State Board of Pharmacy

July 11, 2017

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BOARD MEMBERS:

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Janet Getzey Hart, R.Ph., Chairperson Ian Harlow, Commissioner of Professional and Occupational Affairs - Absent

10 Terry Talbott, R.Ph., Vice Chairperson 11 Robert Frankil, R.Ph., Secretary

12 Gayle Cotchen, Pharm.D., R.Ph. 13 Patrick M. Greene, Esquire, Of:

Patrick M. Greene, Esquire, Office of Attorney General - Absent

Kishor S. Mehta, Public Member 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
Keith Bashore, Esquire, Board Prosecutor
Julia Feld-Caralle, Esquire, Board Prosecutor
Melanie Zimmerman, R.Ph., Executive Secretary
Kevin Knipe, Program Director, Professional Health
Monitoring Program

27 28 29

ALSO PRESENT:

34

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37

38

Kathie Simpson, Director, Secundum Artem - Reaching Pharmacists with Help (SARPH) Craig Moon, R.Ph., Respondent

35 | Carl Harting, CVS Health

Christine Roussel, Pennsylvania Society of Health-System Pharmacists (PSHP), Doylestown Hospital Michael Kenney, Pharm.D., SARPH, PHMP, Nova

Southeastern University, Respondent

39 Southeastern Un 40 Jim Reed, Walgreens

41 John Loxterman, Enclara Pharmacia 42 Edward Bechtel, Bechtel's Pharmacy

43 Andrea Getz, Bechtel's Pharmacy

44 Erin Fegley, Bechtel's Pharmacy

45 Jenna Micallef, Pennsylvania Society of Health-Systems

46 Pharmacists (PSHP), Doylestown Hospital

47 Makindree Nicolosi, Pennsylvania Society of Health-

48 Systems Pharmacists (PSHP)

49 Andrew Trivino, Pennsylvania Society of Health-System

50 Pharmacists (PSHP), Doylestown Hospital

State Board of Pharmacy

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(Continued)

Jenna McCarthy, Malady & Wooten
Andrew Harding, Pennsylvania Medical Society
Theresa Rossetti, CVS Health
Mike Kelly, Central Admixture Pharmacy Services (CAPS)
Pete McGarvey, Central Admixture Pharmacy
Services (CAPS)

Peter Speaks, Deputy Secretary for Regulatory Programs Jill Schachte, CVS Health Greg Smith, Central Admixture Pharmacy Services (CAPS) Christine Renfer, CVS Health

Andrea Farish, ACME Savon Pharmacy

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2 State Board of Pharmacy

July 11, 2017

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The regularly scheduled meeting of the State
Board of Pharmacy was held on Tuesday, July 11, 2017.

Janet Getzey Hart, R.Ph., Chairperson, called the
meeting to order at 8:59 a.m. The Pledge of
Allegiance was recited. A quorum was noted to be
present.

11 | ***

13 {Chairperson Hart requested the introduction of Board

14 Members, Board staff and audience members in

Introduction of Board and Audience Members

15 | attendance.]

