State Board of Pharmacy August 22, 2017

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BOARD MEMBERS:

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Janet Getzey Hart, R.Ph., Chairperson Kathryn Waters, Deputy Commissioner of Professional and Occupational Affairs - Absent

Terry Talbott, R.Ph., Vice Chairperson

10 Robert Frankil, R.Ph., Secretary 11 Gayle Cotchen, Pharm.D., R.Ph.

Patrick M. Greene, Esquire, Office of Attorney General

Kishor S. Mehta, Public Member - Absent Mark Zilner, R.Ph.

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BUREAU PERSONNEL:

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Kerry Maloney, Esquire, Board Counsel Ray Michalowski, Esquire, Board Prosecution Liaison Melanie Zimmerman, R.Ph., Executive Secretary

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ALSO PRESENT:

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Bailey Colvin, Philadelphia College of Pharmacy Amber Dietrich, Wilkes University

29 Yosef Nissim, Philadelphia College of Pharmacy 30

Faith Kerr, CVS Specialty

Denise Getgen, Director, Pennsylvania Department of Aging, Protective Services Office

Tina Kotsalos, Director, Investor Education and Consumer Outreach, Department of Banking and Securities

Theresa Rossetti, CVS Health

Pat Epple, Pennsylvania Pharmacists Association

38 Leigh Shirley, Giant Pharmacy

Lauren Shirley, University of Pittsburgh/Hershey Medical Center, Advanced Pharmacy Practice Experience

Andrew Trivino, Doylestown Hospital Christy Vu, ACME Sav-On Pharmacy

43 Makindree Nicolosi, Doylestown Hospital 44

Andrew Harvan, Pennsylvania Medical Society

45 Jeenu Philip, Walgreens 46

Jeff Stuby, Pennsylvania Pharmacists Association 47 48

Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists

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(Continued)

Jenna McCarthy, Malady & Wooten Greg Smith, Central Admixture Pharmacy Services Bob Grobinski, Cardinal Health Brian Sesack, UPMC Hillman Cancer Center Jim Reed, Walgreens

CHAIRPERSON HART: We would like to add under 2 Miscellaneous, the application for an 3 intern from Colorado. We would like to 4 5 add some requests for the Cancer Drug Repository Program related to REMS. 6 7 And also the consideration of the 8 application for Geriscript, LLC. So do I have a motion to amend the 9 10 agenda with those items MS TALBOTT: 11 I'll make that motion to amend the 12 13 agenda with those items. DR COTCHEN: Second. 15 CHAIRPERSON HART: 16 All in favor? Thank you. 17 18 [The motion carried unanimously.] 19 Introduction of Audience 20 21 {Chairperson Hart requested the introduction of audience in attendance.] 22 * * * 23 Report of Prosecutorial Division 24 25 [Chairperson Hart noted VRP Consent Agreements for

1 File No. 17-54-04854 and File No. 17-54-05345 to be 2 discussed during Executive Session.]

[Ray Michalowski, Esquire, Board Prosecutor, discussed the Prescription Drug Monitoring Program (PDMP) and its coordinated efforts with the Department of Health to develop reports to identify improper prescribing

8 and dispensing patterns.]

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10 [Terry Talbott, R.Ph., Vice Chairperson, exited the meeting at 9:14 a.m. and reentered at 9:15 a.m.]

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- 13 New Business
- 14 Appointments
- 15 | Elder Financial Abuse Prevention Awareness
- 16 | [Denise Getgen, Director, Pennsylvania Department of
- 17 Aging, Protective Services Office, and Tina Kotsalos,
- 18 Director, Investor Education and Consumer Outreach,
- 19 Department of Banking and Securities, presented before
- 20 the Board to discuss elder financial exploitation. A
- 21 | video regarding the matter was shown.
- 22 Ms. Kotsalos discussed the roles of the
- 23 | Department of Aging and Banking and Securities in
- 24 | working to fight elder financial abuse. Ms. Kotsalos
- 25 stated grant funding has made training available to

frontline professionals.

Ms. Getgen noted a significant increase in elder abuse over the past ten years. She discussed red flags such as isolation, medication issues, change in behavior, and self-neglect.

