the staff 20 at the Professional Health Monitoring Programs (PHMP) 21 for their fabulous job with COVID-19 issues in keeping 22 things moving at the voluntary recovery program (VRP) 23 and disciplinary monitoring unit (DMU). 24 Mr. Michalowski addressed inspections, noting 25 that well over 700-800 complaints were submitted to

the agency for different licensing boards and 1 2 commissions regarding licensees who the complainants 3 believed were violating federal, state, or other 4 standards of practice relating to protecting the 5 public and each other from the spread of COVID-19. Mr. Michalowski informed the Board of a number of 6 7 cases investigated on behalf of the Pharmacy Board with the vast majority concerning masking issues. 8 He mentioned complaints regarding reusing pens, which was 9 remedied very quickly. 10

11 Mr. Michalowski stated most of the mask complaints were not with individuals taking care of 12 13 patients or other customers at the checkout counter 14 but with individuals working away from the public 15 where medications were being prepared for dispensing. He noted receiving an equal number of complaints from 16 17 consumers and employees of the pharmacy concerning 18 lack of masks and social distancing.

Mr. Michalowski explained that investigators are following the current Centers for Disease Control and Prevention (CDC) guidelines and call for universal face coverings and masks in the pharmacy.

23 Mr. Michalowski stated the pharmacies not 24 following the guidelines receive a failed inspection. 25 He mentioned not charging for the first failed

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1 inspection because of something minor, where the 2 inspectors can conduct a re-inspection and confirm the 3 minor violations have been remediated.

4 Mr. Michalowski commented that the only 5 alternative would be to refer those individuals to the 6 Department of Health to issue citations and implement 7 civil penalties for violations of the Governor's and Physician General/Secretary of Health's orders. 8 Нe 9 mentioned having the inspections done in-house, kept 10 it under the control of the Pharmacy Board, rather 11 than referring the less egregious cases to the 12 Department of Health.

Mr. Frankil noted receiving several phone calls and emails from pharmacy owners who failed inspections because of the masking issue and requested further explanation on how someone could fail something that does not have to do with pharmacy regulations.

18 Mr. Michalowski explained that cleanliness and 19 sanitary standards on the inspection form had expanded 20 since the pandemic and state of emergency.

21 Mr. Michalowski noted being aware of the concern 22 from individuals having a failed inspection on their 23 record. He stated there had not been a single person 24 who had not corrected the issue by the next visit. He 25 commented that the agency was trying to avoid

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1	prosecution but also noted the importance of the
2	inspection and the inspectors doing their job.
3	Mr. Michalowski suggested the Board send out a

4 blast email of CDC guidelines specific to pharmacies. 5 He mentioned an alternative to a failed inspection, 6 where the violation could be noted and the inspectors 7 would return in 30 days, where a repeat violation 8 would then become a failed inspection. He commented 9 that the violations could be documented and enforced 10 but not create more difficulties for the industry.

11 Chairperson Talbott would like Mr. Michalowski to 12 have the inspectors place a notation on the inspection 13 report with follow-up in 30 days rather than creating 14 a failing inspection report and would like the agency 15 to find a way to make that happen. She suggested Mr. 16 Ruiz and Mr. Michalowski work together to develop 17 verbiage to be sent to pharmacies regarding CDC 18 quidelines via an email blast.

Mr. Michalowski mentioned other Boards were sending letters with a warning stating it believed there was a violation of the law, which sounds harsher than having a notation on an inspection.]

\* \* \*

## 24 MOTIONS

23

25 MR. GREENE:

On agenda Item No. 2, I make a motion 1 2 that we approve the Consent Agreement at 3 Case No. 20-54-001305. CHAIRPERSON TALBOTT: 4 5 Do I have a second? 6 MS. HART: 7 Second. 8 CHAIRPERSON TALBOTT: 9 Any additional discussion? Call the 10 vote. 11 12 Frankil, aye; Greene, aye; Slagle, aye; 13 Talbott, recuse; Roussel, aye; Hart, aye. 14 [The motion carried. Chairperson Talbott recused 15 herself from deliberations and voting on the motion. 16 The Respondent is CVS Pharmacy 4216.] \* \* \* 17 MR. GREENE: 18 19 On agenda Item No. 3, I make a motion 20 that we approve the Consent Agreement at 21 Case No. 20-54-003461. 22 MS. HART: 23 Second. 24 CHAIRPERSON TALBOTT: 25 I have a motion and a second. Any