16 ***

17 Evacuation Announcement

18 | [Melanie Zimmerman, R.Ph., Executive Secretary,

19 reviewed the emergency evacuation procedures for One

20 Penn Center.1

21 ***

22 | Report of Prosecutorial Division

23 | [Keith Bashore, Esquire, Board Prosecutor, presented

24 | the following Consent Agreements: File No. 16-54-

25 | 04452, File No. 16-54-11517, File No. 17-54-03746,

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File No. 17-54-04536, and File No. 17-54-05394.]
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 2
 3
    [Ray Michalowski, Esquire, Board Prosecution Liaison,
    on behalf of Monty Batson, Esquire, Board Prosecutor,
 5
   presented a Consent Agreement for File No.
    13-54-05193.1
 6
 7
 8
   Report of Board Counsel
 9
    [Chairperson Hart reviewed the recusal guidelines.]
10
   Medicaid/Medicare Preclusion - Reinstated Pharmacists
11
   Should Contact the Office of Inspector General
12
    [Kerry Maloney, Esquire, Board Counsel, noted the
   Medicaid/Medicare preclusion information for the
13
   Board's information.
14
15
        Kathie Simpson informed the Board members that
    (SARPH) Secundum Artem Reaching Pharmacists with Help
16
   automatically checks the Medicare/Medicaid Preclusion
17
18
   List for consideration of reinstatement.
                                               She noted
19
   the availability of attorneys to assist pharmacists in
   that regard.]
20
21
                              * * *
22
   Report of Board Chairperson - No Report
                              * * *
23
   Report of Probable Cause Committee - No Report
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1 Report of Board Counsel Continued [Kerry Maloney, Esquire, Board Counsel, noted that 2 there is no regulation update, other than to note that 3 August will be regulation intensive. There will only be one Adjudication and Order for consideration at the 5 upcoming August meeting. He referred to the recent NABP newsletter which 7 noted the Pennsylvania (PDMP) Prescription Drug 8 Monitoring Program as currently online with NABP InterConnect. 1 10 11 12 Report of the Executive Secretary [Melanie Zimmerman, R.Ph., Executive Secretary, 13 14 addressed the reason for the delay of the July 15 newsletter. 16 Ms. Zimmerman informed the Board members that pharmacy renewals had not yet been generated. 17 stated the new system for renewals will be online 18 19 only, but the renewal notices will be mailed. 20 Applications will be discussed during Executive Session.l 21 22 * * * New Business 23 24 2017 (MPJE) Multistate Pharmacy Jurisprudence

Examination Item Pool Review and New Item Selection.

25

[Melanie Zimmerman, R.Ph., Executive Secretary,
discussed possible days and times for the pharmacist
Board Members to review this material. A
determination was made to conduct the review on August
21, 2017 from 1 to 5 p.m. and then complete it after
the Board of Pharmacy Meeting on August 22, 2017.]

* * *

Pharmacist Continuing Education - Sponsored by Federal and State Agencies

[This matter was placed on the agenda to discuss whether non-ACPE-accredited programs would be acceptable to the Board. Gayle Cotchen, Pharm.D., R.Ph., noted one example as the continuing education program presented by the Pennsylvania Patient Safety Authority (PPSA). Ms. Cotchen stated the certificate from the PPSA did not have the ACPE logo, but later found it to be a nursing authorization for continuing education. She questioned whether the Board would accept this certificate.

Mr. Maloney stated the Board has only approved (ACPE) Accreditation Council for Pharmacy Education pharmacist continuing education. He explained the Board would need to vote on the matter after receiving public comment at a future meeting.

Ms. Talbott noted that per Board Regulation

Section 27.32(h), continuing education providers which 1 2 are not ACPE accredited may apply to the Board for 3 approval and shall make a showing of program accreditation substantially similar to ACPE accreditation standards. 5 Ms. Talbott was concerned that if it is not ACPE accredited, it is not going to 6 7 show up in the CPE monitor, which would create 8 problems if someone is audited.

Ms. Cotchen suggested either contacting the Pennsylvania Patient Safety Authority or in the future consider expanding allowances for continuing education to mirror that of the Nursing Board.

Kathie Simpson, SARPH, will submit goals and objectives to the Board so SARPH may offer CEs to pharmacists as well.

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Chairperson Hart noted credits for opioid training will be reviewed with the next renewal cycle.

There was further discussion regarding the matter.]

* * *

Food and Drug Administration Intergovernmental Working Meeting on Pharmacy Compounding
[Melanie Zimmerman, R.Ph., Executive Secretary, noted the (FDA) Food and Drug Administration contacted the Board office concerning an intergovernmental working meeting on pharmacy compounding.