Ms. Getgen stated concerned citizens should contact their local area Agency on Aging to assess the situation and initiate a comprehensive and thorough investigation. She stated all aging-related services are lottery funded, which helps with transportation, meals, medical needs, and additional services for older adults.

Ms. Kotsalos offered educational materials, including contact information.]

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16 Report of Board Counsel

[Kerry Maloney, Esquire, Board Counsel, noted items for discussion, including the Compounding Regulation (16A-5419) and the cancer drug repository regulation.

Mr. Maloney also noted a Proposed Adjudication and Order, a hearing transcript for the Board's review, and additional documents to be discussed during Executive Session.

Mr. Maloney referred members to the Compounding Regulation (16A-5419) and the Independent Regulatory

Review Commission (IRRC) comments for further discussion.

He reviewed comments with regard to the Regulatory Analysis Form (RAF) and the attached inspection form; protection of public health, safety, and welfare; House Professional Licensure Committee concerns regarding Section 27.12 relating to the delegation of duties and label information required in Section 27.620; Section 27.603 bulk drug substances; Section 27.604, dispensing compounded drugs for office use, and Section 27.605, resale of compounded drug products; Section 27.606(1), pharmacists may not compound drugs identified by the FDA as withdrawn or removed from the market; Section 27.608 protective apparel; Section 27.617 (c) standard operating procedures required; Section 27.620 DEA number requirements; Section 27.622 master formula record and 27.623 production record for drugs compounded in bulk quantities; and clarification of the term "bulk."

[Janet Getzey Hart, R.Ph., Chairperson, exited the meeting at 10:22 a.m. and reentered at 10:27 a.m.]

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Miscellaneous 24

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25 [Kerry Maloney, Esquire, Board Counsel, discussed

three types of Delegation Orders and the Draft General 1 2 Delegation Order. 3 With the proposed Delegation Order, Mr. Maloney noted that the Prothonotary's Office would then need 5 to refer to only one document.] 6 MS. TALBOTT: 7 I move that we approve this General 8 Delegation Order as proposed in the 9 agenda. 10 DR. COTCHEN: 11 I second that 12 CHAIRPERSON HART: Discussion? All in favor? Opposed? 13 14 [The motion carried unanimously.] 15 16 Report of Board Chairperson 17 [Chairperson Hart discussed her attendance at the 18 Chicago Tri-Regulator Symposium which pharmacists, 19 prescribers, and nurses attended, representing the Federation of State Medical Boards, National 20 21 Association of Boards of Pharmacy, and National 22 Council of State Boards of Nursing 23 Chairperson Hart also attended the National 24 Association of Boards of Pharmacy (NABP) Task Force 25 meeting on long-term care regarding changes to

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    long-term care model rules.]
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    Report of Probable Cause Committee - No Report
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    Report of Deputy Commissioner - No Report
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    Report of the Executive Secretary
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    [Melanie Zimmerman, R.Ph., Executive Secretary,
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    discussed pharmacy renewals. Less than 10% of
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   pharmacies still need to renew.
                                      She informed the
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   Board that the Information Technology (IT) Department
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   was aware of and working to resolve online issues.]
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   New Business
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    [Chairperson Hart noted the presentation on elder
   abuse earlier this morning and the NABP/AACP District
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   I & II Meeting - Roundtable Topic Suggestions.
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   topic list is already comprehensive and no additions
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   to the list were suggested.]
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    [Pursuant to Section 708(a)(5) of the Sunshine Act, at
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   10:57 a.m., the Board entered into Executive Session
   with Kerry Maloney, Esquire, Board Counsel, to receive
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   legal advice and engage in quasi-judicial
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   deliberations.
                    The Board returned to open session at
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1 Move to adjourn. 2 * * * [There being no further business, the State Board of 3 Pharmacy meeting adjourned at 12:04 p.m.] * * * 5 6 7 CERTIFICATE 8 I hereby certify that the foregoing summary 9 minutes of the State Board of Pharmacy meeting, was 10 11 reduced to writing by me or under my supervision, and 12 that the minutes accurately summarize the substance of 13 the State Board of Pharmacy meeting. 14 15 16 17 Amy L. Warehime. 18 Minute Clerk 19 Sargent's Court Reporting 20 Service Inc. 21 22 23 24

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