discussion? Call the vote. 1 2 3 Frankil, aye; Greene, aye; Slagle, aye; 4 Talbott, aye; Roussel, aye; Hart, aye. 5 [The motion carried unanimously. The Respondent's 6 name is Melissa Jo Callis, R.Ph.] \* \* \* 7 8 MR. GREENE: 9 On agenda Item Nos. 4, 5, and 6, I move 10 that we approve the following VRP Consent Agreements at Case No. 20-54-000067, Case 11 12 No. 20-54-006407, and Case No. 20-54-004715. 13 MS. HART: 14 15 Second. 16 CHAIRPERSON TALBOTT: 17 A motion and a second. Do we have any discussion? Call the vote. 18 19 20 Frankil, aye; Greene, aye; Slagle, aye; 21 Talbott, aye; Roussel, aye; Hart, aye. 22 [The motion carried unanimously.] 23 \* \* \* 24 Report of Board Counsel 25 [Juan A. Ruiz, Esquire, Board Counsel, noted Recusal

Guidelines. He mentioned the addition of two new 1 2 Board members, Dr. Roussel and Mr. Slagle. He advised 3 everyone to review the guidelines and offered his 4 assistance regarding any recusal questions or 5 concerns. 6 Mr. Ruiz noted an application for stay of the 7 June 22, 2020 final adjudication and order in the 8 matter of Norman Steinberg, R.Ph., File No. 16-54-9 001184.1 10 \* \* \* 11 CHAIRPERSON TALBOTT: 12 We discussed this at length in Executive 13 Session. Do we have a motion on this 14 matter? 15 MR. GREENE: 16 I make a motion that we deny the 17 respondent, Norman Steinberg's 18 Application for Stay at File No. 16-54-19 01184. 20 CHAIRPERSON TALBOTT: 21 Do we have a second? 22 MS. HART: 23 Second. 24 CHAIRPERSON TALBOTT: 25 Any further discussion? Call the vote.

1 2 Greene aye; Frankil, aye; Slagle, aye; 3 Talbott, aye; Roussel, aye; Hart, aye. 4 [The motion carried unanimously.] \* \* \* 5 6 [Juan A. Ruiz, Esquire, Board Counsel, informed the 7 Board that the intern immunization package had been forwarded to acting senior regulatory counsel, who 8 9 should soon be forwarding that to the Office of 10 General Counsel (OGC). 11 Chairperson Talbott questioned whether pharmacy 12 interns would be helping with immunizations during flu 13 season. 14 Mr. Ruiz commented that regulations will not 15 totally be in place but should have something in place 16 to get the authorizations done in a faster way.] \* \* \* 17 18 Report of Board Chairperson 19 [Terry M. Talbott, R.Ph., Chairperson, thanked Mr. 20 Ruiz, Commissioner Johnson, and Ms. Zimmerman for all 21 of their hard work in enabling the Board to continue 22 to function during the pandemic. She noted also being 23 thankful to have Mr. Slagle and Dr. Roussel on the 24 Board. 25 Chairperson Talbott thanked Board Members who

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15 helped with the 2800 questions for the Multistate 1 2 Pharmacy Jurisprudence Exam (MPJE) review. 3 Chairperson Talbott requested everyone spread the 4 word that people can renew. She informed everyone 5 that notifications will go out in the mail for those 6 who do not have an email address on file. She 7 commended Board staff and the Bureau, noting it only 8 took two weeks to receive a hard copy of her renewed 9 license. 10 Chairperson Talbott mentioned she and Ms. Hart 11 will be attending the virtual National Association of 12 Boards of Pharmacy (NABP) District I and II Meeting on 13 September 8, 2020, hosted by the Maryland Board of 14 Pharmacy.] \* \* \* 15 16 MS. HART: 17 I make a motion for Melanie to attend District 1 & 2. 18 19 DR. ROUSSEL: 20 I second the motion. 21 CHAIRPERSON TALBOTT: 2.2 All in favor, say aye. 23 24 Greene aye; Frankil, aye; Slagle, aye; 25 Talbott, aye; Roussel, aye; Hart, aye.