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Ms. Zimmerman stated that Gayle Cotchen expressed
 1
    an interest in attending.]
 2
 3
   MS TALBOTT:
                  I make that motion that we send Gayle,
 4
                  once again, because she's so good at it,
 5
                  to the FDA compounding working meeting.
 6
   MR. FRANKIL:
 7
                  I'll second that motion.
 8
   CHAIRPERSON HART:
 9
10
                  Any discussion? All in favor?
11
    [The motion carried unanimously]:
12
   For the Board's Information
13
   Hank Rahe - NonCompliance of CETA CAG-002-2006 Guide
14
   to the ISO 14644-1:2015(E) Standard
15
16
    [Dr.. Cotchen noted that the United States
17
   Pharmacopeia (USP) 797 does not refer to CETA
18
   Guidelines.
                Dr. Cotchen also noted that this appears
   to be a form letter because it references Pennsylvania
19
   regulations and the Board's compounding regulations
20
21
   are still pending.
22
        Mr. Michalowski explained that presently the
   pharmacy inspectors are working on a compliance level
23
   rather than seeking disciplinary action. .]
24
25
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10 Approval of Agenda CHAIRPERSON HART: 2 3 We didn't approve the agenda first thing today, so we should make a motion to 4 5 approve the agenda and second it so that 6 we can vote on it 7 MS TALBOTT: I'll make that motion to approve the 8 9 agenda. MR. MEHTA: 10 I'll second it. 11 12 CHAIRPERSON HART: 13 Any discussion? All those in favor? 14 Opposed? 15 [The motion carried unanimously]. * * * 16 [Pursuant to Section 708(a)(5) of the Sunshine Act, at 17 9:47 a.m., the Board entered into Executive Session 18 19 with Kerry Maloney, Esquire, Board Counsel, to receive legal advice and for the purpose of conducting quasi-20 21 judicial deliberations. The Board returned to open 22 session at 10:42 a.m.l 23 * * * 24 [A Formal Hearing was held from 10:42 a.m. until 11:29 25 a.m. In the Matter of the Petition for Early Release

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11
 1
    from DMU of Craig W. Moon, R.Ph.; File No.
 2
    17-54-05783, Docket No. 1000-54-2017.]
 3
    [A Formal Hearing was held from 11:30 a.m. until 12:10
 4
 5
    p.m. In the Matter of the Petition for Early Release
    from DMU of Michael G. Kenney, R.Ph.; File No.
 7
     17-54-05554, Docket No. 1001-54-2017.]
                               * * *
 8
    [Pursuant to Section 708(a)(5) of the Sunshine Act, at
 9
10
   12:10 p.m., the Board entered into Executive Session
11
   with Kerry Maloney, Esquire, Board Counsel, for the
   purpose of conducting quasi-judicial deliberations.
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13
   The Board returned to open session at 12:40 p.m.]
                               * * *
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   MOTIONS
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   CHAIRPERSON HART:
17
                  The Board of Pharmacy met in Executive
                  Session to discuss and review consent
18
19
                  orders and other legal documents.
                                                       Are
20
                  there any motions regarding these
                  discussions?
21
   DR. COTCHEN:
22
                  Madam Chairperson, I move that we
23
24
                  approve the application for nonresident
25
                  registration submitted by ESI Mail
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13
    DR. COTCHEN:
 1
 2
                   I move that we approve the Consent
                   Agreement for File No. 16-54-04452
 3
    MR. MEHTA:
 5
                   Second
 6
    CHAIRPERSON HART:
                  Any discussion? Call for a vote.
 7
 8
 9
                  Talbott, aye; Cotchen, aye; Hart, aye;
10
                  Mehta, aye; Zilner, aye; Frankil, aye.
11
    [The motion carried unanimously.
                                       The Respondent's
    name is Joseph M. Christmann, R.Ph.]
12
                               * * *
13
   DR. COTCHEN:
14
15
                  I move that we approve the Consent
16
                  Agreement for File No. 16-54-11517
   MR. MEHTA:
17
                  Second.
18
19
   CHAIRPERSON HART:
20
                  Discussion? Terry?
21
                  Talbott, aye; Cotchen, aye; Hart, aye;
22
23
                  Mehta, aye; Zilner, aye; Frankil, aye.
24
    [The motion carried unanimously.
                                       The Respondent's
25
   name is Elizabeth S. Carothers, R.Ph.]
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14 * * * 1 2 DR. COTCHEN: 3 I move that we approve the Consent 4 Agreement for File No. 17-54-03746 5 MR. MEHTA: 6 Second. 7 CHAIRPERSON HART: Any discussion? Call for a vote. 8 9 Talbott, aye; Cotchen, aye; Hart, aye; 10 11 Mehta, aye; Zilner, aye; Frankil, aye. [The motion carried unanimously. The Respondent's 12 13 name is Edward Gaeton Leake, R.Ph.] * * * 14 MS. TALBOTT: 15 16 I make a motion that we accept the 17 agreement for File No. 17-54-04536 MR. MEHTA: 18 19 Second: 20 CHAIRPERSON HART: 21 Any discussion? Call for a vote. 22 23 Talbott, aye; Hart, aye; Mehta, aye; 24 Zilner, aye; Frankil, aye. [The motion carried. Gayle Cotchen recused from 25