[The motion carried unanimously.] 1 \* \* \* 2 3 Report of Probable Cause Screening Committee 4 [Patrick M. Greene, Esquire, Office of Attorney 5 General, noted reviewing and signing an order on one 6 Petition for a Physical and Mental Examination.] \* \* \* 7 8 Report of Commissioner - No Report 9 \* \* \* 10 Report of Executive Secretary 11 [Melanie Zimmerman, R.Ph., Executive Secretary, 12 informed the Board the pharmacist and authorization to administer renewal was available but mentioned an 13 14 issue with not having child abuse continuing education 15 on file for pharmacists. She stated the provider was 16 contractually required to electronically submit the 17 information to the Board office, but some providers 18 are submitting the information only to NABP's CPE 19 Monitor. 20 Ms. Zimmerman cautioned against uploading 21 information to a renewal application because it 22 creates a problem and prevents the system from moving 23 forward with the application if an upload was not required. She also noted that the system provides no 24 25 warning to staff that the application needs modified

if a licensee uploads unnecessary information. 1 Ms. Zimmerman noted motions need to be made on 2 3 applications discussed during Executive Session.] \* \* \* 4 MR. GREENE: 5 6 At agenda Item No. 9, I make a motion 7 that we grant applicant Rudrani Toutam's Request for Reduced Intern Hours as a 8 9 Graduate of a Foreign Pharmacy School, 10 for a reduction of 500 hours requiring 11 the applicant to document 1000 intern 12 hours. CHAIRPERSON TALBOTT: 13 14 Do I have a second? 15 MS. HART: 16 Second. 17 CHAIRPERSON TALBOTT: Any further discussion? Call the vote. 18 19 20 Frankil, aye; Greene aye; Slagle, aye; 21 Talbott, aye; Roussel, aye; Hart, aye. 22 [The motion carried unanimously.] 23 \* \* \* 24 MR. GREENE: 25 At agenda Item No. 10, I make a motion

that we approve the Application of Botros 1 2 Hanna - Requesting Individual Approval as 3 a Graduate of a Foreign Pharmacy School. 4 CHAIRPERSON TALBOTT: 5 Do I have a second? 6 MS. HART: 7 Second. 8 CHAIRPERSON TALBOTT: 9 Any discussion? Call the vote. 10 11 Frankil, aye; Greene aye; Slagle, aye; 12 Talbott, aye; Roussel, aye; Hart, aye. 13 [The motion carried unanimously.] \* \* \* 14 15 New Business MS. HART: 16 17 I make a motion to send Christine to the 18 FDA compound meeting and John as an 19 alternate. 20 CHAIRPERSON TALBOTT: I have a motion. Do I have a second? 21 22 MR. FRANKIL: 23 Second. 24 CHAIRPERSON TALBOTT: 25 All in favor, signify by saying aye.

19 Opposed? 1 2 [The motion carried unanimously.] 3 \* \* \* MS. HART: 4 5 I make a motion for Christine and John to 6 attend the (NABP) Member Forum on January 7 27 as scheduled. I make the motion for Melanie to 8 9 attend the (NABP) Executive Officers 10 forum on September 30. All virtual 11 meetings. 12 CHAIRPERSON TALBOTT: 13 Do I have a second? 14 MR. FRANKIL: 15 Second. 16 CHAIRPERSON TALBOTT: 17 Any discussion? All in favor, say aye. 18 Any opposed? 19 [The motion carried unanimously.] \* \* \* 20 21 [Melanie Zimmerman, R.Ph., Executive Secretary, 22 addressed the request by Raymond Cherry to permanently 23 amend Board regulation Section 27.12. She stated Mr. 24 Cherry did not provide sufficient information to 25 understand his exact circumstances, and she will

provide a response, noting the Board will take his
request under advisement.

3 Chairperson Talbott addressed the extended 4 pharmacist and authorization renewal which goes to 5 12/29/2020 and 2022 continuing education requirements. She noted discussion in Executive Session concerning 6 7 confusion among licensees and guestioned what other boards are doing, ondering whether to push the renewal 8 period out or if individuals who renew in the normal 9 10 time period before October 1 could start counting 11 continuing education (CE) from October 1 to December 12 29.

Mr. Ruiz commented that a statement could read 13 that the Board was interested in allowing those who 14 15 renew by the normal deadline of September 30 to start earning their continuing education for the next 16 17 renewal period starting October 1, and anyone who does 18 not renew by the September 30 deadline and takes 19 advantage of the renewal extension will not be able to 20 start earning continuing education until December 30 21 for the next renewal period.

22 Chairperson Talbott cautioned against spreading 23 that news until Mr. Ruiz had something official and 24 posts that on the website. She mentioned putting 25 something out to the stakeholders who normally get the

agenda and suggested Ms. Zimmerman send an e-mail to 1 2 the PA pharmacy associations for dissemination.] \* \* \* 3 4 [K. Kalonji Johnson, Commissioner, Bureau of 5 Professional and Occupational Affairs, joined the 6 teleconference at 11:20 a.m.] \* \* \* 7 8 [K. Kalonji Johnson, Commissioner, Bureau of Professional and Occupational Affairs, addressed 9 10 renewal periods, suggesting anyone who was concerned 11 about their CE not counting in the appropriate renewal period should treat the renewal cycle as if it was not 12 13 extended and they should renew by the normal 14 expiration date. He mentioned only 1% of individuals 15 had renewed. 16 Chairperson Talbott noted the importance of 17 informing individuals the renewal portal was open. 18 She also wanted licensees to be aware that if they can 19 count CEs from October 1 on to do that but not double 20 She explained that individuals cannot get CEs dip. 21 from October to December and count them for their 2.2 license renewal this year and in 2022. 23 Commissioner Johnson stated individuals should 24 submit their renewal now if they completed their CE 25 for the current cycle.

Ms. Zimmerman commented that people's records are showing the renewal notice had been sent out but she had not received a renewal email herself. Some of the Board Members confirmed that they also had not received a renewal e-mail notice. Commissioner Johnson will investigate as to why the Bureau was under the presumption the renewal

8 notice went out but was not received by licensees.

9 Chairperson Talbot requested Mr. Ruiz and 10 Commissioner Johnson work together on verbiage to be 11 posted on the website.

12 Chairperson Talbott suggested Melanie use the 13 verbiage that was put on the website and send it to 14 stakeholders for those people to send that out also.] 15 \*\*\*

16 Report of Commissioner

17 [K. Kalonji Johnson, Commissioner, Bureau of 18 Professional and Occupational Affairs, thanked the 19 Board for their patience and flexibility during the 20 pandemic. He noted the Bureau's thoughts and prayers 21 are with everyone battling this pandemic. He thanked 22 Mr. Ruiz, Ms. Zimmerman, and program staff for 23 continuing to work under trying conditions. He also 2.4 thanked stakeholders and public members. 25 Commissioner Johnson believed virtual meetings

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were a benefit by helping to inform and educate an 1 2 audience that could not be reached historically.] \* \* \* 3 4 Next Meeting Dates 5 [Terry M. Talbott, R.Ph., Chairperson, noted the next scheduled meeting date is October 13, 2020. 6 7 Commissioner Johnson stated the Board should continue to prepare for virtual meetings till the end 8 9 of the year but commented that alterations could be 10 made to the current procedures if that changes.] \* \* \* 11 12 Adjournment CHAIRPERSON TALBOTT: 13 14 I entertain a motion to adjourn. 15 MR. FRANKIL: 16 I make a motion to adjourn. 17 CHAIRPERSON TALBOTT: Second? 18 19 MS. HART: 20 Second. 21 CHAIRPERSON TALBOTT: 22 All in favor? 23 [The motion carried unanimously.] \* \* \* 24 25 [There being no further business, the State Board of

Pharmacy Meeting adjourned at 11:29 a.m.] \* \* \* CERTIFICATE I hereby certify that the foregoing summary minutes of the State Board of Pharmacy meeting, was reduced to writing by me or under my supervision, and that the minutes accurately summarize the substance of the State Board of Pharmacy meeting. Derek Richmond, Minute Clerk Sargent's Court Reporting Service, Inc. 

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1 2 3 4 5		STATE BOARD OF PHARMACY REFERENCE INDEX
		August 18, 2020
6 7	TIME	AGENDA
8 9	9:00	Executive Session
10 11	10:30	Return to Open Session
12 13	10:31	Official Call to Order
14 15	10:31	Introduction of Board Members
16 17	10:33	Introduction of Board Staff and Audience
18 19	10:39	Approval of Agenda and Minutes
20 21	10:39	Report of Prosecutorial Division
22 23	11:01	Motions
24 25	11:05	Report of Board Counsel
26 27	11:09	Report of Board Chairperson
28 29	11:11	Probable Cause Screening Committee
30 31	11:12	Report of Executive Secretary
32 33	11:14	New Business
34 35	11:25	Report of Commissioner
36 37	11:26	Next Meeting Date
38 39	11:29	Adjournment
40 41		
42 43		
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