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deliberations and voting on the motion.
 1
                                               The
 2
    Respondent's name is Andrea S. Mucenski, R.Ph.]
                               * * *
 3
    MS. TALBOTT:
 4
                  Madam Chair, I make a motion that we
 5
 6
                   accept the agreement for File No.
 7
                   17-54-05394.
 8
   MR. MEHTA:
 9
                  Second.
    CHAIRPERSON HART:
10
                  Call for discussion, vote:
11
12
                  Talbott, aye; Hart, aye; Mehta, aye;
13
14
                  Zilner, aye; Frankil, aye.
15
    [The motion carried. Gayle Cotchen recused from
16
   deliberations and voting on the motion.
17
   Respondent's name is John W. Mucenski, R.Ph.]
                               * * *
18
19
   DR. COTCHEN:
                  I move that we deny the Request for
20
                  Reinstatement for File No. 17-54-05783
21
22
                   and that we direct Counsel to draft an
23
                  Adjudication and Order consistent with
24
                  the terms discussed during Executive
25
                  Session.
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	17
1	MS. TALBOTT:
2	I move that we then table the matter of
3	Michael G. Kenney, File No. 17-54-
4	05554, until the next meeting so Board
5	members who are not present can review
6	the record and we can decide
7	dispensation at that point
8	MR: MEHTA:
9	Second.
10	CHAIRPERSON HART:
11	Any discussion? Call for a vote:
12	
13	Talbott, aye; Cotchen, aye; Hart, aye;
14	Mehta, aye; Zilner, aye; Frankil, aye.
15	[The motion carried unanimously.]
16	* * *
17	DR. COTCHEN:
18	I move that we deny the request
19	submitted by Ashley Karpovich regarding
20	her approval date for pharmacist
21	preceptor,
22	MR. MEHTA:
23	Second.
24	CHAIRPERSON HART:
25	Call for discussion. Call for a vote

1 Cotchen, aye; Hart, aye; Mehta, aye; 2 3 Zilner, aye; Frankil, aye. [The motion carried. Terry Talbott recused from deliberations and voting on the motion.] 5 * * * 6 7 DR. COTCHEN: 8 I move that we approve the request 9 submitted by Claude Touma to reduce the 10 intern hours as a graduate of a foreign 11 pharmacy school and to reduce the hours 12 to 500 intern hours 13 MR. MEHTA: Second. 14 CHAIRPERSON HART: 15 16 Call for discussion, vote. 17 18 Talbott, aye; Cotchen, aye; Hart, aye; 19 Mehta, aye; Zilner, aye; Frankil, aye. 20 [The motion carried unanimously.] * * * 21 22 DR. COTCHEN: 23 I move that we deny the request for

Sargent's Court Reporting Service,

(814) 536-8908

24

25

reduced intern hours as a graduate of a

foreign pharmacy school submitted by

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19
 1
                    Tapan Patel
 2
    MR: MEHTA:
 3
                   Second.
    CHAIRPERSON HART:
 4
 5
                   Any discussion? Call for a vote
 6
 7
                   Talbott, aye; Cotchen, aye; Hart, aye;
                   Mehta, aye; Zilner, aye; Frankil, aye.
 8
 9
    [The motion carried unanimously.]
                                * * *
10
    Adjournment
11
    DR. COTCHEN:
12
13
                   I move that we adjourn.
14
    MS. TALBOTT:
15
                   Second.
    CHAIRPERSON HART:
16
17
                   All right. Another good meeting.
    [The motion carried unanimously.]
18
19
    [The State Board of Pharmacy meeting adjourned at
20
    12:47 p.m.]
21
22
23
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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.

Chasity Barshinger,

Minute Clerk

Sargent's Court Reporting Service, Inc.